IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD., Petitioner,	)	Patent No. 10,888,601
vs.	)	
REGENERON PHARMACEUTICALS, INC., Patent Owner.	)	Inter Partes Review No. IPR2023-00739

VIDEOTAPE DEPOSITION OF:

EDWARD CHAUM, M.D., Ph.D.

Taken on behalf of the Patent Owner

January 5, 2024

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

EXHIBIT
2062

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 1

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Stephanie Freeman - Videographer

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 2

I N D E X

	Page/Line
THE WITNESS: EDWARD CHAUM, M.D., Ph.D.	
EXAMINATION BY MR. BRAUSA	5 24

INDEX OF EXHIBITS

Exhibits	Description	Page/Line
Exhibit 1016	Indication and Use Documents for EYLEA	128 21
Exhibit 1001	U.S. Patent 10,888,601 B2	151 17
Exhibit 1002	Declaration of Dr. Edward Chaum	138 13
Exhibit 1006	Article: Randomized Trial Evaluating Ranibizumab Plus Prompt of Deferred Laser or Triamcinolone Plus Prompt Laser for Diabetic Macular Edema	233 21
Exhibit 1009	September 14, 2009 Regeneron Press Release	263 2
Exhibit 1010	International Application WO 2006/047325 A1	285 1
Exhibit 1044	U.S. Patent 2007/0190058 A1	298 13
Exhibit 1056	U.S. Patent 9,254,338	227 23

The videotape deposition of EDWARD CHAUM, M.D., Ph.D, was taken by counsel for the Patent Owner, on January 5, 2024, commencing at 9:03 a.m., in the offices of Dickinson Wright, 424 Church Street, Suite 1401, Nashville, Tennessee, for all purposes under the Federal Rules of Civil Procedure.

The formalities as to notice, caption, certificate, et cetera, are not waived. All objections, except as to the form of the questions, are reserved to the hearing.

It is agreed that Carissa L. Boone, being a Notary Public and Court Reporter, may swear the witness, and that the reading and signing of the completed deposition by the witness are not waived.

* * *

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 4

THE VIDEOGRAPHER: Good morning. 09:03:31AM
We are going on the record at 9:03 a.m. 09:03:32AM
The attorneys have -- the date is 09:03:39AM
January 5th, 2024. 09:03:41AM
The attorneys have waived the 09:03:43AM
standard video introduction to the video 09:03:44AM
deposition of Dr. Edward Chaum. 09:03:46AM
Counsel, please state your 09:03:49AM
appearance for the record which will 09:03:51AM
then be followed by the swearing in of 09:03:52AM
the witness by the court reporter. 09:03:54AM
MR. SUMMERS: Zach Summers for 09:03:57AM
Petitioner Samsung Bioepis and the 09:03:59AM
witness. 09:04:03AM
MR. BRAUSA: Adam Brausa for 09:04:04AM
patent owner Regeneron. I'm joined by 09:04:06AM
my colleague Jack Lane. We're both from 09:04:09AM
the Morrison & Foerster firm. And on 09:04:10AM
the Zoom is Eileen Woo from Regeneron. 09:04:12AM
EDWARD CHAUM, M.D., Ph.D., 09:04:12AM
having been first duly sworn, was examined and 09:04:12AM
testified as follows: 09:04:22AM
THE WITNESS: I do. 09:04:22AM
EXAMINATION 09:04:24AM
BY MR. BRAUSA: 09:04:24AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 5

Q. Good morning, Dr. Chaum. Thank you for being here. 09:04:24AM 09:04:28AM

A. Good morning. 09:04:29AM

Q. I'll do my best to pronounce your name correctly. If I misstep, please do correct me. 09:04:30AM 09:04:32AM 09:04:35AM

A. That's correct. It's Chaum. 09:04:36AM

Q. Got it. 09:04:37AM

And I know you've been deposed before relating to proceedings between Samsung and Regeneron, but if I ask any questions that you don't understand or they're unclear, please feel free to ask me at to clarify. 09:04:37AM 09:04:39AM 09:04:44AM 09:04:46AM 09:04:49AM

A. Okay. 09:04:50AM

Q. We're here in IPR 2023-739 about U.S. Patent 10,888,601. Is that your understanding? 09:04:51AM 09:05:00AM 09:05:04AM

A. Yes. 09:05:06AM

Q. And if I refer to that as the '601 patent, will that be clear to you? 09:05:08AM 09:05:11AM

A. Yes. 09:05:12AM

Q. Okay. And I may refer to other patents from time to time during today's questioning. I'll do my best to make it clear which patent I'm referring to, but you'll see we 09:05:12AM 09:05:14AM 09:05:17AM 09:05:19AM

patent attorneys always shorten it to three digits. If it's ever unclear, please ask me to clarify, okay? 09:05:22AM 09:05:25AM 09:05:28AM

A. Okay. 09:05:29AM

Q. When were you retained for this particular proceeding? 09:05:29AM 09:05:31AM

A. Probably about -- I was -- about a year and a half ago, I believe, by Quinn Emanuel. 09:05:32AM 09:05:36AM 09:05:39AM

Q. Okay. Do you recall who reached out to you from Quinn Emanuel? 09:05:39AM 09:05:41AM

A. I don't offhand, no. 09:05:43AM

Q. Prior to this representation, had you worked with Quinn Emanuel before? 09:05:44AM 09:05:47AM

A. No. 09:05:49AM

Q. Prior to your work with Quinn Emanuel, had you served as an expert in any patent cases? 09:05:49AM 09:05:52AM 09:05:55AM

A. I initially did some work for another patent firm that was retained by Samsung Bioepis, Desmarais. 09:05:56AM 09:06:01AM 09:06:07AM

Q. Okay. 09:06:08AM

A. And I did some initial work for them. But then that was discontinued, and I was retained by Quinn Emanuel. 09:06:08AM 09:06:11AM 09:06:13AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 7

Q. Okay. And in your work for the Desmarais firm, was that relating to biosimilars work as well -- 09:06:14AM 09:06:17AM 09:06:21AM

A. It was. 09:06:21AM

Q. -- for Samsung? 09:06:23AM

A. It was. 09:06:23AM

Q. What biosimilar was your representation relating to -- 09:06:23AM 09:06:25AM

A. I -- 09:06:25AM

Q. -- if you can disclose it. 09:06:26AM

A. I -- I don't recall offhand. It was an initial interest in my expertise related to -- to biosimilars in general. 09:06:27AM 09:06:28AM 09:06:33AM

Q. Okay. And -- and what expertise do you have with respect to biosimilars in general? 09:06:34AM 09:06:37AM 09:06:39AM

A. I'm a practitioner of ophthalmology. I'm a retina specialist. 09:06:39AM 09:06:43AM

Q. Okay. We talked about your retention by Quinn Emanuel in this proceeding. I had mentioned that you had been deposed previously. And, in fact, you're retained by Quinn Emanuel on behalf of Samsung in a proceeding designated IPR 2023-442 relating to U.S. Patent 10,130,681 or the '681 patent. 09:06:45AM 09:06:49AM 09:06:52AM 09:06:55AM 09:06:58AM 09:07:02AM 09:07:07AM

Are you familiar with that? 09:07:12AM

A. Yes. 09:07:13AM

Q. And, in fact, this is a proceeding in which you were deposed roughly a month or so ago? 09:07:13AM 09:07:16AM 09:07:18AM

A. October of last year, I believe. 09:07:20AM

Q. Okay. So a little more than a month. My math was off. 09:07:22AM 09:07:25AM

After the deposition occurred in that case, did you go back and read your trans- -- read the transcript of your deposition? 09:07:26AM 09:07:29AM 09:07:32AM

A. I have not. 09:07:32AM

Q. Okay. And sitting here today, is there anything that happened during that deposition or testimony that you'd like to correct? 09:07:33AM 09:07:35AM 09:07:38AM 09:07:40AM

A. I haven't had a chance to review it, so I haven't had a chance to correct anything that I might see. 09:07:41AM 09:07:43AM 09:07:46AM

Q. Okay. But sitting here today, there's nothing that is in your mind as something that you need to correct once you review the deposition transcript? 09:07:47AM 09:07:50AM 09:07:52AM 09:07:54AM

A. Not offhand, but I'd have to see the deposition transcript. 09:07:55AM 09:07:57AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 9

Q. Okay. And, again, just sitting here today without reviewing line-by-line the deposition transcript, is there any reason for you to think that the testimony that you provided in that proceeding regarding the '681 patent was not truthful and accurate? 09:07:58AM 09:08:00AM 09:08:03AM 09:08:05AM 09:08:08AM 09:08:10AM

A. No, no reason at all. 09:08:11AM

Q. Okay. Now, you were also retained by Quinn Emanuel on behalf of Petitioner Samsung in IPR 2023-884 regarding U.S. Patent 11,253,572 or the '572 patent, correct? 09:08:12AM 09:08:15AM 09:08:17AM 09:08:23AM

A. Yes. 09:08:27AM

Q. And we were actually just discussing, you've not been deposed in that matter. We're anticipating a deposition in that matter in the next month or so, right? 09:08:27AM 09:08:30AM 09:08:35AM 09:08:36AM

A. As I understand it, yes. 09:08:39AM

Q. Okay. And so if I have done my math right this time, those are three separate proceedings in which you've been retained by Quinn Emanuel on behalf of Petitioner Samsung, correct? 09:08:41AM 09:08:42AM 09:08:45AM 09:08:48AM

A. Yes. 09:08:51AM

Q. Are there any other IPR proceedings in which you've been retained as an expert by Quinn Emanuel? 09:08:51AM 09:08:54AM 09:08:56AM

A. Not that I'm aware of at this time. 09:08:58AM 09:08:59AM

Q. Okay. And when you were retained by Quinn Emanuel -- about a year and a half ago, I think you said? 09:08:59AM 09:09:02AM 09:09:04AM

A. Something like that. Year and a half to two years. 09:09:06AM 09:09:07AM

Q. Was it with respect to a particular patent, or was it just with respect to subject matter in general? 09:09:08AM 09:09:10AM 09:09:14AM

A. Subject matter in general. 09:09:15AM

Q. Okay. And if you recall, when did you -- or when were you informed that there would be a need for three different declarations in three different proceedings? 09:09:16AM 09:09:19AM 09:09:22AM 09:09:25AM

A. I was not informed in advance of that. I've become aware of it as these proceedings have continued. 09:09:28AM 09:09:30AM 09:09:33AM

Q. Okay. And I'm going to ask you some questions about your -- your preparation process and the work that you did preparing your declarations. I want to make it clear, I don't want to hear about conversations that you had with your attorneys, unless I'm specifically asking about it. 09:09:35AM 09:09:36AM 09:09:39AM 09:09:42AM 09:09:44AM 09:09:46AM 09:09:48AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 11

So if there's a question or -- or you have any concern that it will reveal the substance of those communications, just ask me to rephrase and I can do that, okay? 09:09:49AM 09:09:52AM 09:09:54AM 09:09:59AM

A. Okay. 09:10:00AM

Q. So when you were in the process -- it -- let me establish -- actually, in each of these proceedings, you understand there's a petition filed by Samsung and then that petition for Inter Partes Review is supported by an expert declaration from yourself? 09:10:00AM 09:10:03AM 09:10:05AM 09:10:07AM 09:10:13AM 09:10:17AM

A. Yes. 09:10:19AM

Q. And so in each of these proceedings, you're the author of three separate expert opinions, correct? 09:10:19AM 09:10:21AM 09:10:24AM

A. Yes. 09:10:25AM

Q. And in each of these proceedings, you've offered opinions on whether the claims that are challenged by Samsung in those proceedings are valid, correct? 09:10:26AM 09:10:29AM 09:10:32AM 09:10:36AM

A. In part, yes. 09:10:37AM

Q. Okay. In each of these proceedings, it's your opinion that all of the claims challenged by Samsung are invalid, correct? 09:10:40AM 09:10:42AM 09:10:47AM

A. I'm -- I'm sorry, just if you 09:10:49AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 12

could restate the question so I understand it fully. 09:10:51AM 09:10:54AM

Q. Sure. 09:10:54AM

In each of the three IPR proceedings in which you have provided expert opinions on behalf of Samsung, your overarching opinion is that the claims in each patent challenged by Samsung are invalid, correct? 09:10:55AM 09:10:57AM 09:10:59AM 09:11:03AM 09:11:05AM

A. Yes. 09:11:08AM

Q. Have you ever provided any expert opinions, on behalf of anyone, that claims of a patent are valid? 09:11:09AM 09:11:11AM 09:11:15AM

A. No. 09:11:18AM

Q. In terms of your work process preparing the three declarations for Samsung in which you've been retained by Quinn Emanuel, did the work on those declarations occur independently or did it occur in parallel? 09:11:18AM 09:11:24AM 09:11:27AM 09:11:30AM 09:11:33AM

MR. SUMMERS: Objection, vague. 09:11:36AM

THE WITNESS: As I think back to my preparation, for the most part, the work was done independently, but there is overlap in terms of the literature and some of the issues with respect to the patents. So there was some parallel 09:11:41AM 09:11:43AM 09:11:46AM 09:11:49AM 09:11:52AM 09:11:55AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 13

work that was done in that regard. 09:11:59AM

BY MR. BRAUSA: 09:12:02AM

Q. Okay. I think it's -- it's in 09:12:02AM

your report and you mentioned it. You've been an 09:12:08AM

ophthalmologist for, what, 30 years now? 09:12:12AM

A. Yes. 09:12:14AM

Q. Okay. And you started out in 09:12:14AM

pediatrics and then moved into ophthalmology, if I 09:12:16AM

have that correct? 09:12:20AM

A. Yes. 09:12:20AM

Q. When you were working in 09:12:20AM

pediatrics, was that pediatric ophthalmology, or 09:12:22AM

was that pediatrics more generally? 09:12:25AM

A. No, that was a pediatric 09:12:26AM

residency. 09:12:29AM

Q. Okay. And what led to your 09:12:30AM

interest in ophthalmology to move from the 09:12:31AM

pediatric residency? 09:12:36AM

A. So my -- I'm both a 09:12:37AM

physician/medical doctor and a Ph.D. My doctoral 09:12:40AM

thesis was in the genetics of a pediatric eye 09:12:45AM

disease called retinoblastoma, which is a tumor of 09:12:48AM

the developing retina. And in the course of my 09:12:51AM

doctoral work, I became interested in two 09:12:53AM

different areas of clinical medicine as I was 09:12:56AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 14

conceiving of my practice going forward. 09:12:59AM

One was in the area of pediatric 09:13:01AM

gene transfer/gene therapy, which in the 1980s was 09:13:07AM

an exciting and new area of clinical medicine. 09:13:10AM

And at that time, the concept of gene therapy in 09:13:13AM

pediatrics was predicated around bone marrow 09:13:16AM

transplantation. We were going to take and fix 09:13:19AM

the gene of patients with sickle cell anemia, 09:13:22AM

cystic fibrosis, other conditions. 09:13:26AM

And so my plan at that time was 09:13:28AM

to become a pediatric oncologist, do marrow -- 09:13:30AM

bone marrow transplantation, and apply my interest 09:13:35AM

in gene transfer, which I had done in my doctoral 09:13:37AM

work, to the application of gene therapy in 09:13:41AM

clinical medicine. 09:13:44AM

So I started in pediatrics. But 09:13:44AM

after two years in pediatrics and working in 09:13:47AM

pediatric oncology and bone marrow 09:13:50AM

transplantation, I heard -- I realized that that 09:13:52AM

was not the career path that I wanted to take. 09:13:55AM

And so I -- again because of my interest in 09:13:58AM

ophthalmology and retinal diseases and the work 09:14:01AM

that I had done as part of my doctoral work, I 09:14:04AM

applied and was accepted into an ophthalmology 09:14:07AM

program and then went on to become a retina 09:14:11AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 15

specialist. 09:14:14AM

Q. I see. 09:14:14AM

And in looking back, why was it 09:14:15AM

that that was not a career path that you decided 09:14:16AM

to take? 09:14:18AM

A. I -- I think a couple reasons. 09:14:18AM

One is as a clinician, as a physician working with 09:14:21AM

the families of children who were dying is a very, 09:14:24AM

very difficult process. 09:14:28AM

Q. Sure. 09:14:29AM

A. And experiencing that firsthand, 09:14:30AM

there are, you know, wonderful physicians who go 09:14:32AM

into that for a career. From my perspective, it 09:14:36AM

was, I think, just too difficult of a career path 09:14:40AM

for me in terms of my initial experience with it. 09:14:43AM

And so that's the -- that -- that's the main 09:14:47AM

reason. 09:14:51AM

Q. Okay. And when you made the 09:14:52AM

switch or when you moved more to a focus on 09:14:54AM

ophthalmology, at -- at all points in your career, 09:14:57AM

you've been a prescribing physician, so to speak; 09:15:00AM

meaning you've been treating and -- and 09:15:03AM

administering drugs to patients, correct? 09:15:05AM

A. Yes. 09:15:07AM

Q. And in this case, we are -- we're 09:15:07AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 16

dealing with a specific type of drug that -- that 09:15:10AM
I see referred to in your declaration and 09:15:13AM
elsewhere, it's an anti-VEGF antagonist? 09:15:17AM
A. An anti-VEGF agent, yeah. So 09:15:18AM
VEGF antagonist. 09:15:21AM
Q. Okay. Agent or antagonist, do 09:15:22AM
you call -- have a preference? 09:15:23AM
A. It -- it doesn't matter to me. 09:15:25AM
Q. Okay, got it. 09:15:27AM
And my understanding is VEGF is a 09:15:28AM
protein that the body naturally produces, correct? 09:15:30AM
A. Yes. 09:15:33AM
Q. And in certain individuals, it's 09:15:33AM
overexpressed? 09:15:37AM
A. In certain disease states -- 09:15:39AM
Q. Okay. 09:15:40AM
A. -- it can be overexpressed, yes. 09:15:41AM
Q. Okay. And what's the impact of 09:15:43AM
that overexpression, for instance, in diabetic 09:15:45AM
macular in-depth [sic] -- or edema? Excuse me. 09:15:48AM
A. So the impact of VEGF expression 09:15:52AM
in diabetes is actually quite diverse. So as the 09:15:54AM
retina becomes damaged from high blood sugars in 09:15:59AM
patients with diabetes, a couple of things happen. 09:16:04AM
One is that the retinal vessels 09:16:07AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 17

start to become incompetent. The connections 09:16:11AM
between the -- the tight junctions between the 09:16:15AM
cells that control the egress of fluid from the 09:16:17AM
vessels into the retina become incompetent, they 09:16:20AM
become dilated, and the fluid can begin to leak 09:16:24AM
into the retina. The retina is like the film of 09:16:28AM
the camera. It's the part of the eye that we see 09:16:31AM
with. As that leakage occurs, the retina can 09:16:33AM
become swollen and that becomes a manifestation of 09:16:36AM
diabetic eye disease. In this case, as we're 09:16:41AM
discussing it, what's caused macular edema and can 09:16:43AM
cause vision loss in patients. 09:16:46AM
VEGF also plays a role in 09:16:46AM
diabetes in that as the vessels continue to become 09:16:49AM
damaged, over time, the small retinal vessels will 09:16:52AM
start to close off. The retina starts to lose its 09:16:55AM
blood supply. And as it loses its blood supply, 09:16:58AM
the biological response of the retina is to try 09:17:01AM
and grow new blood vessels. 09:17:05AM
That's what happens in a normal 09:17:07AM
healing process. If you cut your hand, the body 09:17:08AM
recognizes that injury, it stimulates the 09:17:11AM
proliferation of fibrous tissue and the growth of 09:17:14AM
new vessels to heal that wound. 09:17:17AM
The same thing is basically 09:17:19AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 18

happening in the eye. The retina is losing its blood supply, it's trying to grow new blood vessels, and -- and in -- to do it, what it does is it liberates vascular endothelial growth factor, VEGF. And that VEGF has two effects on the retina which are deleterious to the retina's function. 09:17:20AM 09:17:24AM 09:17:27AM 09:17:29AM 09:17:34AM 09:17:37AM 09:17:40AM

One is that it stimulates the proliferation of vascular endothelial cells, and those cells begin to grow, but they grow abnormally. They don't repopulate the retinal tissue that's lost its blood supply, rather they grow into the vitreous gel above the retina and they begin to cause fibrovascular changes that can put traction on the retina, and patients can develop what's call proliferative diabetic retinopathy, which is a much more severe form of the disease and can be blinding in many patients. 09:17:41AM 09:17:43AM 09:17:48AM 09:17:51AM 09:17:53AM 09:17:53AM 09:17:57AM 09:18:01AM 09:18:03AM 09:18:06AM 09:18:09AM

In addition, VEGF has another biological impact, and that is it causes the vessels to be leaky in the retina. So those vessels are already damaged because of the high blood sugars, and the additional VEGF load causes those vessels to -- to leak more fluid or be more likely to leak fluid into the retina and so can 09:18:12AM 09:18:15AM 09:18:18AM 09:18:21AM 09:18:25AM 09:18:29AM 09:18:32AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 19

contribute to the development and progression of macular edema. 09:18:35AM 09:18:41AM

Q. Okay. And you've been an active clinician since 2011, correct? If we're talking 30 years, you were an active clinician in 2011? 09:18:42AM 09:18:44AM 09:18:47AM

A. I've been a clinician since 1987. 09:18:49AM

Q. Sure. Okay. So -- so we can go back to 2011. If you try and think about, given your understanding, which seems in-depth and -- and very informative of the impact of VEGF and -- and the way it impacts individuals with diabetes or can manifest itself in individuals with diabetes, what has changed in the understanding or your understanding of these various indications from 2011 to the present? 09:18:52AM 09:18:54AM 09:18:58AM 09:19:00AM 09:19:06AM 09:19:08AM 09:19:10AM 09:19:15AM 09:19:18AM

A. I'm not sure I -- 09:19:20AM

MR. SUMMERS: Objection to form. 09:19:22AM

THE WITNESS: Yeah. I'm not sure I understand your question. If you could -- 09:19:23AM 09:19:24AM 09:19:24AM

BY MR. BRAUSA: 09:19:24AM

Q. Sure. 09:19:24AM

A. -- make it shorter and clearer. 09:19:25AM

Q. Sure. I'll do my best. 09:19:27AM

So you'd agree with me, I think, 09:19:28AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 20

that over time, you -- you get a better 09:19:30AM
understanding of, for instance, how VEGF works, 09:19:32AM
why it causes certain indications or why it causes 09:19:35AM
certain issues that are diagnosed as certain 09:19:38AM
indications, right? 09:19:40AM
A. We understand the biological 09:19:41AM
impact of VEGF on the eye, yes. 09:19:44AM
Q. Okay. So let's -- let's start 09:19:46AM
with diabetic macular edema or DME for short. 09:19:49AM
A. Okay. 09:19:57AM
Q. So I don't have to continue 09:19:57AM
mispronouncing edema. 09:19:57AM
In -- in DME, have there been any 09:19:58AM
key advances or new learnings about the disease or 09:20:01AM
how it works since 2011? 09:20:05AM
MR. SUMMERS: Objection, form. 09:20:07AM
THE WITNESS: I mean, I'd have to 09:20:08AM
go back to the literature. There is a 09:20:11AM
lot that's known about the impact of 09:20:12AM
high blood sugars and diabetes on the 09:20:16AM
retina, on the retinal vasculature on 09:20:20AM
the eye, on the body in general. 09:20:22AM
And so to answer your question, 09:20:24AM
I'd say there's probably a lot that has 09:20:25AM
been learned in the past 14, 13 years 09:20:27AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 21

about diabetic macular edema from a biological and a molecular perspective. There -- there are lots of studies in the literature that are -- that have looked at that. 09:20:30AM 09:20:35AM 09:20:38AM 09:20:40AM 09:20:42AM

BY MR. BRAUSA: 09:20:42AM

Q. Okay. And -- and so fair to say that it -- it was and is an area of active research, understanding and treating DME -- 09:20:43AM 09:20:44AM 09:20:46AM

MR. SUMMERS: Object -- 09:20:50AM

BY MR. BRAUSA: 09:20:50AM

Q. -- since 2011? 09:20:51AM

MR. SUMMERS: Objection, form. 09:20:53AM

THE WITNESS: I think I would answer your question in general to say, yes, we are still -- many of us, many labs are still doing research on understanding the impact and the biology of diabetes on -- and -- on the retina. 09:20:54AM 09:20:55AM 09:20:57AM 09:21:00AM 09:21:01AM 09:21:05AM

BY MR. BRAUSA: 09:21:05AM

Q. Okay. You also mentioned diabetic retinopathy or retinopathy, correct? 09:21:09AM 09:21:12AM

A. I -- yes. 09:21:15AM

Q. Are -- are you familiar with that? 09:21:15AM 09:21:16AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 22

A. Yes. 09:21:17AM

Q. What's diabetic retinopathy? 09:21:17AM

A. Well, it's the condition that 09:21:20AM

we're discussing. So, again, the -- the effect of 09:21:21AM

diabetes on the eye and on the retina in 09:21:28AM

particular, in general, broadly is called diabetic 09:21:30AM

retinopathy. So that's an overarching term that 09:21:34AM

can be used to describe the various manifestations 09:21:37AM

of the disease in the eye. 09:21:40AM

So depending on how specific you 09:21:41AM

want to be, diabetic retinopathy can refer, in 09:21:44AM

general, to the changes that we see in the retina 09:21:48AM

in the eye. But within that overarching term, can 09:21:49AM

be considered terms like, or is included in some 09:21:57AM

cases, terms like diabetic macular edema, 09:22:01AM

proliferative diabetic retinopathy, 09:22:04AM

nonproliferative retinopathy, and so forth. 09:22:07AM

Q. So is it okay if I refer to 09:22:10AM

diabetic retinopathy as "DR" for short? Does that 09:22:11AM

make sense to you? 09:22:15AM

A. Sure. Yes. 09:22:15AM

Q. Okay. So your testimony, if I 09:22:17AM

understand it correctly, is that DR is an umbrella 09:22:18AM

term, and under that umbrella is DME? 09:22:21AM

A. I think that that would be a 09:22:24AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 23

reasonable way to think about it. Diabetic 09:22:27AM
retinopathy in general -- again, it depends on 09:22:28AM
whose using the term -- 09:22:32AM
Q. Uh-huh. 09:22:32AM
A. -- the context in which they're 09:22:33AM
using, and how specific they -- they want to be. 09:22:35AM
But the concept of diabetic retinopathy can and 09:22:37AM
does include features, numerous features, of 09:22:40AM
diabetic retinopathy, some of which incl- -- one 09:22:44AM
of which includes diabetic macular edema. 09:22:46AM
Q. Okay. In your practice, do you 09:22:51AM
view DR and DME as separate diseases? 09:22:53AM
MR. SUMMERS: Objection, form. 09:22:56AM
THE WITNESS: I -- in my own 09:22:57AM
practice, I try to be specific about 09:22:58AM
what I'm seeing in the patient. 09:23:01AM
BY MR. BRAUSA: 09:23:02AM
Q. Uh-huh. 09:23:03AM
A. So a patient who has diabetic 09:23:03AM
retinopathy without macular edema, I would say, 09:23:08AM
for example, that person has non- -- mild 09:23:11AM
nonproliferative diabetic retinopathy or moderate 09:23:12AM
nonproliferative diabetic retinopathy. If the 09:23:12AM
patient has macular edema, then I would say that 09:23:18AM
patient has dia- -- mild nonproliferative diabetic 09:23:21AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 24

retinopathy with macular edema. 09:23:17AM

Macular edema is a manifestation 09:23:30AM

of a feature of -- of various levels of diabetic 09:23:31AM

retinopathy, various severities, but doesn't 09:23:17AM

invariably occur with each one. Each -- each 09:23:37AM

patient is different. 09:23:39AM

Q. Okay. And -- and so if I 09:23:40AM

understand the relationship between DR and DME 09:23:41AM

correctly, it's your testimony that you could 09:23:44AM

observe DR in a patient without observing DME; is 09:23:47AM

that fair? 09:23:52AM

A. Right. I think you could say 09:23:52AM

that, yes. 09:23:54AM

Q. But if you're observing DME in a 09:23:54AM

patient, do they necessarily have DR, too? 09:23:57AM

A. Well, that's -- that's the 09:24:00AM

definition of the -- of the adjective that defines 09:24:02AM

the macular edema. You're saying they have 09:24:05AM

diabetic macular edema, so if they have diabetic 09:24:07AM

macular edema, using the plain and ordinary 09:24:09AM

understanding of the word, that macular edema is 09:24:15AM

associated with the presence of diabetes in that 09:24:21AM

patient, which means that patient has diabetic 09:24:23AM

retinopathy with macular edema. 09:24:26AM

Q. Okay. Got it. I -- I think I 09:24:28AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 25

understand. Just for my own benefit, I want to confirm, though. 09:24:29AM 09:24:32AM

DR can be observed in a patient who does not have DME, correct? 09:24:33AM 09:24:35AM

A. Yes. 09:24:38AM

Q. In your practice, do you treat patients that have DR without DME? 09:24:38AM 09:24:41AM

MR. SUMMERS: Objection, form. 09:24:46AM

THE WITNESS: So if you are using the term "diabetic retinopathy" as -- again, it -- it depends on how the person is using -- how that physician is using that term. 09:24:47AM 09:24:50AM 09:24:56AM 09:24:59AM 09:25:02AM

So some physicians might say -- might use the term "diabetic retinopathy" to include macular edema which they would treat, and some patients [sic], myself, might use the term "diabetic retinopathy" that doesn't include macular edema and that patient -- for example, nonproliferative diabetic retinopathy without macular edema -- and that patient wouldn't be treated because there's no indication to treat the patient. 09:25:03AM 09:25:06AM 09:25:08AM 09:25:10AM 09:25:12AM 09:25:14AM 09:25:17AM 09:25:19AM 09:25:24AM 09:25:25AM 09:25:27AM 09:25:29AM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 26

BY MR. BRAUSA: 09:25:30AM

Q. Okay. And in -- in your 09:25:30AM

practice, and I -- I want to focus on your -- your 09:25:31AM

own experience. I -- I appreciate the 09:25:33AM

clarification. 09:25:35AM

But if you have a patient come in 09:25:35AM

and you examine them and you say: Okay. It looks 09:25:37AM

like you've got DR, but I'm not seeing the 09:25:41AM

hallmarks of DME, what do you do? 09:25:44AM

MR. SUMMERS: Objection to form. 09:25:47AM

THE WITNESS: So it depends on 09:25:48AM

the level of diabetic retinopathy they 09:25:50AM

have and other manifestations of the 09:25:53AM

disease and the features that they 09:25:56AM

present. 09:25:57AM

So, for example, if a patient has 09:25:57AM

mild nonproliferative diabetic 09:26:00AM

retinopathy without macular edema, 09:26:04AM

there's no treatment required for that 09:26:06AM

patient. 09:26:06AM

BY MR. BRAUSA: 09:26:07AM

Q. Okay. 09:26:07AM

A. And so the management of that 09:26:07AM

patient would be to counsel them on controlling 09:26:09AM

their blood sugars, maintaining good blood 09:26:12AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 27

pressure control, and recommending a follow-up visit to evaluate that patient for progression of that level of disease at some point in time in the future, based upon the severity of the disease. 09:26:14AM 09:26:17AM 09:26:21AM 09:26:25AM

Alternatively, a patient could come in with a vitreous hemorrhage from proliferative disease and not have macular edema, and they have proliferative disease and bleeding in the eye, and that patient might require surgery. 09:26:28AM 09:26:31AM 09:26:35AM 09:26:36AM 09:26:39AM 09:26:41AM

So it depends on what the level of the disease is, what the manifestations, the specific features the disease manifestations are in that patient as to how that patient would be managed. 09:26:42AM 09:26:43AM 09:26:46AM 09:26:52AM 09:26:55AM

Q. Understood. 09:26:55AM

Are -- are there any patients that do not -- that you do not observe DME, you do observe DR, that you would administer a VEGF antagonist to? 09:26:56AM 09:26:57AM 09:27:03AM 09:27:06AM

MR. SUMMERS: Objection to form. 09:27:07AM

THE WITNESS: So in -- in my own practice, I would not give a VEGF antagonist to a patient who does not have an indic- -- a specific indication 09:27:08AM 09:27:12AM 09:27:15AM 09:27:18AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 28

to receive that medication. 09:27:21AM

BY MR. BRAUSA: 09:27:25AM

Q. Okay. Are -- are you aware that 09:27:25AM

EYLEA on its label has DR as an indication? 09:27:30AM

A. Yes. 09:27:33AM

Q. Okay. And do you ever -- I -- I 09:27:34AM

think you answered the question, but to confirm. 09:27:36AM

You don't prescribe EYLEA or any other VEGF agent 09:27:39AM

to patients that only have DR? 09:27:44AM

MR. SUMMERS: Objection to form. 09:27:47AM

THE WITNESS: Well, again, the 09:27:48AM

way that I practice is I am prescribing 09:27:51AM

a medication to treat a specific feature 09:27:53AM

of disease presentation that would 09:27:56AM

benefit from the use of that agent. So 09:27:58AM

if, in my own practice, a patient has 09:28:02AM

nonproliferative diabetic retinopathy 09:28:06AM

without macular edema, then I would not 09:28:09AM

prescribe the drug for that patient. 09:28:10AM

I don't know how other physicians 09:28:15AM

interpret the phrase "diabetic 09:28:18AM

retinopathy" and whether or not that 09:28:20AM

phrase for another physician might 09:28:25AM

encompass or might incorporate in their 09:28:26AM

own definition the presence of macular 09:28:28AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 29

edema. 09:28:32AM

BY MR. BRAUSA: 09:28:32AM

Q. Are -- are you aware of whether 09:28:35AM

DR is listed as a separate indication from DME on 09:28:36AM

the EYLEA label? 09:28:55AM

A. You'd have to show me the EYLEA 09:28:41AM

label. I haven't -- I haven't looked at it. 09:28:43AM

Q. Okay. Do you know whether the 09:28:46AM

FDA separately approved EYLEA for DR as compared 09:28:48AM

to DME? 09:28:55AM

A. I don't know what the FDA's 09:28:56AM

determination is, but if it's on the label, then 09:28:57AM

there may be -- they may have received that 09:29:01AM

determination from the FDA. 09:29:04AM

Q. Okay. And -- and so sitting here 09:29:05AM

right now, you don't know whether the FDA 09:29:07AM

separately approved DR as an indication from DME? 09:29:10AM

A. I -- 09:29:15AM

MR. SUMMERS: Objection, form. 09:29:16AM

THE WITNESS: I -- I don't know 09:29:16AM

what the FDA's process was in approving 09:29:17AM

the -- the label. 09:29:19AM

BY MR. BRAUSA: 09:29:19AM

Q. Okay. If we now talk about 09:29:19AM

patients that you see that -- that do show the 09:29:23AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 30

presence of a condition you'd treat with a VEGF antagonist -- so this is a patient with DR; they have manifestation of DME -- what are you looking for? What's the determinative factor that you say: Okay. That patient has DR with DME? 09:29:26AM 09:29:31AM 09:29:34AM 09:29:38AM 09:29:42AM

MR. SUMMERS: Objection, form. 09:29:45AM

THE WITNESS: So the features of disease in terms of the presentation of diabetic macular edema are fluid within the retina -- 09:29:46AM 09:29:49AM 09:29:51AM 09:29:54AM

BY MR. BRAUSA: 09:29:54AM

Q. Uh-huh. 09:29:54AM

A. -- and the relationship of that fluid and its location to the center of the retina called the -- the macular. 09:29:55AM 09:29:56AM 09:29:59AM

Q. And what are you looking for? What tests do you do to determine whether there's -- there's fluid in the retina? 09:30:01AM 09:30:03AM 09:30:07AM

MR. SUMMERS: Objection, form. 09:30:09AM

THE WITNESS: So there -- there are many tests that we can do. There are many aspects to determining the presence of fluid, the -- the most important of which is examining the patient. The biomicroscopic examination 09:30:10AM 09:30:11AM 09:30:14AM 09:30:16AM 09:30:18AM 09:30:19AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 31

of the patient's retina at the slit lamp by the ophthalmologist is -- is -- it will demonstrate the features of diabetic macular edema, fluid in the retina. It's -- it's -- and other manifestations of the disease. 09:30:23AM 09:30:27AM 09:30:30AM 09:30:33AM 09:30:35AM 09:30:38AM

There are imaging studies that can also assist in the determination of fluid, the presence of fluid, in the macula. The most common one that we use today is optical coherence tomography. It's a noninvasive test that looks at the retina -- or is able to look at the retina in cross-section and in 3D to look at the volume of tissue in the retina and -- and see the presence of fluid in the macula. 09:30:38AM 09:30:40AM 09:30:44AM 09:30:47AM 09:30:50AM 09:30:55AM 09:30:58AM 09:31:00AM 09:31:02AM 09:31:05AM 09:31:10AM

But there are also diagnostic tests. Prior to the advent of OTC technology, fluorescein angiography was used to look at the presence and look for leakage and the presence of fluid in the macula. In that study, a -- a dye called fluorescein is injected into a vein. It goes through the blood vessels 09:31:12AM 09:31:14AM 09:31:18AM 09:31:21AM 09:31:22AM 09:31:25AM 09:31:29AM 09:31:32AM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 32

of the retina and in the areas where there is vascular incompetence. There's leakage of dye into the retina, and that can be seen on photograph studies. 09:31:34AM 09:31:36AM 09:31:41AM 09:31:43AM

BY MR. BRAUSA: 09:31:45AM

Q. And I may be mistaken, but you also have a patent yourself on diagnosis methods using that type of fluorescein dye, right? 09:31:45AM 09:31:47AM 09:31:51AM

A. I don't have one on fluorescein dye. I have -- I have a patent related to computer-based analyses of the eye. 09:31:52AM 09:31:54AM 09:31:56AM

Q. Okay. 09:31:59AM

A. Of the retina. 09:31:59AM

Q. And -- and you're an inventor on that patent? 09:32:00AM 09:32:02AM

A. I am. 09:32:03AM

Q. Do you recall when you came up with that idea that's reflected in the patent? 09:32:04AM 09:32:05AM

MR. SUMMERS: Objection, form. 09:32:08AM

THE WITNESS: I -- you know, I'd have to -- I'd have to look back. I began work in trying to develop methods to teach computers how to diagnose and manage diabetic retinopathy going back to about 2004-2005 with colleagues at 09:32:09AM 09:32:10AM 09:32:12AM 09:32:16AM 09:32:21AM 09:32:25AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 33

Oak Ridge National Laboratory, and that patent came out of that collaboration. 09:32:29AM 09:32:30AM

BY MR. BRAUSA: 09:32:31AM

Q. Okay. And beyond that patent or that -- that set of patents with that -- with respect to that collaboration, are you an inventor on any other patents? 09:32:32AM 09:32:33AM 09:32:36AM 09:32:39AM

A. I think I have ten patents. 09:32:40AM

Q. Okay. What was -- if you recall, what was your involvement in the drafting process of the patent that you worked at [sic] with respect to computer diagnosis? 09:32:42AM 09:32:44AM 09:32:46AM 09:32:48AM

MR. SUMMERS: And objection. I just want to caution the witness not to reveal the substance of any -- 09:32:50AM 09:32:51AM 09:32:53AM

MR. BRAUSA: Sure. 09:32:54AM

MR. SUMMERS: -- attorney-client communications. 09:32:55AM 09:32:56AM

THE WITNESS: I -- I if you could, just repeat the question. I'm unsure.... 09:32:56AM 09:32:57AM 09:33:00AM

BY MR. BRAUSA: 09:33:00AM

Q. Sure. 09:33:01AM

With respect to the patent we were discussing on computer diagnosis with respect 09:33:01AM 09:33:02AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 34

to DR, what was your involvement in the drafting process? 09:33:05AM 09:33:13AM

A. Well -- 09:33:13AM

MR. SUMMERS: Form. Objection to form and same -- same caution. 09:33:14AM 09:33:15AM

THE WITNESS: I think what I would say is I was the ophthalmologist who brought the technology and the idea to the computer scientists at Oak Ridge National Laboratory. 09:33:21AM 09:33:22AM 09:33:24AM 09:33:27AM 09:33:30AM

BY MR. BRAUSA: 09:33:31AM

Q. Okay. And in putting together the patent, do you recall whether you drafted yourself any portions of the patent? 09:33:31AM 09:33:32AM 09:33:35AM

A. I don't recall. 09:33:37AM

Q. Okay. Do you recall whether you reviewed the patent before it was filed with the patent office? 09:33:37AM 09:33:40AM 09:33:43AM

A. I don't recall. 09:33:43AM

Q. Okay. Now, in your declaration, you refer to various legal standards that I understand were explained to you by counsel. 09:33:44AM 09:33:49AM 09:33:51AM

Do you recall at that point in time whether you understood the concept of, for instance, obviousness? 09:33:53AM 09:33:54AM 09:33:58AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 35

A. At that time, I was not aware of that concept. 09:34:03AM 09:34:05AM

Q. Okay. Sitting here today, are you aware of any differences in the level of data that needs to be presented for an academic publication in a peer-reviewed journal, compared to a patent at the patent office? 09:34:07AM 09:34:08AM 09:34:12AM 09:34:15AM 09:34:18AM

A. Yeah -- 09:34:20AM

MR. SUMMERS: Objection to form. 09:34:20AM

THE WITNESS: Yeah, you'd have to rephrase that question. I'm not -- 09:34:21AM 09:34:22AM

BY MR. BRAUSA: 09:34:23AM

Q. Sure. 09:34:23AM

A. If you could just break it down. 09:34:23AM

Q. You're an author, your expert report says, on numerous academic publications, right -- 09:34:25AM 09:34:26AM 09:34:29AM

A. Yes. 09:34:29AM

Q. -- in peer-reviewed journals? 09:34:29AM

Do you know what a peer-reviewed journal is? 09:34:33AM 09:34:34AM

A. Yes. 09:34:35AM

Q. And do you have to include data in peer-reviewed studies to get published, typically? 09:34:35AM 09:34:37AM 09:34:40AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 36

A. Yes. 09:34:41AM

Q. Okay. Why is that? 09:34:41AM

A. Because the data gen- -- 09:34:42AM

generates the -- the in- -- the new information 09:34:45AM

that creates the study that is of interest to the 09:34:48AM

community and -- you know, and is -- is being 09:34:57AM

published. 09:35:00AM

Q. Okay. And do you have any 09:35:00AM

understanding, now turning to the -- the patent 09:35:02AM

world, whether in order to get a patent, you have 09:35:04AM

to include data as well? 09:35:07AM

A. I -- I have no comment about 09:35:08AM

that. I -- I don't know what the law -- what the 09:35:11AM

patent law is. 09:35:13AM

Q. Okay. And so you don't know what 09:35:14AM

the patent law is with respect to the amount of 09:35:15AM

data that you need to provide in a patent? 09:35:17AM

MR. SUMMERS: Objection, form. 09:35:20AM

THE WITNESS: If you could, just 09:35:20AM

rephrase the question for me. 09:35:22AM

BY MR. BRAUSA: 09:35:23AM

Q. Sure. I -- I think I understood 09:35:24AM

you to say you don't know what the law is with 09:35:25AM

respect to the amount of data necessary in a 09:35:27AM

patent; fair? 09:35:30AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 37

MR. SUMMERS: Objection, form; 09:35:31AM
mischaracterizes his testimony. 09:35:32AM
THE WITNESS: I'm -- I'm sorry, 09:35:35AM
repeat the question one more time for 09:35:39AM
me. 09:35:40AM
BY MR. BRAUSA: 09:35:41AM
Q. Sure. 09:35:41AM
You referenced the fact that you 09:35:47AM
-- you don't know the law with respect to patents 09:35:49AM
in a certain respect, correct? 09:35:52AM
MR. SUMMERS: Objection, form; 09:35:55AM
mischaracterizes his testimony. 09:35:57AM
THE WITNESS: I'm not a patent 09:35:57AM
attorney. 09:35:59AM
BY MR. BRAUSA: 09:35:59AM
Q. Okay. I understand that. But 09:36:00AM
I'm going back to your answer and testimony where 09:36:01AM
you said you weren't familiar with the law on a 09:36:03AM
certain issue, right? 09:36:05AM
MR. SUMMERS: Object to form; 09:36:07AM
mischaracterizes his testimony. 09:36:09AM
THE WITNESS: I -- I'm sorry. 09:36:11AM
What -- 09:36:13AM
BY MR. BRAUSA: 09:36:13AM
Q. Okay. Let -- let me try again. 09:36:13AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 38

Sorry. I'm not trying to be difficult here. 09:36:14AM

Do you have any understanding of 09:36:16AM

how much data is required in a patent to be 09:36:18AM

entitled to a patent? 09:36:23AM

MR. SUMMERS: Objection, form. 09:36:25AM

THE WITNESS: Yeah -- yeah, I 09:36:25AM

don't understand what you mean "how much 09:36:30AM

data is required." That -- that -- that 09:36:31AM

doesn't have meaning to me. 09:36:31AM

BY MR. BRAUSA: 09:36:32AM

Q. Okay. Do you have to include any 09:36:33AM

data in a patent to be entitled to a patent? 09:36:34AM

MR. SUMMERS: Objection to form. 09:36:37AM

THE WITNESS: So it -- again, I'm 09:36:38AM

-- I'm having difficulty understanding 09:36:44AM

your question. For example, if I am 09:36:46AM

going to submit a patent application for 09:36:49AM

a new widget -- 09:36:53AM

BY MR. BRAUSA: 09:36:54AM

Q. Uh-huh. 09:36:54AM

A. -- there doesn't have to 09:36:55AM

necessarily be data, as you define it, for -- 09:36:57AM

that's a new thing and I want to get it -- I want 09:37:01AM

to get a patent for it. 09:37:03AM

So your use of the term "data" 09:37:05AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 39

with respect to patents in general is confusing to me. 09:37:08AM 09:37:11AM

Q. Okay. Well, let's go back to the academic articles that we talked about. And you testified, I believe, that in general you need to include data to get published in a peer-reviewed journal, right? 09:37:11AM 09:37:13AM 09:37:17AM 09:37:19AM 09:37:22AM

A. Yes. 09:37:23AM

Q. Okay. Let's limit ourselves to the same types of data that you would include in an academic publication, okay? 09:37:23AM 09:37:27AM 09:37:31AM

A. Okay. 09:37:36AM

Q. Okay. Do you have to include that same type of data in a patent to be entitled to the patent? 09:37:36AM 09:37:38AM 09:37:41AM

MR. SUMMERS: Object to the form; calls for a legal conclusion. 09:37:42AM 09:37:43AM

THE WITNESS: Yeah, I -- I don't -- again, I'm -- I'm not a patent attorney. I don't know the requirements regarding that, and so I can't answer your question. 09:37:43AM 09:37:46AM 09:37:48AM 09:37:49AM 09:37:52AM

BY MR. BRAUSA: 09:37:52AM

Q. Okay. Thank you. 09:37:52AM

In your report, you refer to 09:37:53AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 40

anti-VEGF agents, anti-VEGF antagonists as the current gold standard for the treatment of DME, DR, AMD? 09:38:01AM 09:38:08AM 09:38:11AM

MR. SUMMERS: Objection, form. 09:38:12AM

THE WITNESS: Yeah, I'm not sure I used that exact term, but they are certainly in common use and effective for patients, yes. 09:38:12AM 09:38:13AM 09:38:17AM 09:38:19AM

BY MR. BRAUSA: 09:38:20AM

Q. Okay. Do you consider them to be the gold standard? 09:38:20AM 09:38:24AM

A. I think they are the standard of care in clinical practice today. I don't know what gold standard means, but -- 09:38:25AM 09:38:27AM 09:38:31AM

Q. Okay. 09:38:33AM

A. -- standard of care, yes. 09:38:33AM

Q. Okay. And so you don't -- you don't know what gold standard, in terms of treatment of intravitreal diseases, means? 09:38:34AM 09:38:36AM 09:38:39AM

A. It would mean -- whatever it means to you, it means to you. Whatever it means to someone else, it could be something different. 09:38:43AM 09:38:45AM 09:38:47AM

Q. I'm just asking about you specifically. Do you have an understanding of what that means? 09:38:47AM 09:38:49AM 09:38:50AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 41

A. I -- I don't use that term. 09:38:51AM

Q. Okay. 09:38:52AM

A. I think standard of care is the 09:38:52AM
appropriate use of a term that -- that we're 09:38:53AM
discussing. 09:38:57AM

Q. Okay. What does standard of care 09:38:57AM
mean to you? 09:39:00AM

A. To me, standard of care is the 09:39:02AM
accepted method of treating a particular disease 09:39:03AM
or clinical condition that is accepted and used 09:39:07AM
within the community and is at -- at a spec- -- 09:39:12AM
and is the appropriate level of care for a 09:39:17AM
patient. 09:39:20AM

Q. Okay. In your view, would a -- 09:39:20AM
would administering an agent that performs worse 09:39:24AM
than the current standard of care be considered an 09:39:27AM
effective treatment? 09:39:30AM

MR. SUMMERS: Objection, form. 09:39:31AM

THE WITNESS: Yeah, I -- I think 09:39:33AM
your -- your term "worse" needs to -- to 09:39:38AM
be -- I think you need to kind of 09:39:40AM
recharacterize the question. 09:39:43AM

BY MR. BRAUSA: 09:39:44AM

Q. Okay. Fair. 09:39:44AM

What's the -- sitting here today, 09:39:44AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 42

if a patient comes to you with DR and DME and you look at the imaging studies and the -- the slit test and the OTC map and you say: Okay. They've got DME -- 09:39:46AM 09:39:51AM 09:39:54AM 09:39:58AM

A. Okay. 09:39:59AM

Q. -- I need to treat them -- 09:39:59AM

A. Okay. 09:40:00AM

Q. -- what's the standard of care that you employ? 09:40:01AM 09:40:01AM

MR. SUMMERS: Objection to form. 09:40:03AM

THE WITNESS: So the standard of care can be many treatments. So some physicians would -- depending on the results of a fluorescein study, might recommend a focal laser treatment. That's still considered standard of care. 09:40:03AM 09:40:05AM 09:40:07AM 09:40:10AM 09:40:13AM 09:40:14AM 09:40:16AM

Some physicians in patients who have diffuse macular edema, who have poor perfusion, perhaps who have failed an anti-VEGF agent, might recommend an intravitreal steroid injection. That's standard of care. 09:40:17AM 09:40:19AM 09:40:22AM 09:40:25AM 09:40:30AM 09:40:34AM

And then there are half a dozen, maybe eight now -- probably half a dozen 09:40:35AM 09:40:37AM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 43

FDA-approved drugs that are anti-VEGF agents; also, off-label anti-VEGF agents that are used to treat diabetic macular edema. 09:40:40AM 09:40:43AM 09:40:48AM 09:40:48AM

So there is a broad range of treatment options for patients with diabetic macular edema, all of which would be considered standard of care. 09:40:51AM 09:40:53AM 09:40:55AM 09:40:57AM

BY MR. BRAUSA: 09:40:58AM

Q. Okay. And I guess my question is specific to your own prescribing habits. What -- do you have a view on what the standard of care is that you personally employ, not other doctors? 09:40:58AM 09:41:01AM 09:41:03AM 09:41:07AM

A. So -- 09:41:09AM

MR. SUMMERS: Objection, form. 09:41:10AM

THE WITNESS: So the standard of care that I -- and are you asking what decision do I make regarding the -- the choice of a drug or clinical regimen in the patient? 09:41:10AM 09:41:12AM 09:41:15AM 09:41:19AM 09:41:23AM

BY MR. BRAUSA: 09:41:23AM

Q. Sure. 09:41:24AM

A. Depends on how the patient presents, what their imaging studies are, what their clinical history is, what their previous 09:41:25AM 09:41:29AM 09:41:32AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 44

responses have been, and what my own experience has been with that patient in terms of their response to intervention. 09:41:35AM 09:41:36AM 09:41:38AM

So the standard of care, even within my own practice, can and does change, or the method of care and the treatment of that patient can and does change based upon all of those clinical features. And that doesn't mean that there's a difference in the standard of care; it means that it's a reflection of the intricacies of clinical medicine, the nature of patient responses to acceptable and appropriate standard-of-care interventions, and that patient's history. 09:41:39AM 09:41:41AM 09:41:45AM 09:41:47AM 09:41:51AM 09:41:55AM 09:41:58AM 09:42:03AM 09:42:07AM 09:42:10AM 09:42:13AM

Q. Understood. Are you familiar with the phrase "treatment naïve" or a patient that's naïve to treatment? 09:42:14AM 09:42:17AM 09:42:23AM

MR. SUMMERS: Objection. 09:42:24AM

THE WITNESS: Yes. 09:42:25AM

BY MR. BRAUSA: 09:42:25AM

Q. What does that mean? 09:42:25AM

A. Well, that -- that treatment [sic] is used primarily in, as I see it or as I read it, in clinical trial studies. So in the development of treatments for various conditions, 09:42:26AM 09:42:27AM 09:42:30AM 09:42:35AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 45

if a new drug is being tested and the -- there is interest in understanding what the effect, the impact of that drug is on the disease being treated, it is beneficial for the patient not to have been previously treated with a drug -- that drug or a similar drug in order to best understand what the impact of that drug, that intervention on that patient within that clinical study is. 09:42:38AM 09:42:44AM 09:42:48AM 09:42:50AM 09:42:55AM 09:42:57AM 09:43:01AM 09:43:05AM

Q. Okay. In your own practice outside of the clinical context, is there a term you refer to for patients that come to you that haven't had any treatment previously? 09:43:08AM 09:43:10AM 09:43:13AM 09:43:16AM

A. I -- I don't use that term. I mean, I -- depending on what the patient presented with, I might say the patient has new onset. If the patient has been previously treated, I would document what those previous treatments are and when they were and -- and if I knew what the responses were. 09:43:17AM 09:43:20AM 09:43:24AM 09:43:27AM 09:43:30AM 09:43:32AM 09:43:39AM

Q. Sure. So it sounds like may- -- is "new onset" a term that you use in your practice? 09:43:40AM 09:43:41AM 09:43:42AM

A. For -- in terms of features of disease that require treatment? Yes, that's a term that I use. 09:43:42AM 09:43:45AM 09:43:47AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 46

Q. Okay. So if we have a patient that comes to you with new onset of DME, would you treat them with laser only? 09:43:47AM 09:43:49AM 09:43:52AM

MR. SUMMERS: Objection, form. 09:43:54AM

THE WITNESS: So, again, I -- I think I made myself clear. The decision regarding how to treat the patient, it would be predicated on the nature of the features of the manifestations of the disease, how much leakage, where that leakage is occurring from, why it's occurring, and -- and, you know, what I thought would be the best treatment option for that patient based upon the clinical exam and the manifestations of disease. 09:43:55AM 09:43:58AM 09:44:01AM 09:44:03AM 09:44:07AM 09:44:09AM 09:44:11AM 09:44:12AM 09:44:17AM 09:44:20AM 09:44:23AM 09:44:25AM

BY MR. BRAUSA: 09:44:25AM

Q. Understood. 09:44:25AM

I understand there are multiple variables, multiple factors you consider as part of the evaluation process. In your practice, do you ever administer laser only, sitting here today, to a patient that has new onset of DME? 09:44:26AM 09:44:28AM 09:44:31AM 09:44:34AM 09:44:38AM

A. I might. 09:44:41AM

Q. Okay. Have you? 09:44:42AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 47

A. I have in the past, certainly, yeah. 09:44:43AM 09:44:44AM

Q. Okay. When was the most recent time you prescribed laser only to a patient? 09:44:44AM 09:44:46AM

A. Well, it -- I'd have to go back and look at my -- my clinical records. 09:44:48AM 09:44:52AM

Q. Okay. And -- and have you looked at your clinical records in preparation for today's deposition? 09:44:54AM 09:44:55AM 09:44:58AM

A. No. 09:44:59AM

Q. Okay. And did you look at your clinical records in preparation for the deposition that occurred in October? 09:44:59AM 09:45:02AM 09:45:06AM

A. No. 09:45:07AM

Q. How far back do your clinical records go, if I can ask? 09:45:07AM 09:45:10AM

A. Well, it depends on which institution you look at. 09:45:12AM 09:45:14AM

Q. Sure. 09:45:14AM

A. So my -- my clinical records at Vanderbilt go back to April 1st of 2018; my clinical records at University of Tennessee Health Science Center go back to July 1st, 2000; and my clinical records at the Massachusetts Medical Center go back to July 1st, 198- -- 1994. 09:45:15AM 09:45:18AM 09:45:21AM 09:45:24AM 09:45:29AM 09:45:32AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 48

Q. Okay. And -- and I'm just curious. Do those get preserved for all time, or do the individual institutions have document retention policies? 09:45:35AM 09:45:37AM 09:45:40AM 09:45:42AM

A. Your -- your guess is as good as mine. 09:45:43AM 09:45:46AM

Q. Okay. 09:45:46AM

A. I mean, they are -- they are preserved, obviously, for a period of time and then archived in some manner. So they may or may not be available. 09:45:46AM 09:45:49AM 09:45:50AM 09:45:53AM

Q. Okay. And those clinical records, I assume, would show for an individual what the treatment was, what the dosing schedule was, if a drug was prescribed, that sort of thing? 09:45:53AM 09:45:54AM 09:45:56AM 09:45:59AM

MR. SUMMERS: Objection, form. 09:46:03AM

THE WITNESS: They might. I -- I don't know. 09:46:03AM 09:46:05AM

BY MR. BRAUSA: 09:46:05AM

Q. Okay. Do you have the opportunity -- if you wanted to, could you go back and review those records? 09:46:05AM 09:46:06AM 09:46:09AM

MR. SUMMERS: Objection, form. 09:46:10AM

THE WITNESS: I wouldn't know where to start or how to archive, you 09:46:11AM 09:46:14AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 49

know, 10,000 individual records within the health -- health -- you know EHR in my own current institution. I wouldn't know how to -- how to search that. 09:46:19AM 09:46:21AM 09:46:28AM 09:46:29AM

BY MR. BRAUSA: 09:46:31AM

Q. Okay. You referred to about, I think, half a dozen VEGF agents that you're familiar with -- 09:46:31AM 09:46:32AM 09:46:35AM

A. Uh-huh. 09:46:35AM

Q. -- fair? 09:46:36AM

A. Yes. 09:46:36AM

Q. Can you name those for me, please? 09:46:36AM 09:46:37AM

A. Well, there's Avastin. There's ranibizumab. Or Avastin is bevacizumab. LUCENTIS, ranibizumab. EYLEA is aflibercept. SYFOVRE is another one. BEOVU is another one that's just come on the market. I think there's -- there may be one more. 09:46:38AM 09:46:43AM 09:46:47AM 09:46:55AM 09:46:55AM 09:46:58AM

Q. Okay. Are you familiar with the drug called Macugen? 09:46:59AM 09:47:02AM

A. Yeah, Macugen, it was -- was the first anti-VEGF agent that was introduced to the market, but it's not in use anymore. 09:47:03AM 09:47:06AM 09:47:11AM

Q. Why is it not in use? 09:47:12AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 50

A. It didn't work as well as the biologics that came subsequent to it. 09:47:13AM 09:47:16AM

Q. Okay. And so do you know of any physicians today that consider Macugen to be the standard of care they employ? 09:47:18AM 09:47:20AM 09:47:24AM

A. You know, I don't know. I can't answer that question. Macugen is still used in conjunction with, for example, multiple drug therapies. I believe Macugen is still being examined for use in studies of diseases that are difficult to manage with single anti-VEGF agents. 09:47:26AM 09:47:27AM 09:47:32AM 09:47:35AM 09:47:38AM 09:47:43AM

So, you know, if you ask me: Is Macugen standard of care? Macugen is not in common use, but it is still in -- used in the care of patients. And so in that regard, I think you would have to include it into -- in the spectrum of agents that are considered, at least currently, standard of care. It may not be as good, based upon our understanding of its -- its impact, but it would still be within the realm of standard of care. 09:47:48AM 09:47:52AM 09:47:55AM 09:47:58AM 09:48:00AM 09:48:02AM 09:48:05AM 09:48:08AM 09:48:12AM 09:48:15AM

Q. Okay. In your clinical practice, have you ever prescribed Macugen? 09:48:15AM 09:48:20AM

A. No. 09:48:22AM

Q. Why not? 09:48:22AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 51

A. So, again, my -- my clinical practice at the time that these agents were being developed was The University of Tennessee Health Science Center. That -- The University of Tennessee was not at the leading edge of using agents that were just coming onto market, and so we didn't -- we didn't -- pharmacies -- the pharmacy at The University of Tennessee did not have Macugen on -- on-label, and so it was not a drug that I used. 09:48:23AM 09:48:28AM 09:48:32AM 09:48:37AM 09:48:38AM 09:48:45AM 09:48:49AM 09:48:53AM 09:48:56AM 09:48:59AM

Q. Okay. And -- and my understanding is that at -- at The University of Tennessee and -- and other institutions like Vanderbilt, there are certain drugs that are made available to clinicians and -- and certain drugs that are not on a -- a list, so to speak. 09:49:00AM 09:49:01AM 09:49:03AM 09:49:07AM 09:49:09AM 09:49:12AM

A. That's -- 09:49:14AM

MR. SUMMERS: Objection: Form, scope. 09:49:15AM 09:49:17AM

THE WITNESS: Again, I'm not -- I'm not in the pharmacy. I don't know how the -- I don't know that -- how that works. 09:49:17AM 09:49:19AM 09:49:21AM 09:49:23AM

BY MR. BRAUSA: 09:49:23AM

Q. Right. But at -- when you were 09:49:24AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 52

at University of Tennessee, you said Macugen wasn't available to you, right? 09:49:25AM 09:49:27AM

A. Yeah. I -- I did not use it. Whether or not someone might have been able to get access to it to use it, that, I don't know. 09:49:28AM 09:49:30AM 09:49:33AM

Q. And so you didn't have access to it, correct? 09:49:35AM 09:49:36AM

A. I personally didn't use it. 09:49:37AM

Q. Okay. And I guess I just want to make sure I'm clear. Did -- did you have -- could you have used it if you'd wanted to at University of Tennessee? 09:49:39AM 09:49:42AM 09:49:45AM 09:49:47AM

A. I -- I don't know. 09:49:47AM

MR. SUMMERS: Objection. 09:49:49AM

THE WITNESS: I didn't -- I didn't investigate that. I didn't use it. 09:49:50AM 09:49:51AM 09:49:52AM

BY MR. BRAUSA: 09:49:52AM

Q. Okay. And -- and why didn't you investigate it? 09:49:53AM 09:49:54AM

A. Just at that time, it was not part of my practice to -- so -- I would just leave it at that. I -- I just didn't use it. 09:49:54AM 09:49:56AM 09:50:07AM

Q. Okay. It was the -- Macugen was the first approved VEGF antagonist, correct? 09:50:08AM 09:50:11AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 53

A. Yes. 09:50:15AM

Q. Do you recall when it was approved? 09:50:15AM 09:50:16AM

A. I'd have to look at the literature. I think maybe 2002, something like that. 09:50:16AM 09:50:18AM 09:50:22AM

Q. Okay. And if we're thinking about the time where Macugen -- it is the only approved VEGF antagonist on the market -- did you do any investigation of whether you should think about using it? 09:50:22AM 09:50:23AM 09:50:25AM 09:50:31AM 09:50:33AM

MR. SUMMERS: Objection, form. 09:50:34AM

THE WITNESS: I -- I just did not make a determination that I would use it in my practice. 09:50:35AM 09:50:36AM 09:50:38AM

BY MR. BRAUSA: 09:50:39AM

Q. I understand that you didn't make a determination that you'd use it. Did you do any investigation of whether it would be beneficial to your patients? 09:50:39AM 09:50:41AM 09:50:43AM 09:50:46AM

MR. SUMMERS: Objection to the form. 09:50:46AM 09:50:47AM

THE WITNESS: Well, I -- I was aware of the literature around it -- 09:50:47AM 09:50:48AM

BY MR. BRAUSA: 09:50:51AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 54

Q. Okay. 09:50:51AM

A. -- but I decide -- I decided not 09:50:52AM

to use it. 09:50:55AM

Q. Okay. And -- and why did you 09:50:55AM

decide not to use it, based on your awareness of 09:50:57AM

the literature? 09:50:59AM

A. Well, I think there are a couple 09:50:59AM

of reasons. One is that my practice was not a -- 09:51:01AM

a large practice at that time, and so I didn't 09:51:08AM

have large numbers of patients to -- to treat. 09:51:11AM

The second was that having been 09:51:16AM

trained in the previous era, I had very good 09:51:18AM

experience with an expertise with focal laser 09:51:21AM

treatment. 09:51:24AM

The third is that there were 09:51:25AM

other drugs that were available. Steroids in 09:51:26AM

particular were also available at that time and 09:51:32AM

were being used for the treatment of these 09:51:33AM

conditions, and so it -- it just -- as a new agent 09:51:35AM

that showed potential promise but was not -- you 09:51:37AM

know, it was just being developed in the market. 09:51:41AM

It wasn't something that I was interested in 09:51:44AM

using. 09:51:45AM

Q. Okay. And then your decision or 09:51:46AM

determination didn't change once it became FDA 09:51:48AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 55

approved as the first in its class? 09:51:51AM

A. I -- I didn't use it. 09:51:53AM

Q. Okay. And was there ever a point where you considered using it after it was approved and affirmatively determined not to? 09:51:54AM 09:51:57AM 09:51:58AM

A. I didn't think about it that way. I don't know. 09:52:01AM 09:52:03AM

Q. Okay. What was the first VEGF antagonist -- antagonist that you decided to use in patients? 09:52:04AM 09:52:07AM 09:52:09AM

A. It was actually Avastin. 09:52:11AM

Q. Okay. And do you recall about when you started using Avastin? 09:52:13AM 09:52:16AM

A. Again, I'd have -- I'd have to go back and look. Probably 20- -- I -- I'd have to go look. 2007, 2008, something like that. 09:52:18AM 09:52:21AM 09:52:28AM

Q. Okay. And at that time, was LUCENTIS approved for -- or was LUCENTIS approved for an anti-VEGF -- 09:52:31AM 09:52:33AM 09:52:37AM

A. It was. 09:52:39AM

Q. -- agent? 09:52:39AM

And why did you use Avastin instead of LUCENTIS? 09:52:40AM 09:52:41AM

A. Because The University of Tennessee pharmacy did not purchase LUCENTIS. 09:52:43AM 09:52:45AM

Q. Okay. And -- and so this is what I wanted to make sure I understood. When you say "The University of Tennessee did not purchase LUCENTIS," did you have any input into what The University of Tennessee did purchase? 09:52:48AM 09:52:49AM 09:52:51AM 09:52:53AM 09:52:57AM

MR. SUMMERS: Objection, form. 09:52:59AM

THE WITNESS: I -- I'll answer your question. I -- I did not. 09:52:59AM 09:53:01AM

Understand that at that time that I began using VEGF antagonists, the two drugs that were available for use were ranibizumab/LUCENTIS and Avastin or bevacizumab. 09:53:05AM 09:53:10AM 09:53:17AM 09:53:21AM 09:53:21AM

The difference between these drugs used that -- when ranibizumab came on the market, it was about $2,000 a dose for patients, and those patients were being treated on a monthly basis. 09:53:25AM 09:53:27AM 09:53:29AM 09:53:31AM 09:53:37AM

And the bevacizumab was a compounded reformulation that was about $50 a dose in its compounded format. 09:53:39AM 09:53:44AM 09:53:46AM

And understand that my practice in Memphis, Tennessee at The University of Tennessee Health Science Center was comprised very much of middle class, 09:53:49AM 09:53:51AM 09:53:54AM 09:53:56AM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 57

poorer, and poorer lower/middle class patients who had limited access to healthcare insurance, who -- for whom even Medicare copays were a substantial and significant financial burden. 09:54:00AM 09:54:05AM 09:54:07AM 09:54:09AM 09:54:12AM

And so my decision to incorporate anti-VEGF agents into my practice was predicated on two things. One was my patient's ability to afford it, but more importantly, the data that was coming out that demonstrated that bevacizumab appeared to have the same clinical benefit in terms of disease mitigation as ranibizumab did. 09:54:14AM 09:54:19AM 09:54:21AM 09:54:24AM 09:54:28AM 09:54:29AM 09:54:33AM 09:54:37AM 09:54:42AM

And so I made a decision within my own practice to use bevacizumab instead of ranibizumab for those reasons. 09:54:44AM 09:54:46AM 09:54:51AM 09:54:53AM

BY MR. BRAUSA: 09:54:53AM

Q. Okay. And -- and you said those were the two VEGF agents available at the time. But there's actually a third, right, Macugen? 09:54:53AM 09:54:54AM 09:54:57AM

A. Correct. 09:54:59AM

Q. Do you recall what the relative cost of Macugen was to your patients? 09:54:59AM 09:55:01AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 58

A. I don't know. I never looked at it. 09:55:03AM 09:55:04AM

Q. Okay. And were there any patients that you thought LUCENTIS might be a better option for, notwithstanding the fact that you didn't have access to it? 09:55:04AM 09:55:07AM 09:55:10AM 09:55:12AM

MR. SUMMERS: Objection to form. 09:55:15AM

THE WITNESS: So, again, my decision-making regarding the use of these agents is predicated upon the patient's underlying condition and their response to the intervention. And so there were occasional patients for whom I would give doses of a -- the bevacizumab in whom I -- and, again, this was -- at that time, this was for neovascular macular degeneration. And for those patients, I didn't get what I felt was an adequate response to that medication. And after, again, a series of injections, based on that own patient's response and -- and -- and time, the -- for some of those patients, for a handful of those patients, if I determined that the Avastin/bevacizumab 09:55:16AM 09:55:17AM 09:55:20AM 09:55:23AM 09:55:26AM 09:55:28AM 09:55:31AM 09:55:37AM 09:55:39AM 09:55:41AM 09:55:42AM 09:55:46AM 09:55:49AM 09:55:53AM 09:55:57AM 09:55:58AM 09:56:02AM 09:56:04AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 59

was not effective, then I would refer them to a colleague in the community who was using rani- -- ranibizumab and they would go to that practice and get the drug. 09:56:07AM 09:56:09AM 09:56:12AM 09:56:14AM 09:56:17AM

BY MR. BRAUSA: 09:56:17AM

Q. Okay. And when you say if you made a determination that bevacizumab was not effective, what would lead you to that determination in a given patient? 09:56:18AM 09:56:20AM 09:56:23AM 09:56:26AM

A. Well, again, the patient's response to the injection based upon their clinical exam, OCT imaging, and potentially fluorescin angiography. 09:56:27AM 09:56:29AM 09:56:31AM 09:56:37AM

Q. Okay. So if we take a patient with DME that you've prescribed bevacizumab to, what would you need to see in a patient to conclude that the treatment is not effective? 09:56:38AM 09:56:40AM 09:56:43AM 09:56:45AM

MR. SUMMERS: Objection, form. 09:56:47AM

THE WITNESS: Okay. So at -- at that time we were talking about, I was not treating patients with diabetic macular edema. I was treating patients with neovascular AMD. 09:56:47AM 09:56:51AM 09:56:52AM 09:56:54AM 09:56:54AM

So are you asking a different 09:56:57AM

question? 09:56:58AM

BY MR. BRAUSA: 09:56:58AM

Q. Okay. Sure. 09:57:00AM

When was the first time you 09:57:00AM

administered -- or do you recall when the first 09:57:02AM

time was that you administered VEGF antagonists 09:57:04AM

for DME? 09:57:06AM

A. It was a couple years after the 09:57:07AM

intit- -- initiation of treatment for neovascular 09:57:11AM

AMD. 09:57:15AM

Q. Okay. And what was it -- why did 09:57:15AM

that occur later in your practice? 09:57:17AM

A. Well, there wasn't evidence -- 09:57:19AM

there wasn't a clinical trial that had been run at 09:57:22AM

that time to demonstrate the -- that it would be 09:57:25AM

efficacious. There was interest. There was a 09:57:30AM

general belief that it would be effective. I 09:57:31AM

think persons of ordinary skill in the art like 09:57:38AM

myself at that time, we were all sort of hoping 09:57:39AM

that we would be able to expand the results of 09:57:41AM

drug use of these anti-VEGF agents for neovascular 09:57:47AM

AMD into other disease states, and clearly that -- 09:57:53AM

that was -- that was performed in the industry. 09:57:56AM

And so once -- once we began to 09:57:59AM

see early evidence that it was showing efficacy in 09:58:02AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 61

diabetic macular edema, then physicians like myself began to adopt it and use it for patients. 09:58:07AM 09:58:10AM

Q. Okay. And when you say their -- once there were clinical studies showing it was efficacious in DME, what do you mean by that? 09:58:13AM 09:58:17AM 09:58:20AM

MR. SUMMERS: Objection, form. 09:58:24AM

THE WITNESS: Well, there were -- again, the -- there were studies that were being presented at meetings to -- that were talking about the early clinical studies to demonstrate the efficacy for DME. 09:58:25AM 09:58:27AM 09:58:29AM 09:58:32AM 09:58:33AM 09:58:35AM

BY MR. BRAUSA: 09:58:37AM

Q. Okay. And -- and what's neces-- or what was it that demonstrated the efficacy, in your view? 09:58:37AM 09:58:39AM 09:58:42AM

MR. SUMMERS: Objection to form. 09:58:43AM

THE WITNESS: Well, so the initial studies looked at things like improvement in diabetic macular edema in terms of macular thickness. And so that was one outcome that was being examined in those initial studies. But also things like visual acuity. 09:58:44AM 09:58:45AM 09:58:49AM 09:58:53AM 09:58:56AM 09:58:59AM 09:59:02AM

BY MR. BRAUSA: 09:59:03AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 62

Q. And when you say "macular thickness is one thing that was being looked at," that's related to the amount of fluid in the retina; is that fair? 09:59:05AM 09:59:07AM 09:59:11AM 09:59:13AM

A. Yes. 09:59:14AM

Q. Okay. And so the more fluid, the thicker the -- the macula or retina is? 09:59:15AM 09:59:17AM

A. Well, it's a little but more nuanced than that, because the macula is a 3D structure. 09:59:20AM 09:59:23AM 09:59:26AM

Q. Uh-huh. 09:59:26AM

A. And so the amount of fluid and -- can be -- is a function not only of the area in which that fluid is, but also some -- some -- so a smaller amount of fluid in a -- in a -- in one area might have a different -- might have a larger impact than a larger amount of fluid over a much broader area, if that makes sense. 09:59:27AM 09:59:28AM 09:59:32AM 09:59:35AM 09:59:37AM 09:59:40AM 09:59:43AM

Q. In your own practice, do you use or do you measure macular thickness as part of the diagnosis process? 09:59:44AM 09:59:49AM 09:59:53AM

MR. SUMMERS: Objection, form. 09:59:54AM

THE WITNESS: I use the optical coherence tomography imaging to evaluate the status of the macula. I -- the 09:59:55AM 09:59:59AM 10:00:00AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 63

1	macular thickness algorithms are part of	10:00:01AM
2	the -- of that imaging, you know, of	10:00:05AM
3	that technology.	10:00:07AM
4	BY MR. BRAUSA:	10:00:08AM
5	Q. Okay. And -- and so is that an	10:00:08AM
6	output that you get from that type of technology	10:00:11AM
7	that says this is the macular thickness?	10:00:13AM
8	A. It can be. There are various	10:00:16AM
9	metrics that can be used, yeah.	10:00:18AM
10	Q. Okay. Do you -- do you use that	10:00:20AM
11	metric when you're getting the results from an OCT	10:00:21AM
12	scan?	10:00:25AM
13	A. Sometimes. I -- I also use my	10:00:25AM
14	own judgment in -- in terms of looking at the --	10:00:28AM
15	the images themselves.	10:00:30AM
16	Q. And when you say you're looking	10:00:31AM
17	at these images themselves and using your clinical	10:00:32AM
18	judgment, what are you looking for when you look	10:00:35AM
19	at the image?	10:00:36AM
20	A. So in -- when there is macular	10:00:37AM
21	edema present in the OCT, you see thickening of	10:00:40AM
22	the retina. You see evidence of thickening of	10:00:46AM
23	layers of tissue within the retina, which is a	10:00:50AM
24	laminated structure. You can see areas of what's	10:00:53AM
25	called cystic fluid, fluid-filled cysts within the	10:00:56AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 64

retina. You can see evidence of a fluid 10:00:59AM
underneath the retina. 10:01:04AM
So there are many different 10:01:05AM
features of fluid within -- or a fluid as it 10:01:06AM
presents in macular edema. And so all of those 10:01:11AM
are part of my assessment as to the status of the 10:01:14AM
macula and its response to treatment. 10:01:19AM
Q. Is there a way that you can 10:01:21AM
characterize for me what you'd need to see in 10:01:24AM
order to say: Okay. Looking at this retinal 10:01:27AM
image, I'm going to start this patient on a VEGF 10:01:31AM
antagonist? 10:01:34AM
MR. SUMMERS: Objection, form. 10:01:34AM
THE WITNESS: Yeah, you'd have to 10:01:35AM
-- you'd have to clarify that -- 10:01:37AM
BY MR. BRAUSA: 10:01:37AM
Q. Sure. 10:01:37AM
A. -- question for me a little bit. 10:01:39AM
Q. So I think you -- I think I 10:01:40AM
understood you to say that you -- you sometimes 10:01:42AM
use the OCT data or sometimes use the retinal 10:01:43AM
thickness in your diagnosis decisions or -- or 10:01:47AM
prescribing decisions; is that fair? 10:01:51AM
A. I'd say I commonly use it, yes. 10:01:52AM
Q. Okay. You commonly use that. 10:01:55AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 65

I think you mentioned that 10:01:57AM
sometimes you just look at the retinal image and 10:01:58AM
use your clinical expertise to make a prescribing 10:02:01AM
decision? 10:02:05AM
A. Well, I -- I use both. It's part 10:02:05AM
of -- both are -- are part of the assessment of 10:02:06AM
the patient. 10:02:08AM
Q. Okay. And -- and I guess I'm 10:02:09AM
just trying to understand. What would you need to 10:02:13AM
see in that assessment to decide: Okay. I'm 10:02:15AM
going to prescribe or start this patient on a VEGF 10:02:17AM
antagonist? 10:02:22AM
MR. SUMMERS: Objection, form. 10:02:23AM
THE WITNESS: So what I'm looking 10:02:23AM
for is the features that I described. 10:02:26AM
The presence of fluid, the location of 10:02:28AM
that fluid. Another important aspect of 10:02:31AM
a treatment decision is the visual 10:02:36AM
acuity of the patient; is the fluid 10:02:38AM
that's there having an impact on their 10:02:41AM
vision. 10:02:43AM
Another important feature or 10:02:44AM
aspect is the -- for example, the 10:02:45AM
clinical history and previous images. 10:02:47AM
Is there a -- is there a trend in terms 10:02:51AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 66

of the amount of fluid that's there? 10:02:54AM

I -- you have to understand that 10:02:55AM

diabetic macular edema is a dynamic 10:02:57AM

process. It's not a thing that's there. 10:03:00AM

It's not like a broken bone, right? 10:03:03AM

It's a dynamic process. The -- the 10:03:05AM

vessels are leaking fluid because of the 10:03:07AM

retina -- of the damage. The retina is 10:03:11AM

continuously pumping that fluid out, and 10:03:14AM

the amount of fluid that's there is a 10:03:16AM

result of the equilibrium of that 10:03:20AM

dynamics. 10:03:23AM

And so understanding and 10:03:24AM

incorporating that understanding into 10:03:25AM

decision-making is also part of it. 10:03:27AM

It's not, you know, is there a thing 10:03:28AM

there that I'm seeing that I'm going to 10:03:31AM

make a decision on. It's -- it's 10:03:34AM

predicated on a number of different 10:03:35AM

features of the manifestations of the 10:03:37AM

disease. 10:03:38AM

Is the patient's A1C under 10:03:39AM

control? Is their hypertension under 10:03:42AM

control? Am I willing to do an 10:03:43AM

injection in a patient who has just a 10:03:45AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 67

little bit of fluid but who -- for whom better blood sugar control might actually be the best course of action? Is there ischemia in the peripheral retina that's contributing to the macular edema for whom laser treatment might be a better treatment than an anti-VEGF agent? 10:03:48AM 10:03:52AM 10:03:55AM 10:03:58AM 10:04:00AM 10:04:02AM 10:04:04AM 10:04:07AM

There are -- there are lots of different considerations that need to -- that I incorporate in terms of making a decision for that patient about what the best course of action is to manage their disease. 10:04:08AM 10:04:09AM 10:04:11AM 10:04:15AM 10:04:18AM 10:04:20AM

BY MR. BRAUSA: 10:04:21AM

Q. Got it. 10:04:21AM

If we focus on macular thickness, the units for that are micrometers; is that -- my understanding correct? 10:04:22AM 10:04:25AM 10:04:28AM

A. Yes, uh-huh. 10:04:29AM

Q. Okay. Is there a -- if -- if you're considering a macular thickness, is there a threshold or a guide, rule of thumb, that you use to determine when treatment with a VEGF antagonist is warranted? 10:04:30AM 10:04:32AM 10:04:35AM 10:04:39AM 10:04:44AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 68

MR. SUMMERS: Objection to form. 10:04:45AM

THE WITNESS: Yeah, I -- I don't 10:04:46AM

-- I don't know about the practice of 10:04:47AM

other practitioners. I -- I don't know 10:04:51AM

that practitioners measure the macular 10:04:53AM

thickness in microns every visit. 10:04:57AM

BY MR. BRAUSA: 10:05:00AM

Q. Uh-huh. 10:05:00AM

A. That information is available, 10:05:01AM

but it's not necessarily useful in making a 10:05:03AM

decision about what's best to do for that patient. 10:05:05AM

So, yes, macular thickness is important in terms 10:05:08AM

of being able to quantitatively demonstrate some 10:05:13AM

improvement or lack thereof. 10:05:17AM

So if we want to know, you know, 10:05:20AM

has the thickness gone from 400 microns to 350 10:05:21AM

microns, that's -- that's useful. Do I need to do 10:05:25AM

a measurement, or can I look at the previous 10:05:28AM

cross-sectional image and look at the current 10:05:32AM

cross-sectional image and say: Yes, we're making 10:05:36AM

progress here, and I'm going to continue doing 10:05:40AM

what I'm doing. 10:05:42AM

So it's a combination of both. 10:05:42AM

It's examining the image. It's looking at the 10:05:45AM

time frame of images as they change. And also 10:05:46AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 69

using quantitative data that -- that gener- -- 10:05:49AM
that's generated by the device. 10:05:52AM
Q. Okay. And -- and so in a patient 10:05:53AM
that comes to you for the first time, you do the 10:05:55AM
OCT, you have the macular thickness data available 10:05:57AM
-- 10:05:57AM
A. Uh-huh. 10:05:57AM
Q. -- and -- and you see it. You 10:06:00AM
see the numbers -- 10:06:02AM
A. Yeah. 10:06:02AM
Q. -- and they have a macular 10:06:02AM
thickness of 400 microns, let's say. 10:06:04AM
A. Okay. 10:06:07AM
Q. Would that cause you alone to 10:06:07AM
prescribe them a VEGF antagonist? 10:06:11AM
MR. SUMMERS: Objection, form. 10:06:15AM
THE WITNESS: So I -- I don't 10:06:15AM
make treatment decisions for patients 10:06:16AM
based upon a picture, right? I have to 10:06:18AM
take into account my clinical exam, a 10:06:20AM
patient's history, all the things that 10:06:24AM
-- that I've described. 10:06:25AM
So if a patient presents and has 10:06:27AM
diabetes and has diabetic macular edema 10:06:30AM
and has a macular thickness of 400 10:06:32AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 70

microns, as you say, and I feel that they would benefit from an injection of an anti-VEGF agent, then I would recommend that and do it. 10:06:35AM 10:06:40AM 10:06:42AM 10:06:45AM

BY MR. BRAUSA: 10:06:46AM

Q. Okay. Under- -- understood. 10:06:46AM

And I understand it's one of various factors you consider, the macular thickness. Is there any rule of thumb you have in terms of where you draw the line between treat/don't treat with a VEGF antagonist in terms of macular thickness? 10:06:48AM 10:06:50AM 10:06:52AM 10:06:55AM 10:06:59AM 10:07:02AM

MR. SUMMERS: Objection, form. 10:07:04AM

THE WITNESS: Yeah, if you -- if you could just, I'm sorry, repeat the question. 10:07:04AM 10:07:05AM 10:07:07AM

BY MR. BRAUSA: 10:07:07AM

Q. Sure. 10:07:08AM

So what's the -- in a patient without DME, without DR, a healthy subject, what's the -- what would the OCT show in terms of macular thickness? 10:07:08AM 10:07:10AM 10:07:14AM 10:07:18AM

MR. SUMMERS: Objection, form. 10:07:19AM

THE WITNESS: Again, they -- the -- the macular OCT varies in thickness 10:07:19AM 10:07:21AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 71

depen- -- depending on where you are -- 10:07:26AM

BY MR. BRAUSA: 10:07:26AM

Q. Uh-huh. 10:07:26AM

A. -- in the retina. So there isn't a number. 10:07:27AM 10:07:29AM

Q. Okay. And -- and what's the range of numbers that you're looking at? 10:07:30AM 10:07:31AM

MR. SUMMERS: Objection, form. 10:07:32AM

THE WITNESS: Again, in normal retina at -- at its height, perhaps 250 microns at the base of the fovea, maybe 180 microns. Everybody's a little bit different and the retinal thicknesses varies a little bit. 10:07:33AM 10:07:35AM 10:07:38AM 10:07:42AM 10:07:44AM 10:07:45AM

BY MR. BRAUSA: 10:07:46AM

Q. Okay. And -- and there's not a portion of the retina that you're looking at for macular thickness when you're looking for DME? 10:07:46AM 10:07:47AM 10:07:49AM

A. Well, so, again, that -- 10:07:52AM

MR. SUMMERS: Objection, form. 10:07:52AM

Objection to form. 10:07:54AM

THE WITNESS: The -- the clinical trials use central subfield thickness. The macula can be parsed into different areas. And so, again, that's -- that's 10:07:54AM 10:08:00AM 10:08:05AM 10:08:07AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 72

what's looked at as the central macula. 10:08:09AM

BY MR. BRAUSA: 10:08:12AM

Q. Okay. Do you look at other areas 10:08:13AM

of the retina in your practice, beyond the central 10:08:14AM

subfield? 10:08:18AM

A. I -- I look -- 10:08:19AM

MR. SUMMERS: Objection, form. 10:08:19AM

THE WITNESS: I look at the 10:08:19AM

entire retina when I examine the 10:08:20AM

patient. 10:08:21AM

BY MR. BRAUSA: 10:08:22AM

Q. Okay. And so if we focus on the 10:08:23AM

central or center subfield, is there a thickness 10:08:25AM

that you view as -- as too thick, so to speak, for 10:08:28AM

DME? 10:08:31AM

MR. SUMMERS: Objection to form. 10:08:32AM

THE WITNESS: Yeah. Again, I -- 10:08:33AM

I don't treat patients based upon 10:08:34AM

numbers. 10:08:36AM

BY MR. BRAUSA: 10:08:37AM

Q. Okay. 10:08:37AM

A. So I'll -- I'll give you an 10:08:37AM

example. So recent study has shown that many 10:08:42AM

patients who have macular edema -- diabetic 10:08:46AM

patients who have macular edema -- and good visual 10:08:52AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 73

acuity, even in the presence of macular edema, do just as well in terms of their visual acuity two years on if you don't treat them, if you treat with the anti- -- anti-VEGF agents, or if you treat them with a laser. 10:08:54AM 10:08:58AM 10:09:03AM 10:09:07AM 10:09:10AM

So the presence of macular edema in central and -- and thickening of the macula actually isn't now -- and we're talking about today -- isn't necessarily an indication for treatment based upon what we know about the biology and the natural history of diabetic macular edema. 10:09:12AM 10:09:14AM 10:09:19AM 10:09:22AM 10:09:26AM 10:09:31AM 10:09:35AM

So our -- our thoughts, our -- our management process is changing. And this is one of those examples where the thickness of the macula actually doesn't have any impact on the outcome two years down the road, and, therefore, decisions are being made not to treat patients based upon that new understanding that macular thickness, I mean, is not directly related to visual outcomes in the future. 10:09:35AM 10:09:41AM 10:09:44AM 10:09:47AM 10:09:49AM 10:09:52AM 10:09:56AM 10:10:01AM 10:10:03AM

Q. Okay. Have you talked to any of your colleagues at Vanderbilt about this case? 10:10:05AM 10:10:13AM

A. No. 10:10:15AM

Q. Okay. Do you know Michael Elman? 10:10:16AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 74

A. No. 10:10:19AM

Q. Have you ever been a co-author with him on any papers? 10:10:19AM 10:10:21AM

A. Not that I'm aware of. There was a time at The University of Tennessee where we were a site for one of the DRCR clinical studies, and I don't recall how much patients we contributed to that. So there was a period of time in which we were part of the DRCR, which Michael Elman is, and so I might be in -- some author, you know, on some back page of one of the DRCR studies with him. But I'm not aware. 10:10:23AM 10:10:31AM 10:10:33AM 10:10:39AM 10:10:41AM 10:10:42AM 10:10:45AM 10:10:48AM 10:10:53AM

Q. Okay. And when you say you were the -- The University was a participant in the study, that means you had patients enrolled in the study, but you weren't responsible for the study design, correct? 10:10:56AM 10:10:58AM 10:10:59AM 10:11:02AM 10:11:06AM

A. Correct. 10:11:06AM

Q. Have you ever designed a clinical trial? 10:11:06AM 10:11:08AM

A. I have not designed a clinical trial. 10:11:16AM 10:11:18AM

Q. My understanding is that there are different phases of clinical trials; fair? 10:11:19AM 10:11:21AM

A. Yes. 10:11:24AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 75

Q. And I've heard, essentially, a Phase 1, a Phase 2, and a Phase 3 trial, generally speaking? 10:11:25AM 10:11:27AM 10:11:30AM

A. Those are the -- the general aspects of a clinical trial. They are also postmarketing aspects to clinical trials as well. 10:11:30AM 10:11:33AM 10:11:37AM

Q. Okay. And -- and postmarketing would be after a Phase 3 trial? 10:11:39AM 10:11:41AM

A. After approval, yeah, Phase 3. 10:11:42AM

Q. Okay. What is a -- do you have an under- -- I guess what I'm trying to understand, is there a general purpose for each phase of the trial? 10:11:44AM 10:11:45AM 10:11:47AM 10:11:51AM

A. That's my understanding, yes. 10:11:52AM

Q. Okay. And what's your understanding of the purpose of a Phase 1 trial? 10:11:53AM 10:11:54AM

MR. SUMMERS: Objection, form. 10:11:57AM

THE WITNESS: So, again, just in general, broadly -- 10:11:57AM 10:12:02AM

BY MR. BRAUSA: 10:12:04AM

Q. Sure. 10:12:04AM

A. -- the purpose of a Phase 1 trial is to determine whether or not -- if -- if, for example, we're talking about a drug, a new drug that's being evaluated for clinical efficacy, 10:12:04AM 10:12:06AM 10:12:10AM 10:12:11AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 76

whatever it is, that -- a Phase 1 trial is basically to determine is the use of that drug safe for patients. And that's the primary -- the primary end point for a Phase 1 trial. 10:12:15AM 10:12:18AM 10:12:22AM 10:12:26AM

But there are also potentially clinical end points that can be garnered from that initial Phase 1 data. 10:12:31AM 10:12:33AM 10:12:37AM

Q. Okay. And, generally speaking, again, what's the end point in your understanding or -- or purpose of a Phase 2 trial? 10:12:39AM 10:12:41AM 10:12:43AM

MR. SUMMERS: Objection to form. 10:12:46AM

THE WITNESS: So if I understand your questions correctly, in general, a Phase 2 study looks at initial data to demonstrate clinical efficacy. 10:12:46AM 10:12:52AM 10:12:56AM 10:12:58AM

So the Phase 1 is primarily is it safe to use. The Phase 2 is do we see a clinical benefit that would warrant a larger study to demonstrate potential efficacy. 10:13:01AM 10:13:03AM 10:13:06AM 10:13:09AM 10:13:12AM

Phase 2 studies also can be used to look at different doses of drugs to determine whether or not there are differential efficacies associated with different doses. 10:13:13AM 10:13:16AM 10:13:22AM 10:13:25AM 10:13:27AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 77

BY MR. BRAUSA: 10:13:27AM

Q. Okay. And so your general 10:13:27AM

understanding is that in Phase 1, you're not 10:13:29AM

getting data on whether the drug is efficacious? 10:13:33AM

MR. SUMMERS: Objection, form. 10:13:36AM

THE WITNESS: I would disagree 10:13:37AM

with that statement. I think you are -- 10:13:38AM

they are getting data; it's just not the 10:13:39AM

primary end point for the study. 10:13:42AM

BY MR. BRAUSA: 10:13:44AM

Q. I see. Okay. 10:13:44AM

If we move to Phase 3, what's 10:13:45AM

your understanding of the general purpose of a 10:13:47AM

Phase 3 clinical trial? 10:13:50AM

MR. SUMMERS: Objection, form. 10:13:53AM

THE WITNESS: The Phase 3 10:13:54AM

clinical trial is a more robust, larger 10:13:55AM

clinical study to demonstrate both 10:13:57AM

safety and efficacy in a larger patient 10:14:01AM

population. 10:14:03AM

BY MR. BRAUSA: 10:14:03AM

Q. Okay. And do you have any 10:14:03AM

understanding of -- and I -- I guess, let me back 10:14:05AM

up. 10:14:08AM

A Phase 3 trial is ultimately 10:14:09AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 78

what gets submitted to the FDA, typically, for commercial approval? 10:14:11AM 10:14:14AM

A. Well, I'm not -- I'm not -- I don't know that -- that specific process. 10:14:15AM 10:14:20AM

Q. Okay. 10:14:21AM

A. The other thing I would say also is that that Phase 3 study, unlike the Phase 1 and the Phase 2, typically Phase 3 clinical trials are prospective and blinded and have control arms. And so it looks at efficacy relative to sham or other controls or other standard of care. 10:14:21AM 10:14:23AM 10:14:25AM 10:14:30AM 10:14:33AM 10:14:36AM

But I -- I -- I don't know exactly which data. I -- I would expect -- I would predict that the Phase 1, the Phase 2, and the Phase 3 data would also be required by the FDA. 10:14:39AM 10:14:40AM 10:14:44AM 10:14:47AM 10:14:50AM

Q. Okay. And -- and so you have not gone through that process of getting a drug approved and what data the FDA needs to see to approve a drug? 10:14:50AM 10:14:51AM 10:14:54AM 10:14:57AM

A. No, I have not. 10:14:57AM

Q. Okay. And I just want to make sure I'm clear: You mentioned that you hadn't designed any clinical trials. Have you ever designed dosing regimens to be explored in 10:14:58AM 10:14:59AM 10:15:03AM 10:15:08AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 79

clinical trials? 10:15:12AM

A. No. 10:15:13AM

Q. And so you have never looked at data, for instance, from a Phase 1 trial and then said: Hey, let's explore these dosing regimens in Phase 2 trial for any drug? 10:15:13AM 10:15:15AM 10:15:18AM 10:15:22AM

A. I have not. 10:15:23AM

Q. Okay. And similarly, you have not looked at the design of a Phase 2 trial and said: Let's -- let's use this dosing regimen in the Phase 3 trial? 10:15:24AM 10:15:25AM 10:15:28AM 10:15:32AM

A. I have not. 10:15:34AM

Q. Okay. Do you know whether Phase 2 trials are always successful in showing efficacy? 10:15:36AM 10:15:38AM 10:15:42AM

MR. SUMMERS: Objection, form. 10:15:44AM

THE WITNESS: I'm sure that there are Phase 3 trials that have not shown efficacy. 10:15:45AM 10:15:48AM 10:15:51AM

BY MR. BRAUSA: 10:15:52AM

Q. Okay. Are -- are you familiar with any particular Phase 2 trials that have not shown efficacy? 10:15:52AM 10:15:53AM 10:15:55AM

A. I -- I can't name one for you off the top of my head. 10:15:56AM 10:15:59AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 80

Q. Okay. Do you have any knowledge or awareness of the percentage of drugs that go into Phase 2 trials that don't proceed into Phase 3 trials? 10:16:00AM 10:16:01AM 10:16:04AM 10:16:07AM

A. No. 10:16:08AM

Q. Okay. Do you know whether it's a lot or a little, generally speaking? 10:16:08AM 10:16:11AM

A. I have no idea. 10:16:13AM

Q. Okay. And do you know how many drugs that proceed to Phase 3 trials ultimately get approved by the FDA or not? 10:16:14AM 10:16:17AM 10:16:21AM

A. I do not know. 10:16:22AM

Q. Are you familiar with VIVID and VISTA trials for aflibercept? 10:16:23AM 10:16:26AM

A. I just -- just generally. 10:16:29AM

Q. Okay. What's your general familiarity with that? 10:16:31AM 10:16:32AM

A. I -- I'd have to -- I'd have to review the -- 10:16:33AM 10:16:36AM

Q. Okay. 10:16:36AM

A. -- the study. 10:16:37AM

Q. Do you have any understanding of what those studies are about? 10:16:38AM 10:16:39AM

A. I haven't reviewed them for this declaration -- or for this deposition, so I'd have 10:16:40AM 10:16:42AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 81

to go back and look at it. 10:16:45AM

Q. Got it. 10:16:46AM

Do you remember whether they -- 10:16:47AM

you reviewed them at the time they were published, 10:16:47AM

the results? 10:16:50AM

A. I don't recall that. 10:16:50AM

Q. Okay. 10:16:51AM

MR. SUMMERS: And, Counsel, are 10:16:53AM

we -- are you about to move to a 10:16:54AM

different topic? 10:16:56AM

MR. BRAUSA: I think so. We can 10:16:57AM

take a break. 10:16:59AM

MR. SUMMERS: Yeah, now's a good 10:16:59AM

time to take a break, if that's all 10:17:00AM

right. 10:17:01AM

MR. BRAUSA: Sounds good. 10:17:01AM

THE VIDEOGRAPHER: We are going 10:17:03AM

off the record at approximately 10:17 10:17:04AM

a.m. 10:17:06AM

(Brief recess observed.) 10:34:26AM

THE VIDEOGRAPHER: We are going 10:34:26AM

back on the record at approximately 10:34:29AM

10:34 a.m. 10:34:31AM

BY MR. BRAUSA: 10:34:32AM

Q. During the break, Dr. Chaum, did 10:34:35AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 82

you talk to your counsel at all? 10:34:37AM

A. I did. 10:34:39AM

Q. What'd you talk about? 10:34:39AM

A. Just how I'm doing. 10:34:40AM

Q. Okay. You talk about your testimony at all? 10:34:42AM 10:34:44AM

A. No. 10:34:45AM

Q. Before we broke, we had talked about your prior deposition in a different IPR proceeding that occurred in October. 10:34:45AM 10:34:48AM 10:34:52AM

Do you recall that? 10:34:54AM

A. Yes. 10:34:54AM

Q. And at that deposition, you testified that you used EYLEA primarily for your diabetic patients because it can provide, quote: "A better effect for their disease than Avastin," end quote, in some instances. Is that fair? 10:34:54AM 10:34:58AM 10:35:04AM 10:35:06AM 10:35:10AM

A. I'd have to go back and look at that testimony. 10:35:13AM 10:35:14AM

Q. Okay. And in your clinical practice, have you observed EYLEA to provide a better effect for their disease than Avastin in some instances? 10:35:14AM 10:35:16AM 10:35:19AM 10:35:21AM

A. In some instances, yes. 10:35:22AM

Q. Okay. And are there any specific 10:35:23AM

instances you can tell me about? 10:35:25AM

A. Not that I can recall offhand. 10:35:27AM

In my practice, as I mentioned, I would start patients on Avastin for the reasons that we discussed. And if there wasn't a desired benefit for those patients after some period of time, depending on that patient, then I would consider switching over to a different agent. And EYLEA was available. 10:35:30AM 10:35:36AM 10:35:38AM 10:35:46AM 10:35:49AM 10:35:53AM 10:35:56AM

Q. Okay. And -- and is there any particular amount of time that you wait before making that switch, or does it just depend on the patient and the results of your multi-factored analysis of that patient? 10:35:57AM 10:36:00AM 10:36:04AM 10:36:06AM 10:36:10AM

MR. SUMMERS: Objection, form. 10:36:10AM

THE WITNESS: Just -- if you could just shorten the question for me. 10:36:11AM 10:36:13AM

BY MR. BRAUSA: 10:36:15AM

Q. Sure. 10:36:15AM

You said that if the -- you start a patient on Avastin and you're not seeing the desired benefits by a certain point in time, you might consider switching them to EYLEA, correct? 10:36:16AM 10:36:18AM 10:36:20AM 10:36:22AM

A. Yes. 10:36:25AM

Q. Is there a certain amount of time 10:36:25AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 84

that you would wait before making that decision? 10:36:27AM

A. Not necessarily, no. 10:36:30AM

Q. Is there a minimum amount of time you would prescribe Avastin before switching to EYLEA? 10:36:33AM 10:36:36AM 10:36:39AM

A. Not that I recall, no. 10:36:39AM

Q. And is there a maximum amount of time you would wait before switching a patient from Avastin to EYLEA? 10:36:40AM 10:36:43AM 10:36:45AM

A. Not that I would recall. 10:36:47AM

Q. Okay. When you start a patient on Avastin, what dosing regimen do you use? 10:36:49AM 10:36:50AM

A. What do you mean by "dosing regimen"? 10:36:56AM 10:36:58AM

Q. Sure. 10:36:58AM

Do you have an understanding of what a dosing regimen is? 10:36:59AM 10:37:00AM

A. I -- if you'll define for me what you mean by "dosing regimen." 10:37:02AM 10:37:04AM

Q. I -- I could do that. I'm more interested in whether you use that terminology. Do you refer to a dosing regimen ever in your practice? 10:37:06AM 10:37:09AM 10:37:12AM 10:37:14AM

A. I don't refer to that in my documentation of my patient interactions, no. 10:37:14AM 10:37:16AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 85

Q. All right. In -- in rendering your opinions in this matter, do you have an understanding of what a dosing regimen is? 10:37:19AM 10:37:21AM 10:37:22AM

A. I -- if I understand your question correctly, I -- I do understand the term "dosing regimen," yes. 10:37:25AM 10:37:32AM 10:37:36AM

Q. Okay. And what does it mean to you? 10:37:37AM 10:37:38AM

A. Well, in general, a dosing regimen would mean the schedule upon which you would give a drug for a particular indication. 10:37:38AM 10:37:42AM 10:37:47AM

Q. Does the dosing schedule include the amount of drug given at each point in time? 10:37:49AM 10:37:51AM

A. It -- it may. If there are multiple doses of a drug available, then it might, yes. 10:37:54AM 10:37:58AM 10:38:02AM

Q. Okay. And so if in your report you're using the term "dosing regimen," does that refer to the schedule in terms of time and the amount or just the schedule? 10:38:02AM 10:38:04AM 10:38:07AM 10:38:11AM

A. I -- I mean, I'd have to look at the context in which it's being used. 10:38:15AM 10:38:17AM

Q. Okay. In the patients that you've observed a better effect with EYLEA than Avastin, what do you mean when you say you've 10:38:21AM 10:38:23AM 10:38:25AM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 86

observed "a better effect"? 10:38:29AM

A. Well, I'm not sure that I've 10:38:31AM

observed a better effect in all patients that were 10:38:33AM

switched from one drug to the other. The purpose 10:38:35AM

of switching was to see whether or not a better 10:38:38AM

therapeutic effect could be achieved, but not 10:38:43AM

necess- -- but wasn't always achieved. 10:38:49AM

Q. Okay. And in the patients that 10:38:50AM

you did observe and did achieve a better 10:38:53AM

therapeutic effect, that phrase "therapeutic 10:38:56AM

effect," what do you mean by that? 10:38:59AM

A. I -- in general what I would mean 10:39:00AM

is improvement in the status of the macula and/or 10:39:02AM

improvement in vision. 10:39:06AM

Q. And that's as compared to their 10:39:07AM

status or vision when they were being dosed with 10:39:10AM

Avastin? 10:39:13AM

A. Correct. 10:39:14AM

Q. Okay. And in some patients it 10:39:14AM

sounds like you didn't observe a therapeutic -- a 10:39:18AM

therapeutic effect or benefit from EYLEA? 10:39:22AM

A. That is correct. 10:39:24AM

Q. Okay. Are there any patients 10:39:24AM

that you have observed did -- did worse when they 10:39:26AM

were switched to EYLEA? 10:39:29AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 87

A. Not that I recall, no. 10:39:31AM

Q. Okay. Once you've made the 10:39:33AM

switch from Avastin to EYLEA, have you ever 10:39:35AM

switched patients back to Avastin for any reason? 10:39:38AM

A. I don't recall specific patients, 10:39:46AM

but if I didn't see a therapeutic benefit after 10:39:49AM

using EYLEA, then for some patients for whom I 10:39:54AM

felt an anti-VEGF agent was indicated, then I 10:39:59AM

might have switched back for the economic reasons 10:40:04AM

that I discussed earlier. 10:40:07AM

Q. Okay. And the economics reasons 10:40:08AM

are Avastin is cheaper than EYLEA currently? 10:40:11AM

A. Yes. 10:40:14AM

Q. Okay. In your current practice, 10:40:14AM

do you ever prescribe LUCENTIS? 10:40:18AM

A. I do not. 10:40:22AM

Q. Okay. And is that because it's 10:40:23AM

not on the -- or -- or the pharmacy doesn't 10:40:26AM

purchase it at Vanderbilt? 10:40:28AM

A. That's correct. The pharmacy 10:40:30AM

does not purchase it. 10:40:33AM

Q. Have you ever asked the pharmacy 10:40:35AM

whether they'd be willing to purchase LUCENTIS for 10:40:37AM

your practice? 10:40:40AM

A. LUCENTIS was on the formulary at 10:40:42AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 88

Vanderbilt and -- when I arrived and was subsequently removed from the formulary. 10:40:44AM 10:40:47AM

Q. Do you know why? 10:40:49AM

A. I don't. 10:40:50AM

Q. Okay. 10:40:50AM

A. I -- I can speculate. 10:40:51AM

Q. Sure. 10:40:52AM

A. I can speculate based on cost. 10:40:53AM

Q. Okay. And so your best guess would be that it was removed because it's more expensive than Avastin? 10:40:55AM 10:40:58AM 10:40:59AM

A. I -- that's speculation. 10:41:01AM

Q. Okay. 10:41:02AM

A. I -- speculation that it was removed because of its cost. 10:41:02AM 10:41:03AM

Q. Okay. 10:41:06AM

A. I don't know what -- if that was relative to the cost of any other medication. 10:41:06AM 10:41:08AM

Q. Okay. And do you know what LUCENTIS' cost is relative to EYLEA? 10:41:11AM 10:41:14AM

A. I do not. 10:41:19AM

Q. Okay. But EYLEA is on the formulary at Vanderbilt currently? 10:41:19AM 10:41:21AM

A. EYLEA is. As are other agents. 10:41:22AM

Q. Okay. Do you know whether 10:41:25AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 89

Macugen's on the formulary at Vanderbilt currently? 10:41:29AM 10:41:32AM

A. I don't. 10:41:32AM

Q. And so have you ever -- either at University of Tennessee or at Vanderbilt -- you yourself prescribed LUCENTIS? 10:41:33AM 10:41:39AM 10:41:42AM

A. I have used it in the treatment of patients, but I have not prescribed it as the drug of first choice, if you will. So let me -- let me be clear. 10:41:53AM 10:41:54AM 10:42:01AM 10:42:06AM

Q. Sure. 10:42:07AM

A. So there are patients -- I -- I'm part of a large medical practice. There are ten retina specialists at Vanderbilt, and we all have different practice patterns and we all have different use patterns for the various medications. And we all share patients. 10:42:07AM 10:42:09AM 10:42:14AM 10:42:17AM 10:42:19AM 10:42:21AM

So if a patient comes in and that -- their typical physician, retina physician, is not available, then I might give them an injection based upon their schedule. And for patients, at least early on, for whom they were on ranibizumab/LUCENTIS, if that's the drug that they were being given, then I would give that drug when they presented in my practice for their -- for 10:42:24AM 10:42:28AM 10:42:30AM 10:42:33AM 10:42:38AM 10:42:44AM 10:42:46AM 10:42:49AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 90

their medication. 10:42:52AM

But I do -- do not recall that I have ever initiated ranibizumab for patient care since coming to Vanderbilt. 10:42:55AM 10:42:58AM 10:43:02AM

Q. Okay. And so if I understand it correctly, you sometimes see patients of your colleagues. You, of course, administer the agents that your colleagues have prescribed to those patients. 10:43:03AM 10:43:06AM 10:43:10AM 10:43:17AM 10:43:18AM

And so if a patient's been described LUCENTIS by one of your colleagues, that's what you would administer to that particular patient? 10:43:19AM 10:43:21AM 10:43:23AM 10:43:25AM

A. That's a fair assessment, yes. 10:43:26AM

Q. Okay. And when your colleagues were prescribing LUCENTIS at -- at Vanderbilt, was that during a time when it was on the formulary? 10:43:28AM 10:43:31AM 10:43:35AM

A. Yes. 10:43:38AM

Q. And so do you have any understanding for such patients who were initially prescribed LUCENTIS when it was on the formulary at Vanderbilt, whether they continued to be prescribed LUCENTIS after it was removed from the formulary? 10:43:38AM 10:43:40AM 10:43:44AM 10:43:46AM 10:43:49AM 10:43:52AM

A. I -- I don't know. 10:43:53AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 91

Q. Okay. 10:43:54AM

A. Yeah. All I know is that 10:43:54AM

LUCENTIS is not on the formulary -- 10:43:56AM

Q. Okay. 10:43:57AM

A. -- at this time. 10:43:58AM

Q. And remind me. When you were at 10:43:58AM

The University of Tennessee, was -- Avastin was on 10:44:01AM

the formulary, correct? 10:44:04AM

A. Yes. 10:44:06AM

Q. Okay. Was LUCENTIS on the 10:44:07AM

formulary at any point in time? 10:44:07AM

A. I never used it. I do not know 10:44:09AM

if it was on the formulary. 10:44:11AM

Q. Okay. And when you say you never 10:44:12AM

used it, that included the situation we just 10:44:14AM

discussed, which is administering a VEGF agent to 10:44:16AM

your colleagues' patients based on your 10:44:21AM

colleagues' prescription decisions? 10:44:24AM

A. Yeah, it's a -- again, it's a 10:44:28AM

little more nuanced than that. I was the 10:44:30AM

full-time retina specialist at The University of 10:44:34AM

Tennessee. 10:44:36AM

Q. Okay. 10:44:36AM

A. So I was the primary prescriber. 10:44:37AM

There were not other -- 10:44:39AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 92

Q. Okay. 10:44:39AM

A. -- full-time retina specialists. 10:44:39AM

Q. There wasn't a large team -- 10:44:41AM

A. Correct. 10:44:41AM

Q. -- like you have now? 10:44:42AM

Got it. 10:44:44AM

And then at any point in time 10:44:44AM

when you were at The University of Tennessee, was 10:44:46AM

EYLEA on the formulary at The University of 10:44:48AM

Tennessee? 10:44:49AM

A. I believe so, yes. 10:44:50AM

Q. Okay. Do you recall when it got 10:44:51AM

added to the formulary at The University of 10:44:53AM

Tennessee? 10:44:59AM

A. I don't know. 10:44:59AM

Q. Do you recall why it was added to 10:44:59AM

the formulary at The University of Tennessee? 10:44:59AM

A. I was not part of that 10:44:59AM

decision-making. 10:45:01AM

Q. Okay. And when we talk about 10:45:01AM

adding or removing things from the formulary, do 10:45:07AM

you know who was responsible for that decision at 10:45:09AM

The University of Tennessee? 10:45:11AM

A. I don't. 10:45:12AM

Q. Do you know who's responsible for 10:45:12AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 93

those types of decisions at Vanderbilt? 10:45:16AM

A. The pharmacy makes the decision. 10:45:18AM

How that decision is arrived at, I don't know. 10:45:22AM

Q. Okay. And so you have never 10:45:23AM

interacted with the pharmacy at The University of 10:45:26AM

Tennessee, for instance, and said: Hey, can we 10:45:28AM

get this on the formulary? 10:45:33AM

A. Are you talking about -- and -- 10:45:34AM

when I was at The University of Tennessee? 10:45:36AM

Q. Correct. 10:45:36AM

A. No, I did -- 10:45:38AM

MR. SUMMERS: Objection, form. 10:45:38AM

THE WITNESS: No, I did not. 10:45:39AM

BY MR. BRAUSA: 10:45:40AM

Q. And have you had any 10:45:41AM

conversations with the pharmacy now at Vanderbilt, 10:45:41AM

about adding drugs to the formulary that you'd 10:45:44AM

like to use? 10:45:47AM

A. I have not, no. 10:45:48AM

Q. Okay. Do you know whether you 10:45:49AM

have an opportunity to do that in your clinical 10:45:51AM

practice? 10:45:54AM

A. We do, and there is a process, 10:45:54AM

but I have not been involved in it. 10:45:57AM

Q. Okay. Why haven't you been 10:45:59AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 94

involved in the process? 10:46:01AM

A. It has not been an issue that 10:46:01AM
I've been specifically interested in. I also do 10:46:07AM
research as most -- for 60 percent of my time, and 10:46:11AM
so that aspect of the clinical practice and 10:46:15AM
decision-making has been taken -- or is -- is done 10:46:18AM
by the Division Chief of the retina service and 10:46:23AM
other partners. 10:46:26AM

Q. Do you have any understanding of 10:46:26AM
what type of molecule Avastin is or the active 10:46:31AM
ingredient in Avastin? 10:46:35AM

MR. SUMMERS: Objection, form. 10:46:37AM

THE WITNESS: Yes. 10:46:37AM

BY MR. BRAUSA: 10:46:37AM

Q. What type of molecule is it? 10:46:38AM

A. It's a biologic. 10:46:39AM

Q. Okay. And when you say "a 10:46:40AM
biologic," what does that mean? 10:46:41AM

A. It's an antibody. 10:46:43AM

Q. Okay. Do you know whether it's a 10:46:44AM
full-length antibody? 10:46:47AM

A. I'd have to go back and look at 10:46:48AM
the structure. I haven't reviewed it recently. 10:46:51AM

Q. Okay. Do you know whether it's a 10:46:55AM
human antibody? 10:46:56AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 95

A. Are you asking if it's a humanized drug? I -- I don't know. I'd have to look it up. 10:46:58AM 10:46:59AM 10:47:03AM

Q. Okay. And without looking it up, do you know how it was developed? 10:47:03AM 10:47:05AM

A. It was developed in preclinical and clinical studies. 10:47:07AM 10:47:09AM

Q. And this is a Genentech product, right? 10:47:10AM 10:47:13AM

A. Yes. 10:47:14AM

Q. If we now talk about LUCENTIS, that's also a Genentech product, right? 10:47:14AM 10:47:17AM

A. Yes. 10:47:19AM

Q. Do you have any understanding of what type of molecule it is? 10:47:20AM 10:47:22AM

A. Again, it's a biologic. 10:47:24AM

Q. Okay. And is it also an antibody? 10:47:27AM 10:47:29AM

A. It's a form of an antibody. I'm not sure it's a full antibody molecule. But I -- again, I'd have to look up the structure. 10:47:30AM 10:47:33AM 10:47:37AM

Q. Okay. Do you know whether it's an antibody fragment? 10:47:39AM 10:47:40AM

A. It may be referred to as that. I'd have to look it up. 10:47:42AM 10:47:44AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 96

Q. Okay. And similar questions: Do you know whether it's humanized, how it's produced, without looking it up? 10:47:44AM 10:47:46AM 10:47:49AM

A. I'd have to look it up. 10:47:51AM

Q. Okay. If we talk about now aflibercept/ EYLEA, do you know what type of molecule it is? 10:47:52AM 10:47:57AM 10:48:00AM

A. It's an antibody. 10:48:01AM

Q. Okay. And so your testimony is that aflibercept is the same type of molecule as Avastin? 10:48:02AM 10:48:03AM 10:48:07AM

A. Well, it depends on what you mean by "type." 10:48:08AM 10:48:14AM

Q. They're -- they're both antibodies is your testimony? 10:48:15AM 10:48:17AM

A. They -- they are antibodies, yes. 10:48:17AM

Q. Okay. And do you -- have you ever done any analysis of the differences in structure between aflibercept, bevacizumab, and ranibizumab? 10:48:20AM 10:48:21AM 10:48:23AM 10:48:29AM

A. I mean, I'm -- I'm familiar with it in general, yes. 10:48:30AM 10:48:32AM

Q. Okay. And do you know whether the differences in the structure between those three molecules have any impact on their efficacy 10:48:33AM 10:48:34AM 10:48:36AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 97

or safety? 10:48:41AM

MR. SUMMERS: Objection, form. 10:48:44AM

THE WITNESS: Well, I don't know about safety. The structure of the molecules, at least in the general -- well, let me take a step back. 10:48:45AM 10:48:46AM 10:48:50AM 10:49:00AM

So the structure of the molecules is somewhat different, and -- but the biologic activity is the same. 10:49:01AM 10:49:05AM 10:49:10AM

BY MR. BRAUSA: 10:49:12AM

Q. Okay. In terms of the effect observed in patients, there are some patients that you'd agree respond better to LUCENTIS than Avastin, correct? 10:49:13AM 10:49:16AM 10:49:20AM 10:49:25AM

A. I don't know. I haven't used LUCENTIS in my practice. 10:49:26AM 10:49:29AM

Q. Okay. And I -- I thought, and maybe I mis- -- misunderstood. I thought there were some patients that you had ben prescribing Avastin to that then you referred out to other physicians who did prescribe LUCENTIS. 10:49:30AM 10:49:33AM 10:49:34AM 10:49:37AM 10:49:39AM

A. In -- at The University of Tennessee, yes. 10:49:41AM 10:49:44AM

Q. Okay. And why did you make that decision? 10:49:44AM 10:49:46AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 98

A. At that time, because The University of Tennessee did not have LUCENTIS and -- and so I -- for those patients, if I felt that they were -- were not benefitting adequately from Avastin, then I referred them for a trial of rani- -- ranibizumab with a physician/partner/colleague in the community. 10:49:46AM 10:49:49AM 10:49:57AM 10:50:02AM 10:50:08AM 10:50:11AM 10:50:14AM

Q. What reason did you have to think, if any, that they'd respond differently to LUCENTIS? 10:50:14AM 10:50:18AM 10:50:21AM

A. I think the answer is you couldn't predict, but if I wasn't getting the therapeutic benefit that I was looking for with the anti-VEGF agent and I felt that there was not an alternative approach that I felt would be beneficial for the patient, then a trial of an alternative anti-VEGF agent I thought was reasonable and -- and that's what I did. 10:50:21AM 10:50:23AM 10:50:28AM 10:50:31AM 10:50:36AM 10:50:39AM 10:50:42AM 10:50:45AM

Q. And I think you said you couldn't predict in -- in your answer just now. You meant that you couldn't predict whether a patient would respond better to LUCENTIS than Avastin? 10:50:47AM 10:50:50AM 10:50:54AM 10:50:56AM

A. Correct. 10:50:58AM

Q. Why not? 10:50:59AM

A. There's -- no physician can 10:50:59AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 99

predict the therapeutic -- exact therapeutic effect of a drug on any patient in advance. 10:51:03AM 10:51:07AM

Q. Okay. You need to see the data; is that fair? 10:51:09AM 10:51:11AM

MR. SUMMERS: Objection, form. 10:51:12AM

THE WITNESS: I'm not sure I understand your question. 10:51:13AM 10:51:14AM

BY MR. BRAUSA: 10:51:15AM

Q. I -- I guess what would you need to see to determine whether a patient responded better to LUCENTIS than Avastin? 10:51:15AM 10:51:16AM 10:51:22AM

A. Well, I would have to see that patient again and follow them and do a clinical exam and look at their exam and their potential imaging studies and determine whether or not a benefit was achieved. 10:51:23AM 10:51:25AM 10:51:30AM 10:51:35AM 10:51:38AM

Q. Okay. And in patients that you've switched from Avastin to EYLEA, do you have any ability to predict which of those patients will respond better to EYLEA? 10:51:39AM 10:51:42AM 10:51:48AM 10:51:50AM

MR. SUMMERS: Objection to form. 10:51:53AM

THE WITNESS: No. 10:51:54AM

BY MR. BRAUSA: 10:51:55AM

Q. Why not? 10:51:55AM

A. Because no physician can predict 10:51:55AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 100

in advance what the response of a patient -- 10:51:58AM
specific patient to a specific intervention is 10:52:01AM
going to be. 10:52:04AM
Q. Okay. And so you're not aware of 10:52:04AM
any information that would suggest to you as a -- 10:52:07AM
as a clinician with 30 years of experience why 10:52:12AM
some patients respond better to EYLEA than Avastin 10:52:15AM
and why some patients respond better to LUCENTIS 10:52:18AM
than Avastin? 10:52:21AM
MR. SUMMERS: Objection, form. 10:52:22AM
THE WITNESS: I'm sorry. Can you 10:52:22AM
break up that question? 10:52:24AM
BY MR. BRAUSA: 10:52:26AM
Q. Sure. 10:52:26AM
Sitting here today, based on your 10:52:27AM
expertise and your -- your years of work in the 10:52:28AM
area, do you know why some patients respond better 10:52:31AM
to EYLEA than Avastin? 10:52:34AM
A. Well, there is some discussion in 10:52:37AM
the literature, and I -- again, I don't know the 10:52:41AM
raw data from the preclinical studies, but the 10:52:45AM
structure of the aflibercept molecule is different 10:52:48AM
than the Avastin molecule. And it binds to the -- 10:52:55AM
the VEGF -- both VEGF receptors because of the 10:53:01AM
nature of the fusion protein, which it is, and it 10:53:06AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 101

1	also has some binding activity for a similar	10:53:09AM
2	growth factor.	10:53:14AM
3	And so there is some at least	10:53:15AM
4	theoretical biological evidence that EYLEA might	10:53:17AM
5	have a better therapeutic profile for patients	10:53:21AM
6	because of the difference in its structure.	10:53:26AM
7	Q. Okay. And -- and do you recall	10:53:28AM
8	when those -- those differences in structure and	10:53:32AM
9	the theoretical better therapeutic profile became	10:53:36AM
10	known or you became aware of that?	10:53:42AM
11	A. I -- I don't know exactly. The	10:53:46AM
12	-- the drug, as it was being developed, was --	10:53:51AM
13	that was part of the conversation regarding why it	10:53:54AM
14	might have additional therapeutic benefits.	10:53:55AM
15	Q. Okay. Now, my understanding is	10:53:57AM
16	that when you're treating a patient with DME, as	10:54:01AM
17	we've established, they often have fluid in the	10:54:05AM
18	retina, correct?	10:54:11AM
19	A. By definition, macular edema is	10:54:13AM
20	fluid in the retina.	10:54:16AM
21	Q. Understood. Thank you.	10:54:17AM
22	And one of your goals when	10:54:17AM
23	treating with a VEGF agent is to, quote/unquote,	10:54:19AM
24	"dry out" the retina, to remove that fluid?	10:54:24AM
25	A. Treating with an anti-VEGF agent,	10:54:26AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 102

1	the goal is to reduce the leakiness of the blood	10:54:29AM
2	vessels, which VEGF tends to or is known to cause	10:54:34AM
3	and therefore blocking the VEGF molecule reduces	10:54:36AM
4	the leakiness of the vessels. And that's why we	10:54:43AM
5	think it has a benefit for the treatment of	10:54:46AM
6	macular edema.	10:54:48AM
7	Q. Okay. And -- and is that a fair	10:54:48AM
8	characterization is -- is the goal is to -- one of	10:54:51AM
9	the goals is to dry out the retina?	10:54:54AM
10	A. Yes.	10:54:55AM
11	Q. Okay. And I -- I assume you	10:54:55AM
12	never get the retina completely dry, right?	10:54:59AM
13	A. I think that assumption would be	10:55:01AM
14	incorrect.	10:55:03AM
15	Q. Okay.	10:55:03AM
16	A. Well, it depends on what you mean	10:55:04AM
17	by "completely dry." You mean, like, desiccated?	10:55:06AM
18	No, that would be bad.	10:55:09AM
19	Q. Sure.	10:55:10AM
20	A. Right? But the fluid in the	10:55:10AM
21	retina can be reduced with treatment, various	10:55:13AM
22	treatments, and the retina can re-establish a	10:55:16AM
23	normal anatomy in response to various treatments.	10:55:20AM
24	Q. Okay. And given the differences	10:55:22AM
25	in structure between Avastin, LUCENTIS and EYLEA,	10:55:26AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 103

would you expect that to have a different impact on the rate at which the retina dries if a patient's administered one of those anti-VEGF agents? 10:55:31AM 10:55:34AM 10:55:38AM 10:55:40AM

MR. SUMMERS: Objection, form. 10:55:41AM

THE WITNESS: Yeah, I -- again, can you break that up for me a little bit? 10:55:41AM 10:55:44AM 10:55:48AM

BY MR. BRAUSA: 10:55:48AM

Q. Sure. 10:55:48AM

If we compare a patient who's receiving Avastin that you -- actually, let me withdraw that. 10:55:48AM 10:55:51AM 10:55:52AM

For a patient that you've switched from Avastin to EYLEA, do you have any expectation that EYLEA will dry out the retina faster than Avastin? 10:55:52AM 10:55:54AM 10:56:00AM 10:56:04AM

A. I don't think there's any evidence, clinical evidence, that I've seen that demonstrates that. 10:56:06AM 10:56:09AM 10:56:12AM

Q. Okay. And -- and so the differences in structure that you referred to between EYLEA on the one hand and Avastin on the other wouldn't have any impact on the rate at which the retina's dried out? 10:56:13AM 10:56:16AM 10:56:20AM 10:56:23AM 10:56:27AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 104

A. I don't know if there's data to -- to -- that looks at that, so I can't answer the question. 10:56:28AM 10:56:31AM 10:56:33AM

Q. Okay. Have you observed that at all in your clinical practice? 10:56:33AM 10:56:35AM

A. I think it would be difficult to demonstrate that because patients are treated -- a patient would get an injection, and then a typical follow-up injection for a patient who is being treated for macular edema would be, perhaps, a month later. And you're not imaging the patient on a daily basis between the first injection and the next time you see that patient. 10:56:36AM 10:56:43AM 10:56:48AM 10:56:52AM 10:56:54AM 10:56:57AM 10:57:01AM 10:57:06AM

So in order to answer that question, you would have to do a clinical study and look at daily OCT images for a cohort of patients to demonstrate the potential benefit that you are suggesting. 10:57:08AM 10:57:09AM 10:57:13AM 10:57:20AM 10:57:22AM

Q. Okay. Previously I think you testified that EYLEA can be associated with a longer duration of activity as compared to Avastin. Does that sound correct? 10:57:23AM 10:57:28AM 10:57:31AM 10:57:34AM

A. Well, there was -- there's -- in the press and in the general retinal community, there was interest in data to suggest that it 10:57:37AM 10:57:38AM 10:57:41AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 105

might have a longer therapeutic benefit. 10:57:45AM

Q. Okay. And I think you touched on 10:57:47AM

it, but my question was: What do you mean when 10:57:50AM

you say "longer duration of activity"? 10:57:52AM

A. Well, the use of anti-VEGF 10:57:54AM

agents, although we've seen that it's been very 10:58:02AM

effective for patients, is problematic because 10:58:05AM

what the clinical studies for ranibizumab and 10:58:07AM

bevacizumab showed was that patients required 10:58:12AM

monthly injections in order to achieve a benefit 10:58:14AM

and maintain a benefit, and there is a risk 10:58:19AM

associated with those injections; risk of 10:58:24AM

infection, risk of cataract, and risk of 10:58:27AM

detachment. And although those risks are small, 10:58:31AM

the risk is present, and when millions of patients 10:58:33AM

are being treated, they -- the cohort risk is not 10:58:36AM

insubstantial. 10:58:41AM

In addition, patients do not like 10:58:42AM

having needles put in their eye every month. We 10:58:46AM

try and make it as tolerable as possible, but it's 10:58:49AM

not a pleasant procedure. And it's a huge burden 10:58:52AM

not only on the patient but on the physician as 10:58:55AM

well. 10:58:57AM

And so although these drugs have 10:58:57AM

been demonstrated to be very effective and part of 10:59:00AM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 106

our practice, there's a significant interest in trying to mitigate the frequency in which those drugs have to be given, in order to maintain a clinical benefit that -- that is being achieved. 10:59:03AM 10:59:08AM 10:59:11AM 10:59:15AM

And so from a theoretical perspective, based upon, as I understand it, what some of the original preclinical data was showing, that -- that an extension of a therapeutic benefit, their extension of potential efficacy that people were talking about with aflibercept was something of interest and would potentially be beneficial to your patients in your practice. 10:59:18AM 10:59:24AM 10:59:25AM 10:59:28AM 10:59:33AM 10:59:37AM 10:59:40AM 10:59:44AM

Q. Okay. And -- and so when you say "a longer duration of activity," you mean you can spread out the doses; is that fair? 10:59:47AM 10:59:49AM 10:59:52AM

A. Potentially that's what was -- that was the -- the interest is can -- can we do it -- 10:59:55AM 10:59:56AM 10:59:59AM

Q. Okay. 10:59:59AM

A. -- and -- and how best to do it. 11:00:00AM

Q. Okay. And ranibizumab. Ran- -- ranibizumab, excuse me, I think you mentioned, is dosed monthly, correct? 11:00:03AM 11:00:08AM 11:00:10AM

A. The clinical trials and the -- the dosing was on a monthly basis, yes. 11:00:11AM 11:00:14AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 107

Q. Okay. And -- and does ranibizumab have a label indicating a dosing regimen? 11:00:17AM 11:00:19AM 11:00:22AM

A. Yeah, I don't -- I haven't read the label. I don't know. 11:00:23AM 11:00:24AM

Q. Okay. So you don't know what the label for LUCENTIS says in terms of how frequently it should be dosed? 11:00:25AM 11:00:27AM 11:00:30AM

A. No. I -- I don't know what the label says. 11:00:31AM 11:00:33AM

Q. Do you know whether Genentech ever did clinical trials trying to lengthen the duration activity for LU- -- LUCENTIS? 11:00:35AM 11:00:37AM 11:00:40AM

A. I do not. 11:00:40AM

Q. Okay. And so you don't know whether Genentech ever did any studies where LUCENTIS was dosed less -- 11:00:41AM 11:00:42AM 11:00:45AM

A. Well -- 11:00:45AM

Q. -- frequently? 11:00:47AM

A. Well, no, I -- I -- I misspoke. So the -- the PIER study looked at that. 11:00:48AM 11:00:49AM

Q. Okay. 11:00:52AM

A. And it -- it was an interest in determining whether or not you could see an extended -- a more extended clinical benefit. So 11:00:53AM 11:00:55AM 11:00:58AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 108

1	the PIER study was done.	11:01:01AM
2	Q. Okay. And -- and this is the	11:01:02AM
3	PIER study on which an individual by the name of	11:01:03AM
4	Naveed Shams was the clinical investigator, or one	11:01:09AM
5	of the investigators?	11:01:12AM
6	A. Not that I'm aware of. That --	11:01:14AM
7	that -- actually, it's part of the -- my	11:01:16AM
8	declaration. You can show me the -- the author	11:01:18AM
9	list. I don't -- I don't know if --	11:01:21AM
10	Q. Okay.	11:01:21AM
11	A. -- Shams was on it.	11:01:21AM
12	Q. Okay. Do you know whether a	11:01:23AM
13	Dr. Brown was involved in the PIER study?	11:01:27AM
14	A. Yes.	11:01:29AM
15	Q. And do you know a Dr. David	11:01:29AM
16	Brown?	11:01:31AM
17	A. I know who he is, yes.	11:01:31AM
18	Q. How do you know who he is?	11:01:32AM
19	A. He's well-known in the field.	11:01:33AM
20	He's been involved in these clinical studies for a	11:01:36AM
21	long time.	11:01:39AM
22	Q. And do you have any professional	11:01:39AM
23	opinion of Dr. Brown?	11:01:44AM
24	A. He's a well-respected retina	11:01:44AM
25	specialist.	11:01:45AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 109

Q. What about Dr. Thomas Albini? 11:01:45AM

A. I know the name, but I don't know 11:01:47AM

Dr. Albini. 11:01:49AM

Q. Okay. And do you have any 11:01:49AM

professional opinion of him? 11:01:50AM

A. I don't. 11:01:51AM

Q. Do you know an individual named 11:01:51AM

Dr. Michael Stewart? 11:01:53AM

A. I don't. 11:01:55AM

Q. What about Dr. Alexander Klibenon 11:01:56AM

(phonetic)? 11:02:00AM

A. I don't. 11:02:00AM

Q. Dr. Diana Do? 11:02:01AM

A. I know Dr. Do. 11:02:03AM

Q. Okay. How do you know Dr. Do? 11:02:05AM

A. Again, a colleague. She's at 11:02:06AM

Stanford. 11:02:08AM

Q. Okay. And do you have any 11:02:09AM

professional opinion of Dr. Do? 11:02:09AM

A. I think she's a well-respected 11:02:11AM

retina specialist. 11:02:14AM

Q. Okay. Do you recall reading or 11:02:15AM

were you familiar with the PIER study, rather, 11:02:18AM

when it was being conducted? 11:02:21AM

A. I -- I don't recall offhand 11:02:23AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 110

whether or not I specifically read that study at that time. 11:02:26AM 11:02:28AM

Q. Okay. Were you involved at all or did you participate in the PIER clinical trial? 11:02:28AM 11:02:30AM

A. I did not. 11:02:33AM

Q. Do you recall reading the data that was reported out from the PIER study when it came out? 11:02:34AM 11:02:39AM 11:02:41AM

A. I have read the PIER study, yes. 11:02:42AM

Q. And do you recall whether you were familiar with it contemporaneously? 11:02:44AM 11:02:45AM

A. I -- I can't recall offhand the first time I read it. 11:02:47AM 11:02:49AM

Q. Okay. Do you recall any press releases about the PIER study results? 11:02:50AM 11:02:52AM

A. I don't recall. 11:02:55AM

Q. Sitting here today, do you have any opinion as to what the results of the PIER study showed? 11:03:01AM 11:03:10AM 11:03:13AM

A. You'd have to ask a more specific question. I don't understand what you're asking. 11:03:14AM 11:03:16AM

Q. Sure. 11:03:18AM

What's your interpretation of the -- the data from the PIER study regarding the quarterly dosing schedule? 11:03:18AM 11:03:20AM 11:03:23AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 111

MR. SUMMERS: Objection: Form, foundation. 11:03:25AM 11:03:26AM

THE WITNESS: Yeah, so, again, if you'd show me the PIER study, I'll show you what it reported out. 11:03:26AM 11:03:28AM 11:03:30AM

BY MR. BRAUSA: 11:03:31AM

Q. Okay. What did you do to prepare for today's deposition? 11:03:31AM 11:03:33AM

A. I reviewed my declaration and many of the exhibits that are part of the declaration. 11:03:34AM 11:03:38AM 11:03:40AM

Q. Okay. And one of the exhibits to your declaration that we'll -- we'll get to is what's referred to in your declaration as the Shams reference? 11:03:41AM 11:03:43AM 11:03:46AM 11:03:49AM

A. Yes. 11:03:50AM

Q. Okay. And do you have any understanding of how that exhibit or that Shams reference relates to the PIER study, if at all? 11:03:50AM 11:03:52AM 11:03:55AM

A. Well, the -- the -- the Shams is a patent application related to an anti-VEGF agent, and so the -- the relationship is -- is what it is. The PIER study used an anti-VEGF agent, so I -- I don't know if there's any additional relationship. 11:03:58AM 11:04:03AM 11:04:08AM 11:04:11AM 11:04:15AM 11:04:16AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 112

Q. Okay. Do you recall without looking at it whether the Shams referenced in the patent application reports any clinical data? 11:04:16AM 11:04:18AM 11:04:21AM

A. I'd have to look at it. 11:04:25AM

Q. So you reviewed the declaration, your exhibits. 11:04:26AM 11:04:33AM

Did you do anything else to prepare for your deposition today? 11:04:33AM 11:04:34AM

A. Again, I had conversations -- general conversations with counsel about the deposition. 11:04:35AM 11:04:39AM 11:04:41AM

Q. Okay. And, again, I don't want to get into the specifics of any of those conversations. But did you meet with counsel at any point in preparation for your deposition? 11:04:41AM 11:04:43AM 11:04:46AM 11:04:47AM

A. We met via Zoom. 11:04:49AM

Q. Okay. And when was that? 11:04:52AM

A. We had multiple meetings. 11:04:52AM

Q. How many meetings did you have? 11:04:56AM

A. Perhaps six, seven. 11:04:58AM

Q. Okay. Were those six or seven meetings in between your deposition in October and today? 11:05:04AM 11:05:07AM 11:05:11AM

A. Yes. 11:05:11AM

Q. And do you recall how many hours 11:05:12AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 113

total those meetings lasted? 11:05:14AM

A. I don't. 11:05:16AM

Q. Was it more than ten? 11:05:16AM

A. Probably around that range. 11:05:18AM

Q. Okay. Do you know whether it was more than 15? 11:05:25AM 11:05:27AM

A. I don't. 11:05:27AM

Q. Again, don't want to get into specifics of conversations with counsel, but did you do anything differently to prepare for your deposition, sitting here today, than you did for your deposition in October? 11:05:28AM 11:05:32AM 11:05:35AM 11:05:37AM 11:05:40AM

MR. SUMMERS: Objection, form. Caution the witness not to reveal the substance of any attorney-client communications. 11:05:42AM 11:05:43AM 11:05:45AM 11:05:48AM

THE WITNESS: Yeah, I don't -- I'm not sure I understand your question. 11:05:49AM 11:05:49AM

BY MR. BRAUSA: 11:05:51AM

Q. Sure. 11:05:51AM

Did you prepare for your deposition in October? 11:05:51AM 11:05:52AM

A. Yes. 11:05:53AM

Q. And what did you do to prepare for that deposition? 11:05:53AM 11:05:55AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 114

A. To -- reviewed my declaration and reviewed the documents. 11:05:56AM 11:05:59AM

Q. Okay. And you did that in preparation for today's deposition as well, right? 11:06:00AM 11:06:01AM

A. I did. 11:06:03AM

Q. Just besides the fact that it's obviously a different declaration and different documents, in your mind, did you do anything differently to prepare for today's deposition as compared to your preparation for your deposition in October? 11:06:03AM 11:06:09AM 11:06:12AM 11:06:14AM 11:06:20AM 11:06:21AM

A. Differently in what way? 11:06:21AM

Q. In any way. 11:06:22AM

A. Not -- not that I would say. 11:06:25AM

Q. Okay. Can you recall after you were retained by Quinn Emanuel 18 months ago, when you started work on your declaration in this case? 11:06:28AM 11:06:34AM 11:06:38AM

A. Well, the declaration in this case was submitted in March of last year, so it would have been in advance of that. 11:06:43AM 11:06:47AM 11:06:53AM

Q. Okay. And prior to your work with Quinn Emanuel in the three matters we discussed previously, had you ever been involved in the process of putting a declaration together like the one served in this case? 11:06:54AM 11:06:56AM 11:06:58AM 11:07:00AM 11:07:03AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 115

MR. SUMMERS: Objection to form. 11:07:09AM

THE WITNESS: A declaration -- 11:07:13AM

are -- I'm not sure I understand what 11:07:14AM

you're asking. Are you asking have I 11:07:15AM

done a declaration related to a patent 11:07:21AM

case? 11:07:23AM

BY MR. BRAUSA: 11:07:23AM

Q. Correct. 11:07:24AM

A. Is that your ask [sic] -- is that 11:07:25AM

your question? 11:07:26AM

Q. Correct. 11:07:27AM

A. The answer is no. 11:07:28AM

Q. Okay. And so what was the 11:07:29AM

process that you went through? Again, I just want 11:07:31AM

to know the actions you took, not any discussions 11:07:34AM

you had with counsel. But what was the process 11:07:37AM

you went through to put together the declaration 11:07:41AM

that's been marked Exhibit 1002 in this 11:07:43AM

proceeding? 11:07:46AM

MR. SUMMERS: Objection, form. 11:07:46AM

And I'll caution the witness not 11:07:47AM

to reveal the substance of any 11:07:49AM

attorney-client communication. 11:07:52AM

THE WITNESS: So the process -- 11:07:53AM

process was to understand from counsel 11:07:54AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 116

1	what the issues were with respect to the	11:07:56AM
2	'601 patent; what the issues are related	11:08:00AM
3	to the -- to the IPR; what the standards	11:08:05AM
4	were with respect to generating a	11:08:10AM
5	declaration; my opinion about key	11:08:16AM
6	aspects of the issues that were	11:08:20AM
7	addressed, that were discussed; a review	11:08:23AM
8	of the literature and prior art related	11:08:27AM
9	to that declaration; discussions	11:08:33AM
10	providing some clinical expertise	11:08:40AM
11	related to understanding what the issues	11:08:42AM
12	were around a clinical perspective.	11:08:44AM
13	Those are the types of things	11:08:49AM
14	that we discussed.	11:08:50AM
15	BY MR. BRAUSA:	11:08:50AM
16	Q. Okay. And -- and prior to your	11:08:51AM
17	retention in this matter, were you familiar with	11:08:52AM
18	the '601 patent?	11:08:54AM
19	A. No.	11:08:55AM
20	Q. Okay. And prior to your	11:08:56AM
21	retention in this matter, are there any of the	11:08:58AM
22	exhibits that you cite in your declaration that	11:09:01AM
23	you were familiar with?	11:09:04AM
24	A. Well, you'd have to show me my	11:09:05AM
25	declaration and I can tell you which ones I was	11:09:08AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 117

familiar with. 11:09:10AM

Q. Okay. I -- I take it then that 11:09:10AM

some of the exhibits were provided to you by 11:09:13AM

counsel? 11:09:15AM

A. Yes. 11:09:16AM

Q. And, again, if I wanted to know 11:09:16AM

which ones were provided by counsel versus which 11:09:19AM

ones you already knew about, we could go through 11:09:21AM

that list? 11:09:24AM

A. Yes. 11:09:24AM

Q. Okay. Do you know whether the 11:09:25AM

2009 Regeneron press release is one of the 11:09:26AM

references you were familiar with? 11:09:32AM

A. I don't recall offhand that I was 11:09:33AM

familiar with that particular press release. 11:09:35AM

Q. Okay. You talked about Shams 11:09:37AM

patent application as well. Is that a reference 11:09:39AM

that you were familiar with? 11:09:41AM

A. That is not a reference that I 11:09:41AM

was previously familiar with. 11:09:43AM

Q. And there's also a reference 11:09:44AM

that's been designated Elman 2010 in this 11:09:46AM

proceeding. Are you familiar with that? 11:09:50AM

A. Is that the clinical study? 11:09:52AM

Q. It is. 11:09:55AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 118

A. I was familiar with that, yes. 11:09:55AM

Q. Okay. Did you read the entire '601 patent? 11:09:56AM 11:10:07AM

A. I did. 11:10:09AM

Q. And did you -- what was the process that you went through to review that? 11:10:09AM 11:10:14AM

A. I read it. 11:10:16AM

Q. Okay. You just started at page 1 and read it front to back? 11:10:17AM 11:10:20AM

A. Well, I -- I -- I read the -- the text of the patent. I didn't review all of the references and previous patents. 11:10:21AM 11:10:23AM 11:10:27AM

Q. Sure. 11:10:30AM

Did you start with the Claims by any chance? 11:10:31AM 11:10:33AM

A. I didn't start with the Claims. The Claims are at the end of the patent. 11:10:34AM 11:10:35AM

Q. Okay. And -- and so you did read it like a book, so to speak, front to back? 11:10:37AM 11:10:40AM

A. Yes. 11:10:42AM

Q. Okay. Now, in your declaration, there's reference to something called "the priority date." 11:10:42AM 11:10:50AM 11:10:52AM

A. Yes. 11:10:53AM

Q. Do you have an understanding of 11:10:53AM

what the priority date is of the '601 patent? 11:10:54AM

A. So it's in my declaration. If 11:10:58AM

you provide it to me, I'd be happy to review it 11:10:59AM

with you. 11:11:03AM

Q. Okay. Prior to your retention in 11:11:04AM

this matter, based on your own patents, for 11:11:05AM

example, were you familiar with what the phrase 11:11:07AM

"priority date" means in the context of a patent? 11:11:10AM

A. Not in a legal sense, no. 11:11:13AM

Q. Okay. Your report also says that 11:11:15AM

you looked at final written decisions in other IPR 11:11:20AM

proceedings. Correct? 11:11:26AM

A. I did. 11:11:26AM

Q. Okay. What's your understanding 11:11:27AM

of what a final written decision is in an IPR 11:11:28AM

proceeding? 11:11:32AM

A. In general, it is the decision of 11:11:32AM

the Patent Review Board regarding the issues that 11:11:34AM

are presented as part of the IPR and their 11:11:36AM

decision related to that matter. 11:11:40AM

Q. Okay. And it says you also 11:11:41AM

reviewed institution decisions with respect to 11:11:46AM

certain IPR proceedings. Correct? 11:11:48AM

A. I'd have to look at that. I'm 11:11:50AM

not sure what you're referring to. 11:11:51AM

Q. Okay. If we focus first on the final written decisions, why -- why did you look at those? 11:11:52AM 11:11:54AM 11:11:58AM

A. Which final -- which final written decision are you referring to? 11:11:59AM 11:12:04AM

Q. Sure. Your declaration refers to a final written decision in IPR 2021-8811 relating to U.S. Patent No. 9,254,338. 11:12:06AM 11:12:10AM 11:12:14AM

Do you recall why you looked at that final written decision? 11:12:19AM 11:12:20AM

A. Again, I believe I address that in my declaration, and I can point you to the reason for that in the declaration. 11:12:22AM 11:12:23AM 11:12:26AM

Q. Okay. Beyond the legal documents or documents referenced in your declaration, do you recall reviewing any other documents, either in preparation for your deposition today or in the preparation of your report? 11:12:29AM 11:12:33AM 11:12:37AM 11:12:40AM 11:12:42AM

A. I'm sorry, I'm not sure I understand what you mean by "any other documents." 11:12:44AM 11:12:45AM

Q. Sure. 11:12:47AM

Are there any other materials that you considered to prepare your declaration in this case, beyond those that were cited in your declaration? 11:12:48AM 11:12:51AM 11:12:53AM 11:12:57AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 121

A. If I did, they were -- are not included there, and therefore I did not include them in the declaration. 11:12:57AM 11:12:58AM 11:13:00AM

Q. Okay. Do you recall whether you ever reviewed Samsung's petition for IPR in this case? 11:13:02AM 11:13:04AM 11:13:08AM

A. You'd have to show me the document. I -- I may have seen it. 11:13:12AM 11:13:14AM

Q. Okay. Do you know whether you've reviewed the institution decision in this proceeding? 11:13:15AM 11:13:17AM 11:13:19AM

A. Again, you'd have to show it to me. I'm not -- I'm not sure I -- I -- if I saw the document, I would know. 11:13:19AM 11:13:23AM 11:13:26AM

Q. Okay. And after your declaration was submitted, but before today's proceedings, do you recall ever reviewing Regeneron's preliminary patent owner's response? 11:13:27AM 11:13:29AM 11:13:32AM 11:13:36AM

A. I have seen that, yes. 11:13:37AM

Q. Okay. And do you recall when you reviewed that? 11:13:38AM 11:13:41AM

A. As part of my preparation for this today. 11:13:41AM 11:13:44AM

Q. Okay. And so that was at some point between October and today? 11:13:46AM 11:13:48AM

A. Yes. 11:13:49AM

Q. Okay. Were there any statements in Regeneron's patent owner's -- or preliminary patent owner's response that you disagreed with? 11:13:50AM 11:13:52AM 11:13:57AM

MR. SUMMERS: Object to form. 11:13:59AM

THE WITNESS: I couldn't answer that question. I'd have to -- I'd have go back and look through the document. 11:14:00AM 11:14:01AM 11:14:03AM

BY MR. BRAUSA: 11:14:07AM

Q. Okay. Were there any -- actually, withdraw that. I do want to get to the documents in just a moment, but I wanted to ask you a couple of questions just about background before we get there. 11:14:07AM 11:14:10AM 11:14:13AM 11:14:16AM 11:14:18AM

I see that you were awarded Best Doctor in America between 2006 and 2013; fair? 11:14:20AM 11:14:22AM

A. Well, not the best doctor in America. That's -- that would be -- that'd be very (gesture). 11:14:25AM 11:14:27AM 11:14:31AM

Q. Right, right. 11:14:31AM

A. No, that's -- 11:14:32AM

Q. One of the best doctors in America from -- 11:14:32AM 11:14:34AM

A. That's -- 11:14:34AM

Q. -- 2006 to 2013? 11:14:35AM

A. That's a nice little, you know, pearl, but it -- it's a -- yes. 11:14:38AM 11:14:40AM

Q. And -- and how does one -- one receive that award, or what's the process? 11:14:41AM 11:14:42AM

A. Through patient accolades and other data that are acquired by -- by the agency that does the Best Doctors type of thing. 11:14:44AM 11:14:55AM 11:14:57AM

Q. Okay, got it. 11:14:59AM

And it says you were also awarded the B. Otto Wheeley Award for Excellence in Technology Transfer from The University of Tennessee -- 11:15:00AM 11:15:02AM 11:15:07AM 11:15:08AM

A. Yes. 11:15:09AM

Q. -- correct? 11:15:10AM

So this is obviously an award that you received when you were at The University of Tennessee? 11:15:10AM 11:15:12AM 11:15:13AM

A. Yes. 11:15:14AM

Q. What is that award for? 11:15:14AM

A. It's for translational bioengineering and the work that I'd done over the last decade translating engineering concepts into clinical medicine to create new types of clinical paradigms, devices, drugs, that kind of thing. 11:15:16AM 11:15:18AM 11:15:20AM 11:15:24AM 11:15:29AM

Q. Okay. And so if you'll forgive 11:15:31AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 124

me -- counsel will understand the question. 11:15:33AM
Technology transfer in that award doesn't have 11:15:34AM
anything to do with patent licensing? 11:15:37AM
A. You know, I -- it doesn't have 11:15:39AM
anything to do with patent licensing. 11:15:44AM
Q. Okay. It -- it's taking 11:15:46AM
engineering concepts and applying them, 11:15:47AM
transferring them, to the real world? 11:15:50AM
A. Yes. But as part of that, one 11:15:52AM
aspect of that is what you referred to, which was 11:15:56AM
the patent that came out of Oak Ridge National 11:15:58AM
Laboratory that I was an author on. 11:16:01AM
Q. Okay. And did the award 11:16:03AM
specifically relate to that work? 11:16:05AM
A. No. It was a broad overview of a 11:16:07AM
body of work. 11:16:09AM
Q. Okay. I see. 11:16:10AM
If we can -- well, actually, 11:16:11AM
let's focus on today and then maybe we'll look -- 11:16:24AM
your practice today. 11:16:27AM
What do you do to stay abreast of 11:16:28AM
developments in the field of ophthalmology? 11:16:30AM
A. I read the current literature. I 11:16:33AM
interact with my colleagues. We have weekly 11:16:40AM
retina division conferences that -- in which we do 11:16:43AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 125

literature reviews, in which we discuss challenging patients and different management strategies for challenging patients. We have conferences related to surgical management of challenging patients. We have conferences related to management of retinal and ocular inflammatory diseases. 11:16:49AM 11:16:53AM 11:16:55AM 11:16:59AM 11:17:02AM 11:17:05AM 11:17:11AM

So I keep abreast in a number of different ways, both with -- with my colleagues and on my own reading. 11:17:12AM 11:17:14AM 11:17:15AM

Q. Okay. And -- and if we go back to the 2011 time frame when you were at The University of Tennessee and were not part of a large team of retina specialists, how did you keep abreast of developments then? 11:17:17AM 11:17:18AM 11:17:22AM 11:17:24AM 11:17:28AM

A. Read the literature. 11:17:29AM

Q. Okay. And forgive this question; it may sound a little ignorant. How do -- how do you know which journals to subscribe to, what literature to read? 11:17:30AM 11:17:36AM 11:17:38AM 11:17:41AM

A. Well, there -- there are a number of good journals that are -- that publish good work in ophthalmology and in retina in particular, and so those journals I would -- I would follow and did follow. 11:17:41AM 11:17:42AM 11:17:45AM 11:17:47AM 11:17:51AM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 126

Other areas in which I kept abreast is going to conferences. The American Academy of Ophthalmology has Retina Subspecialty Day every year. Actually, it's subspecialty days every year in which the current literature -- I guess, current practice, the current clinical studies, the current patient -- new patient information, clinical -- new clinical findings, all of that is presented to the retina community as a whole. 11:17:53AM 11:17:55AM 11:17:59AM 11:18:03AM 11:18:06AM 11:18:10AM 11:18:12AM 11:18:15AM 11:18:20AM 11:18:23AM

There are large -- every year, there's a large panel of -- of data that's presented by the American Society of Retina Specialists at Academy that looks at the practice patterns for retina specialists throughout the world. And every year, there's a survey: You have a patient who has this, what would you do? You know, a patient presents in this way, what would you -- how would you manage that patient? 11:18:23AM 11:18:26AM 11:18:29AM 11:18:33AM 11:18:37AM 11:18:40AM 11:18:42AM 11:18:42AM 11:18:42AM

And then all of that data is actually presented. And we get, actually, a very good understanding of how our colleagues are managing the same types of patients that we are and gives us information as to how -- how to practice. 11:18:46AM 11:18:48AM 11:18:54AM 11:18:56AM 11:18:59AM 11:19:02AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 127

Q. Okay. And -- and, again, if we think back to the 2011 time frame when you were at The University of Tennessee, did your review of -- of academic journals and your attending of conferences to keep abreast, did you ever review patent literature as part of that process? 11:19:02AM 11:19:04AM 11:19:07AM 11:19:10AM 11:19:13AM 11:19:16AM

A. No. 11:19:17AM

Q. And have you ever routinely reviewed patent literature as part of your efforts to stay up to date on what's going on in ophthalmology? 11:19:18AM 11:19:22AM 11:19:25AM 11:19:27AM

A. No. 11:19:28AM

Q. Why not? 11:19:28AM

A. The patent pros- -- prosecution is not relevant to the clinical practice in the sense of the way -- I'll just leave it at that. How a patent is making its way into clinical use is not relevant to clinical practice. 11:19:29AM 11:19:35AM 11:19:43AM 11:19:45AM 11:19:48AM

Q. I want to hand you what's been marked Exhibit 1016 in this proceeding. 11:19:52AM 11:20:14AM

(Exhibit 1016 was tendered.) 11:20:21AM

BY MR. BRAUSA: 11:20:30AM

Q. Do you recognize this document, Dr. Chaum? 11:20:30AM 11:20:33AM

A. Well, I don't exhibit this -- I 11:20:38AM

don't -- I mean I recognize this is as an Indication and Use document for EYLEA. 11:20:55AM 11:20:58AM

Q. And -- and when you say "an Indication and Use document for EYLEA," do you know whether that's the same as the label? 11:20:59AM 11:21:03AM 11:21:05AM

A. That would be the label, yes. 11:21:06AM

Q. Okay. 11:21:07AM

A. These other pages I'm not familiar with as being part of the label. 11:21:11AM 11:21:13AM

Q. Okay. And if we look at page 1 of Exhibit 1016, there is a section entitled "Indications and Usage." 11:21:15AM 11:21:21AM 11:21:26AM

Do you see that in the left column? 11:21:28AM 11:21:31AM

A. Yes. 11:21:31AM

Q. And DME is listed as a separate indication from DR, correct? 11:21:33AM 11:21:38AM

A. Yes. 11:21:40AM

Q. And is that consistent with your clinical understanding of DME and DR? 11:21:42AM 11:21:46AM

MR. SUMMERS: Objection to form. 11:21:49AM

THE WITNESS: Well, again, as I -- as I previously testified, diabetic retinopathy is an umbrella term that may include the presence of diabetic macular 11:21:50AM 11:21:55AM 11:22:01AM 11:22:03AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 129

edema. So in my own practice, diabetic retinopathy is -- is -- may or may not include macular edema. I'll just leave it at that. 11:22:06AM 11:22:12AM 11:22:18AM 11:22:24AM

BY MR. BRAUSA: 11:22:24AM

Q. Okay. But you'd agree with me that at least in the label that was approved by the FDA, DME is listed as a separate indication from DR? 11:22:25AM 11:22:30AM 11:22:32AM 11:22:35AM

A. Yes. 11:22:36AM

Q. And so the FDA, at least, thought that those were to be treated as separate indications, not an umbrella term, correct? 11:22:36AM 11:22:40AM 11:22:42AM

A. Again, I -- I was not part of that process. I don't know how the FDA distinguished those two. 11:22:46AM 11:22:48AM 11:22:51AM

Q. Okay. And my understanding is that even though companies like Regeneron go through the process of getting a label approved by the FDA, that physicians like yourself can prescribe drugs, quote/unquote, "off label"? 11:22:51AM 11:22:53AM 11:22:56AM 11:22:59AM 11:23:03AM

A. They can. 11:23:07AM

Q. What does that off-label prescription mean? 11:23:07AM 11:23:09AM

A. Well, the term generically means 11:23:10AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 130

that you are -- that the drug is being used for a clinical purpose that is not specifically defined by the FDA in its approval of that particular medication. 11:23:14AM 11:23:18AM 11:23:24AM 11:23:29AM

Q. Okay. And -- and do you, in your clinical practice, prescribe any drugs off label? 11:23:29AM 11:23:31AM

A. Yes. 11:23:35AM

Q. Which drugs are those? 11:23:39AM

A. We -- we use a number of different drugs to treat a number of different conditions that are not -- you know, for which there is not a specific FDA-approved indication. 11:23:43AM 11:23:49AM 11:23:53AM 11:23:55AM

Q. Okay. Do you use any VEGF antagonists off label? 11:23:57AM 11:24:01AM

A. If -- if you were -- again, if your definition of "off label" is to use that medication to treat something that's not specifically written for approval by the FDA, then the answer is yes. 11:24:02AM 11:24:05AM 11:24:10AM 11:24:12AM 11:24:16AM

Q. Okay. And which -- applying that definition of off label, which anti-VEGF agents are those? 11:24:17AM 11:24:19AM 11:24:23AM

A. Any anti-VEGF agent could be used. 11:24:24AM 11:24:28AM

Q. Okay. In your practice, are 11:24:28AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 131

there specific anti-VEGF agents that you prescribe off label? 11:24:30AM 11:24:34AM

A. So, again, typically, as I mentioned, Avastin is my first choice, bevacizumab. 11:24:34AM 11:24:36AM 11:24:39AM

Q. Okay. And what I'm trying to understand -- and my understanding is this is -- this is common practice. It's not -- prescribing off label is not unique to yourself. But do you have any understanding of why it is that physicians can prescribe things off label after companies have to go through the process of obtaining a label from the FDA? 11:24:39AM 11:24:42AM 11:24:43AM 11:24:46AM 11:24:49AM 11:24:52AM 11:24:55AM 11:24:57AM

A. The answer is because physicians have the ability to do so. 11:24:58AM 11:25:02AM

Q. Okay. 11:25:04AM

A. We are permitted to use any medication for a purpose that we believe would benefit the patient. And so although drugs are approved for specific indications -- and the reason that drugs are approved for specific indications is that they have to undergo clinical trials. And so the clinical trials focus on a particular disease state in order to demonstrate efficacy. 11:25:04AM 11:25:08AM 11:25:13AM 11:25:18AM 11:25:21AM 11:25:24AM 11:25:26AM 11:25:32AM 11:25:35AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 132

But once the drug has been shown to be safe and efficacious for use in clinical practice, physicians have the ability and the flexibility to use drugs for other indications if they believe it will benefit the patient. 11:25:36AM 11:25:38AM 11:25:42AM 11:25:46AM 11:25:50AM

Q. Okay. And so, for instance, Avastin, on its label it doesn't say DME is an indication that it's approved for use in, right? 11:25:51AM 11:25:53AM 11:25:57AM

A. On -- on this label, it does not -- 11:26:00AM 11:26:01AM

Q. Or -- 11:26:01AM

A. -- that I see. 11:26:03AM

Q. -- just to be clear, this is a label for EYLEA, not Avastin. 11:26:03AM 11:26:05AM

A. Oh, I'm sorry, you're talking Avastin? 11:26:06AM 11:26:08AM

Q. Avastin, correct? 11:26:09AM

A. I'm sorry. No, Avastin is the perfect example of an off-label use, because Avastin was not FDA approved for -- for -- in its initial approval, was not approved for use in the eye. It's a -- it's a cancer drug. 11:26:10AM 11:26:13AM 11:26:16AM 11:26:22AM 11:26:25AM

Q. Right. And so how did you as a clinician get comfortable prescribing Avastin to your patients for an intravitreal injection when 11:26:27AM 11:26:29AM 11:26:34AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 133

it is a cancer drug that the FDA hadn't approved for that use? 11:26:39AM 11:26:44AM

A. Well, that came out of studies that were done off label that showed that the drug was actually efficacious for the treatment of neovascular AMD. There were pilot studies that were done under, I presume, Institutional Review Board approval to look at these agents. 11:26:45AM 11:26:47AM 11:26:50AM 11:26:56AM 11:27:00AM 11:27:03AM

We understood from initial biologic data that if we could block VEGF, that it would have an effect or potentially have an effect to treat neovascular AMD and other angiogenic eye diseases. And Avastin was approved for its anti-angiogenic effect in the treatment of cancer, and so Phil Rosenfeld and Betsy Palmer (phonetic) and others looked at whether or not that drug could be safe and used for the treatment of neovascular age-related macular degeneration, and they showed that it could. 11:27:07AM 11:27:13AM 11:27:17AM 11:27:19AM 11:27:26AM 11:27:33AM 11:27:35AM 11:27:41AM 11:27:43AM 11:27:47AM 11:27:52AM

Ultimately, a clinical trial, the CATT trial, which was a head-to-head clinical trial against LUCENTIS to look at safety -- or look at efficacy for the use of Avastin for neovascular AMD, that study was done and was published and it was shown to be safe and 11:27:53AM 11:27:55AM 11:27:57AM 11:28:02AM 11:28:08AM 11:28:11AM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 134

effective. And that's how Avastin came into clinical practice use in ophthalmology. 11:28:13AM 11:28:16AM

Q. And so it was based on the -- in part on the CATT study and the data reported in that study showing Avastin to be safe and efficacious? 11:28:20AM 11:28:21AM 11:28:24AM 11:28:28AM

MR. SUMMERS: Objection, form. 11:28:28AM

THE WITNESS: Yes. And other -- and other clinical data. 11:28:29AM 11:28:30AM

BY MR. BRAUSA: 11:28:31AM

Q. Okay. If we turn back now to Exhibit 1016, the EYLEA label, it says at the top that it had initial U.S. approval in 2011. 11:28:31AM 11:28:33AM 11:28:36AM

Do you see that? 11:28:40AM

A. Yes. 11:28:43AM

Q. And -- and I think you testified earlier, but I want to make sure. You don't have any knowledge as to what the order of approval was for different indications, if they were approved at different times? 11:28:43AM 11:28:44AM 11:28:47AM 11:28:51AM 11:28:54AM

A. I -- I don't know offhand, no. 11:28:55AM

Q. Okay. Do you recall when EYLEA was approved in 2011? 11:28:59AM 11:29:02AM

A. I'd have to look it up. I don't know offhand. 11:29:04AM 11:29:08AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 135

Q. Okay. Do you remember being aware that EYLEA had been approved once it was approved in 2011? 11:29:08AM 11:29:10AM 11:29:12AM

A. Yes. 11:29:13AM

Q. And do you recall how you became aware of that? 11:29:13AM 11:29:16AM

A. Just, again, in the literature. 11:29:16AM

Q. Do you recall when you first prescribed EYLEA after 2011? 11:29:19AM 11:29:20AM

A. I don't recall offhand. I didn't use it much. 11:29:22AM 11:29:24AM

Q. Okay. 11:29:25AM

A. And so.... 11:29:26AM

Q. And when you say you didn't use it much, was that because of the formulary issue we discussed previously, or other reasons? 11:29:27AM 11:29:28AM 11:29:31AM

MR. SUMMERS: Objection, form. 11:29:33AM

THE WITNESS: Again, I -- as I testified before, my choice of anti-VEGF agent was bevacizumab for the reasons that I discussed. 11:29:34AM 11:29:37AM 11:29:42AM 11:29:44AM

BY MR. BRAUSA: 11:29:44AM

Q. Okay. Under the Indications and Usage heading, there's also a Dosage and Administration heading. 11:29:45AM 11:29:50AM 11:29:54AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 136

1	Do you see that?	11:29:55AM
2	A. Yes.	11:29:55AM
3	Q. And it has dosing schedules or	11:29:56AM
4	dosing -- I guess, how would you characterize the	11:30:02AM
5	amounts and time schedules set forth here? Is	11:30:05AM
6	that a dosing regimen, or would you use different	11:30:09AM
7	nomenclature?	11:30:12AM
8	A. I'm not sure -- I'm not sure I	11:30:13AM
9	understand your question.	11:30:16AM
10	Q. Okay. Sure. I guess I just want	11:30:18AM
11	to make sure I'm using a term that you're	11:30:21AM
12	comfortable with. If I refer to the dosing	11:30:22AM
13	schedule referred to under the Dosage	11:30:26AM
14	Administration heading, is that something you're	11:30:28AM
15	familiar with or a term you understand?	11:30:29AM
16	A. I would understand if you define	11:30:31AM
17	-- you know, again, if you define it well enough	11:30:33AM
18	for me.	11:30:35AM
19	Q. Okay.	11:30:35AM
20	A. That's -- that term is okay with	11:30:36AM
21	me.	11:30:37AM
22	Q. Okay. And would you agree with	11:30:37AM
23	me that the dosage and administration -- dosage	11:30:42AM
24	and administration specified under this heading	11:30:46AM
25	are fixed dosing schedules?	11:30:50AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 137

A. No. 11:30:52AM

MR. SUMMERS: Objection, form. 11:30:52AM

THE WITNESS: No, I would not 11:30:54AM

define that as fixed. 11:30:55AM

BY MR. BRAUSA: 11:30:55AM

Q. Okay. Why not? 11:30:56AM

A. Well, "fixed" is jargon. I don't 11:30:57AM

know what you mean by it. 11:31:00AM

Q. Okay. Why don't we introduce 11:31:01AM

Exhibit 1002 into the record, which was your 11:31:05AM

declaration in this case. 11:31:11AM

(Exhibit 1002 was tendered.) 11:31:19AM

MR. SUMMERS: Thank you. 11:31:21AM

BY MR. BRAUSA: 11:31:32AM

Q. And this is a copy of the 11:31:32AM

declaration you've submitted in this proceeding? 11:31:34AM

Is that correct, Dr. Chaum? 11:31:42AM

A. I'm looking through it. 11:31:43AM

Q. Okay. 11:31:44AM

A. (Witness reviews document.) I 11:31:44AM

believe so, yes. 11:32:53AM

Q. Okay. And that's your signature 11:32:54AM

on the back page of the -- 11:32:55AM

A. Yeah. 11:32:57AM

Q. -- Exhibit 1002? 11:32:57AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 138

A. Yes, uh-huh. 11:32:59AM

Q. So let me direct your attention 11:33:00AM

to paragraph 61 on page 22. Or I -- I should 11:33:01AM

clarify for the record: There are two page 11:33:05AM

numbers. One's in the center of the footer and 11:33:07AM

one's in the right-hand portion of the footer. Do 11:33:10AM

you have a preference as to which one I use? 11:33:13AM

A. No. 11:33:14AM

Q. Okay. So for the record, why 11:33:15AM

don't I use the one in bold in the right-hand -- 11:33:17AM

in the bottom right of the footer. So that's page 11:33:20AM

32 of Exhibit 1002, paragraph 61. 11:33:24AM

And let me know when you're 11:33:28AM

there. 11:33:29AM

MR. SUMMERS: And, Counsel, while 11:33:30AM

he's searching, since you said you 11:33:33AM

didn't have your watch. I'll let you 11:33:35AM

know we've been going about an hour. 11:33:37AM

MR. BRAUSA: Great. Let me just

finish up --

MR. SUMMERS: Yeah, yeah, yeah.

MR. BRAUSA: -- this questioning,

and we can take a break.

THE WITNESS: Yes. 11:33:40AM

BY MR. BRAUSA: 11:33:40AM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 139

Q. Okay. And so my question is: 11:33:41AM
What did you mean when you used the jargon "fixed 11:33:42AM
dosing schedules" in line 3 of paragraph 61? 11:33:45AM
A. What I meant here was a regular 11:33:48AM
dosing schedule. 11:34:10AM
Q. Is that different from a fixed 11:34:12AM
dosing schedule, in your view? 11:34:14AM
A. Well, again, in this paragraph, 11:34:23AM
what I'm talking about is the way that these 11:34:25AM
agents are delivered by practitioners. And what 11:34:31AM
I'm talking about here is that the decision about 11:34:37AM
the dose -- the dosing schedule is based upon the 11:34:41AM
patient's response and clinical decision-making 11:34:46AM
based upon that patient's response, as opposed to 11:34:50AM
a -- a predetermined schedule for a particular 11:34:54AM
patient using a medication. 11:35:00AM
Q. Okay. And so you'd agree with me 11:35:01AM
that a fixed dosing schedule is a predetermined 11:35:04AM
dosing schedule, right? 11:35:07AM
MR. SUMMERS: Objection, form. 11:35:09AM
THE WITNESS: Again, I think 11:35:10AM
"fixed" can be defined in any way that 11:35:13AM
you want to define it in that particular 11:35:16AM
setting. So you'd have to -- you'd have 11:35:20AM
to define for me what you mean by -- 11:35:22AM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 140

what you mean by a fixed dosing schedule. 11:35:24AM 11:35:26AM

BY MR. BRAUSA: 11:35:26AM

Q. Well, again, my question is actually what you meant when you used that phrase in paragraph 61 of your report? 11:35:28AM 11:35:29AM 11:35:32AM

A. Just that it's prespecified in some regimen, as opposed to being given based upon the patient's response. 11:35:33AM 11:35:36AM 11:35:40AM

Q. Okay. And in paragraph 61 of your report Exhibit 1002, in fact, you say that: "The labels for these VEGF antagonists specify fixed dosing schedules," correct? 11:35:41AM 11:35:44AM 11:35:48AM 11:35:53AM

A. That they -- that they are -- that -- yes, that they are providing a schedule that's predetermined. 11:35:55AM 11:35:59AM 11:36:12AM

Q. Okay. And -- and when you're referring to the labels for these VEGF antagonists in paragraph 61, that's referring to the labels for bevacizumab, ranibizumab, and aflibercept that you referred to in paragraph 60, right? 11:36:14AM 11:36:16AM 11:36:20AM 11:36:23AM 11:36:27AM

A. I'm sorry. You'll have to ask the question again. 11:36:29AM 11:36:31AM

Q. Sure. 11:36:31AM

When you're referring to the 11:36:32AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 141

labels for these VEGF antagonists, that includes EYLEA, right? 11:36:33AM 11:36:36AM

A. Yes. 11:36:37AM

Q. And that statement in paragraph 61 is truthful and accurate, right? 11:36:38AM 11:36:42AM

A. Yes. 11:36:44AM

Q. The label also specifies, if we go back to paragraph -- or, I'm sorry, if we go back to Exhibit 1016 and we look at the Dosage Administration Schedule for DME and DR -- do you see that subheading? 11:36:47AM 11:36:54AM 11:36:57AM 11:37:03AM 11:37:08AM

A. I'm sorry, where are you? 11:37:09AM

Q. In Exhibit 1016 under the Dosage Administration heading. 11:37:11AM 11:37:14AM

A. Yes. 11:37:15AM

Q. Under Diabetic Macular Edema and Diabetic Retinopathy, there's a dosing schedule specified right? 11:37:15AM 11:37:21AM 11:37:24AM

A. Yes. 11:37:24AM

Q. And under that schedule, EYLEA sequentially administered, right? 11:37:24AM 11:37:34AM

A. Yes. 11:37:36AM

MR. BRAUSA: Okay. I think we can take a break. 11:37:36AM 11:37:37AM

THE VIDEOGRAPHER: We are going 11:37:38AM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 142

off the record at approximately 11:37 a.m. 11:37:39AM 11:37:42AM

(Lunch recess observed.) 12:21:42PM

THE VIDEOGRAPHER: We are going back on the record at approximately 12:24 p.m. 12:22:07PM 12:24:49PM 12:24:51PM

BY MR. BRAUSA: 12:24:53PM

Q. Welcome back, Dr. Chaum. 12:24:53PM

During the lunch break, did you talk with counsel about your testimony at all? 12:24:55PM 12:24:56PM

A. Just in general terms. 12:24:58PM

Q. Okay. What general terms did you talk about? 12:24:59PM 12:25:01PM

A. How I'm doing. 12:25:02PM

Q. Okay. What's the -- what's the verdict? 12:25:03PM 12:25:05PM

A. I'm doing okay. 12:25:06PM

Q. Okay. Any tips? 12:25:07PM

A. No. 12:25:09PM

Q. Okay. Any specific lines of questioning that were discussed? 12:25:09PM 12:25:11PM

A. No. 12:25:12PM

Q. Got it. 12:25:12PM

If we can turn back to your declaration, Exhibit 1002. Let me direct you to 12:25:14PM 12:25:17PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 143

paragraph 2, which is at page 11, again, if we're using the pagination in the lower right-hand corner. 12:25:27PM 12:25:31PM 12:25:34PM

A. Yes. 12:25:46PM

Q. Are you there? 12:25:47PM

And in this paragraph it says that you were asked to provide opinions on the '601 patent regarding the subject matter of the '601 patent, and then it says: "Before and for a period following the earliest priority date of the application that led to the '601 patent." 12:25:48PM 12:25:49PM 12:25:53PM 12:25:56PM 12:25:58PM 12:26:02PM

Do you see that? 12:26:04PM

A. Yes. 12:26:04PM

Q. What -- what time period are we talking about there? 12:26:05PM 12:26:07PM

A. Well, I -- I believe I addressed that in my declaration. Let me find it. So on page 46 by your pagination. 12:26:07PM 12:26:10PM 12:26:36PM

Q. Yes. 12:26:39PM

A. So this is -- this is how I applied it. 12:26:40PM 12:26:43PM

Q. Okay. Would you like me to read it to you? 12:26:44PM 12:26:46PM

A. No, that's okay. 12:26:47PM

Q. If we can -- so I see here you're 12:26:48PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 144

pointing to a Section 9 that's identified as Priority Date, correct? 12:26:50PM 12:26:53PM

A. Yes. 12:26:54PM

Q. Okay. And so then my question is, in paragraph 2 when you refer to "the earliest priority date of the application that led to the '601 patent," what is that date? 12:26:54PM 12:26:56PM 12:27:00PM 12:27:03PM

A. Again, I believe I address this in my declaration. 12:27:07PM 12:27:09PM

Q. Uh-huh. 12:27:12PM

A. So on page 48 in my declaration: "As an initial matter, I note that I further address the priority date of claims 13 to 16, 20, 22 to 24 and 29 to 32 below in Section 10(b). Though as with the remainder of -- of the remainder of the claims, they are not entitled to any priority date before at least July 12th, 2013." 12:27:13PM 12:27:22PM 12:27:24PM 12:27:28PM 12:27:33PM 12:27:35PM 12:27:37PM 12:27:41PM

Q. Okay. And so if we go back to paragraph 2 of your report, when you say: "The earliest priority date of the application that led to the '601 patent," the date you're referring to is July 12th, 2013? 12:27:41PM 12:27:43PM 12:27:46PM 12:27:48PM 12:27:51PM

A. As I understand it, yes. 12:27:54PM

Q. Okay. And so in addition to 12:27:56PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 145

considering scientific and technical knowledge before July 23rd -- July 12th, 2013, according to paragraph 2, you also considered scientific and technical knowledge following July 12th, 2013. 12:28:01PM 12:28:06PM 12:28:10PM 12:28:16PM

Is that fair? 12:28:19PM

MR. SUMMERS: Objection, form. 12:28:19PM

THE WITNESS: I'm sorry, could you rephrase the question? 12:28:20PM 12:28:21PM

BY MR. BRAUSA: 12:28:23PM

Q. Yeah. I'm just -- maybe look at paragraph 2 of your report. I'm trying to understand what this reference to "the period following the earliest priority date of the application that led to the '601 patent" refers to. 12:28:23PM 12:28:25PM 12:28:28PM 12:28:30PM 12:28:33PM 12:28:35PM

Based on our discussion, that would be a period of time following July 12th, 2013, right? 12:28:37PM 12:28:39PM 12:28:45PM

A. Yeah, so, again, I'm not quite sure I understand how to answer your question. 12:28:49PM 12:28:52PM

Q. Let me try it this way: What did you mean when you said: "For a period following the earliest priority date of the application that led to the '601 patent"? 12:28:54PM 12:28:56PM 12:28:58PM 12:29:01PM

A. Again, let me look through my 12:29:02PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 146

declaration. (Witness reviews document.) 12:29:04PM

I believe it refers to the adding 12:29:41PM

of Example 7 to the '601 patent. 12:29:43PM

Q. You believe that paragraph 2 of 12:29:48PM

your expert report is referring to the adding of 12:29:51PM

Example 7 -- 12:29:55PM

A. No. 12:29:56PM

Q. -- to the patent? 12:29:57PM

A. No. What I'm saying is that 12:29:58PM

information after July 12th, 2013 -- again, I'm -- 12:30:00PM

I'm reading my declaration here. "I understand 12:30:04PM

that on July 12th, 2013, Application 370 was filed 12:30:07PM

which issued as the '338 patent adding Example 7, 12:30:10PM

general listing of various dosing regimens to the 12:30:15PM

specification." 12:30:17PM

Q. Okay. And you're reading from 12:30:18PM

paragraph 109 of your report? 12:30:21PM

A. Yes. 12:30:21PM

Q. Okay. So I understand that. 12:30:22PM

And that occurred on July 12th, 12:30:24PM

2013, right? 12:30:26PM

A. Yes. 12:30:27PM

Q. And so it's still not -- and 12:30:30PM

maybe I'm just missing something. But what do you 12:30:33PM

mean in paragraph 2 when you refer to "a period 12:30:36PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 147

following the earliest priority date of the application that led to the '601 patent"? 12:30:39PM 12:30:42PM

A. That may be unclear. I'm not sure I'm -- I'm not sure that I am referring to any specific document. 12:30:47PM 12:31:12PM 12:31:15PM

Q. Okay. Are -- are you referring to any specific time period, is my question? 12:31:16PM 12:31:18PM

A. Based on my review here, I'm not seeing that I am. 12:31:21PM 12:31:25PM

Q. Okay. And so you can't tell me, for instance, whether this period following the earliest priority date that you referred to in paragraph 2 is before or after July 12th, 2013? 12:31:26PM 12:31:28PM 12:31:31PM 12:31:33PM

A. I can't tell you at this time. 12:31:41PM

Q. Okay. Do you recall, when you signed this declaration, whether you understood what this period of time referred to in paragraph 2 was referring to? 12:31:42PM 12:31:45PM 12:31:48PM 12:31:51PM

A. I believe that it was referring to the work that I had been reviewing and that some of that may have been after that date, but I can't cite for you exactly what document would have -- that would have included. 12:31:52PM 12:31:57PM 12:32:00PM 12:32:13PM 12:32:07PM

Q. Okay. And do you have any understanding of whether in considering 12:32:08PM 12:32:10PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 148

anticipation and obviousness, it's appropriate to rely on materials after the earliest priority date of an application? 12:32:13PM 12:32:18PM 12:32:22PM

A. I'm sorry, can you repeat the question, please? 12:32:22PM 12:32:24PM

Q. Sure. 12:32:25PM

One of the opinions that you offer in this case is that the claims, or certain claims, are obviousness, correct? 12:32:25PM 12:32:27PM 12:32:29PM

A. Yes. 12:32:32PM

Q. Obvious from the perspective of a POSA, in your view? 12:32:32PM 12:32:36PM

A. Yes. 12:32:36PM

Q. And POSA, you're familiar with, it stands for person of ordinary skill in the art? 12:32:36PM 12:32:36PM

A. Yes. 12:32:39PM

Q. Do you have any understanding of whether the legal rules about obviousness allow one to consider materials, documents, et cetera, for any period of time following the earliest priority date of the application that led to the '601 patent? 12:32:39PM 12:32:43PM 12:32:48PM 12:32:53PM 12:32:55PM 12:32:58PM

A. Well, let me just look at my comments regarding obviousness. 12:32:59PM 12:33:01PM

(Witness reviews document.) 12:34:07PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 149

Well, what I -- I say in my 12:34:46PM
declaration is that: "I understand that a person 12:34:48PM
of ordinary skill in the art provides a reference 12:34:50PM
point from which the prior art and claimed 12:34:52PM
invention should be viewed." 12:34:54PM
Q. Right. And does that tell you 12:34:57PM
anything about the time period which you can 12:35:00PM
consider when evaluating the prior -- when 12:35:03PM
evaluating the priority -- prior art? Excuse me. 12:35:05PM
MR. SUMMERS: Objection, form. 12:35:17PM
THE WITNESS: So if you could 12:35:22PM
kind of rephrase that question for me, 12:35:23PM
I'd appreciate it. 12:35:25PM
BY MR. BRAUSA: 12:35:26PM
Q. Sure. 12:35:26PM
In rendering your opinions on 12:35:28PM
obviousness, did you consider any materials that 12:35:30PM
were published or available after what you 12:35:34PM
consider to be the earliest priority date of the 12:35:37PM
patent application that issued as the '601 patent? 12:35:42PM
A. So I -- as -- as far as I am 12:35:45PM
aware with the materials that have been provided 12:35:49PM
to me, it -- there were none that were after that 12:35:51PM
priority date of July 12th. 12:35:54PM
Q. Okay. And so my question then 12:35:56PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 150

goes back to paragraph 2 of your report. And I'm just trying to understand what are you referring to when you say that you "considered scientific and technical knowledge regarding the subject matter of the '601 patent before and for a period following the earliest priority date of the application that led to the '601 patent"? 12:35:59PM 12:36:05PM 12:36:09PM 12:36:12PM 12:36:14PM 12:36:19PM 12:36:21PM

MR. SUMMERS: Objection, form. 12:36:23PM

THE WITNESS: So if I -- so if I understand your question correctly -- can you provide me a copy of the patent? 12:36:24PM 12:36:32PM 12:36:35PM

BY MR. BRAUSA: 12:36:37PM

Q. Sure. 12:36:37PM

Let me hand the exhibit -- or hand the witness, excuse me, an exhibit which has been marked as Exhibit 1001. 12:36:39PM 12:36:43PM 12:36:45PM

(Exhibit 1001 was tendered.) 12:36:48PM

MR. SUMMERS: Thank you. 12:36:55PM

THE WITNESS: So I'm -- again, I'm trying to reconstruct my thoughts here. 12:36:57PM 12:36:58PM 12:37:01PM

BY MR. BRAUSA: 12:37:01PM

Q. Sure. 12:37:01PM

A. So the priority date for the patent, as I was -- as I reviewed it, was -- was 12:37:01PM 12:37:08PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 151

filed on January -- the Provisional Application was filed on January 13th, 2011. 12:37:13PM 12:37:16PM

Q. Okay. 12:37:19PM

A. That's the initial priority date for the patent '601. But additional materials related to Exhibit -- Example 7, as I understand it from counsel, were added July of 2013, and therefore, were included in my consideration. 12:37:20PM 12:37:22PM 12:37:28PM 12:37:32PM 12:37:39PM

And so that's what I'm trying to say here, is that the initial filing date that I -- that I examined or that -- so that -- my opinion for the scientific and technical knowledge for the subject matter of '601 before -- for the period following the earlier priority date of January 13th, 2011 also includes material that was provided rely -- related to Example 7 that has a later date. And that's what I'm trying to encompass in this paragraph. 12:37:42PM 12:37:44PM 12:37:48PM 12:37:51PM 12:37:54PM 12:38:00PM 12:38:04PM 12:38:09PM 12:38:15PM 12:38:17PM

Q. Okay. So I -- I think I now understand. 12:38:19PM 12:38:21PM

When you say in paragraph 2 "the earliest priority date of the application," what you're referring to is the January 13th, 2011 Provisional Application? 12:38:21PM 12:38:24PM 12:38:26PM 12:38:31PM

A. Correct. 12:38:32PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 152

Q. And you also considered materials in the period between January 13th, 2011 and July 12th, 2013, correct? 12:38:32PM 12:38:35PM 12:38:41PM

A. Correct. 12:38:42PM

Q. Okay. 12:38:43PM

A. That's my understanding. 12:38:44PM

Q. Did you consider any materials after Janu- -- or withdraw. 12:38:45PM 12:38:47PM

Did you consider any materials after July 12th, 2013? 12:38:49PM 12:38:51PM

A. Not that I'm aware of. 12:38:54PM

Q. Okay. 12:38:55PM

A. But, again, I can look back through the materials that I've examined and -- and provide that, if that's important. 12:38:55PM 12:38:57PM 12:39:00PM

Q. Okay. And you made reference to the Provisional Application filed on January 13th, 2011 that's listed on the face of Exhibit 1001, the '601 patent, right? 12:39:01PM 12:39:04PM 12:39:07PM 12:39:10PM

A. Yes. 12:39:12PM

Q. Do you cite to the Provisional Application anywhere in your expert declaration? 12:39:13PM 12:39:17PM

A. I don't cite to the provisional, but my understanding -- my limited understanding of patents is that that Provisional Application 12:39:20PM 12:39:27PM 12:39:30PM

date is relevant to this proceeding, although the patent is obviously issued at a later date, as I have -- as I understand. 12:39:36PM 12:39:41PM 12:39:43PM

Q. Okay. Do you know whether there's a document that is referred to as the Provisional Application filed on January 13th, 2011? 12:39:44PM 12:39:45PM 12:39:49PM 12:39:52PM

MR. SUMMERS: Objection to form. 12:39:53PM

THE WITNESS: Well, if a Provisional Application was filed, then there is a document somewhere. 12:39:54PM 12:39:57PM 12:39:58PM

BY MR. BRAUSA: 12:39:59PM

Q. Okay. 12:40:00PM

A. Yes. 12:40:00PM

Q. And did you review it -- 12:40:00PM

A. No. 12:40:02PM

Q. -- in offering your opinion? 12:40:02PM

A. No. 12:40:03PM

Q. Okay. I just wanted to confirm because I don't see it cited anywhere in your declaration. 12:40:04PM 12:40:05PM 12:40:08PM

A. No, I just identified the date -- 12:40:08PM

Q. Okay. 12:40:10PM

A. -- of that. And counsel has instructed me that that's the -- that's the prior- 12:40:10PM 12:40:11PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 154

-- that's a priority date. 12:40:14PM

Q. Okay. Got it. 12:40:15PM

And so your knowledge about the 12:40:16PM
Provisional Application and the priority date 12:40:18PM
comes from counsel; is that fair? 12:40:19PM

A. My knowledge about the -- about 12:40:20PM
the dating of documents for this proceeding is 12:40:25PM
based on counsel's instructions, yes. 12:40:29PM

Q. Okay. Let's put that aside. 12:40:30PM
We'll come back to the -- the patent in a few 12:40:41PM
moments, but let's go back into your report, 12:40:43PM
Exhibit 1002. And I wanted to follow up on a 12:40:46PM
discussion we had earlier today about materials 12:40:56PM
from other IPR proceedings that you reviewed in 12:40:58PM
preparation for today's testimony. 12:41:03PM

And if I can direct your 12:41:05PM
attention to paragraph 15 which starts on page 15 12:41:20PM
of Exhibit 1002. 12:41:23PM

A. (Witness complies.) Yes. 12:41:25PM

Q. This refers to the final written 12:41:31PM
decision related to the '338, as you call it? 12:41:34PM

A. Yes. 12:41:39PM

Q. I take it this final written 12:41:39PM
document that's designated Exhibit 1025 was 12:41:42PM
provided to you by counsel? 12:41:44PM

A. Yes, it was. 12:41:46PM

Q. Okay. And if we turn to page 16, 12:41:47PM

it says that -- after saying that you've reviewed 12:41:52PM

this final written decision, you've formed an 12:41:56PM

opinion regarding the '601 claims here independent 12:41:58PM

of the '338-FWD, but that you found the '338-FWD 12:42:01PM

to be consistent with your independent opinion, 12:42:07PM

right? 12:42:10PM

A. Yes. 12:42:10PM

Q. What does that mean? 12:42:15PM

A. There were decisions made as part 12:42:16PM

of the final written decision that I reviewed and 12:42:20PM

found consistent with my opinions here. 12:42:24PM

Q. Okay. Do you recall when, in the 12:42:26PM

process of putting together your declaration for 12:42:27PM

this case, you read the '338 final written 12:42:30PM

decision? 12:42:33PM

A. I don't know the date, but I -- I 12:42:34PM

did read it. 12:42:36PM

Q. Okay. But it was before you put 12:42:36PM

your signature, I take it, on this -- this 12:42:38PM

particular document, Exhibit 1002? 12:42:41PM

A. Yes. 12:42:45PM

Q. Okay. Did you review the '338 12:42:45PM

patent? 12:42:48PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 156

A. I did not. 12:42:51PM

Q. Did you review any other 12:42:51PM

materials from the '338 IPR proceedings, other 12:42:53PM

than the final written decision that you include 12:42:57PM

as Exhibit 1025 to your declaration? 12:43:00PM

A. I did not. 12:43:02PM

Q. Why not? 12:43:03PM

A. From my conversation with 12:43:04PM

counsel, the relevance to this declaration was -- 12:43:12PM

could be found in the final written decision of 12:43:19PM

the board, and that's what I read. 12:43:22PM

Q. Okay. Do you know whether -- 12:43:23PM

again, this is a legal question. But do you know 12:43:25PM

whether you can appeal a final written decision of 12:43:29PM

the board? 12:43:31PM

MR. SUMMERS: Objection to form; 12:43:31PM

calls for a legal conclusion. 12:43:33PM

THE WITNESS: I'm not sure. I 12:43:34PM

don't know. 12:43:35PM

BY MR. BRAUSA: 12:43:35PM

Q. Sure. 12:43:36PM

Do you know if Regeneron has 12:43:36PM

appealed the final written decision? 12:43:38PM

A. I do not know. 12:43:39PM

Q. So you have not read any appeal 12:43:40PM

1	briefs filed by the parties regarding the '338	12:43:43PM
2	final written decision?	12:43:48PM
3	A. No.	12:43:49PM
4	Q. If you were forming an	12:43:49PM
5	independent opinion with respect to the '601	12:43:53PM
6	claims at issue here, why did you bother reading	12:43:55PM
7	the '338 final written decision at all?	12:44:01PM
8	A. Because the '338 decision	12:44:04PM
9	contains relevant information for the '601.	12:44:06PM
10	They're related patents, and the board's decision	12:44:10PM
11	regarding that was informative to my own --	12:44:15PM
12	directing myself in my own decision and opinions	12:44:21PM
13	regarding this information.	12:44:23PM
14	Q. Okay. And so the board's -- if I	12:44:24PM
15	have this right, the board's decision in the '338	12:44:26PM
16	IPR proceedings was informative to your --	12:44:29PM
17	developing your own opinions, fair?	12:44:33PM
18	A. Yes.	12:44:34PM
19	Q. Okay. And you said that the '338	12:44:35PM
20	patent is -- and the '601 patent are,	12:44:37PM
21	quote/unquote related patents. Is that fair?	12:44:40PM
22	A. As I understand them, yes.	12:44:42PM
23	Q. And -- and that was my question.	12:44:43PM
24	How do you know that if you can't review the '338	12:44:45PM
25	patent?	12:44:47PM

A. I was instructed by -- informed by counsel that they are related and the final written decision of the board as, I believe, also indicates that. 12:44:48PM 12:44:51PM 12:44:53PM 12:44:58PM

But I'd have to look at that document. 12:45:00PM 12:45:03PM

Q. In paragraph 16 it refers to another IPR proceeding, IPR 2022-1226. 12:45:03PM 12:45:05PM

Do you see that? 12:45:11PM

A. Yes. 12:45:11PM

Q. And this is -- what you designate as the Mylan IPR? 12:45:12PM 12:45:14PM

A. Yes. 12:45:17PM

Q. And it -- paragraph 16 is not referring to a final written decision; it's referring to an institution decision, correct? 12:45:17PM 12:45:21PM 12:45:25PM

A. Yes. 12:45:27PM

Q. And do you know what the difference is between an institution decision and a final written decision? 12:45:30PM 12:45:32PM 12:45:34PM

A. Not offhand, no. 12:45:35PM

Q. Okay. And to be clear, the '601 or the Mylan IPR deals with the same patent that we're dealing with here, the '601 patent? 12:45:36PM 12:45:42PM 12:45:44PM

A. Again, I'd have to look at it. 12:45:48PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 159

Q. Okay. 12:45:49PM

A. But I believe it does. 12:45:49PM

Q. Do you know whether it relates to the same claims that we're dealing with on the '601 patent or not? 12:45:50PM 12:45:52PM 12:45:55PM

A. I'd have to review it. I can't say offhand. 12:45:56PM 12:45:59PM

Q. Do you know whether there is a final written decision in that proceeding? 12:46:00PM 12:46:01PM

A. I do not know. 12:46:03PM

Q. Did you ask why you were provided an institution decision from that proceeding? 12:46:04PM 12:46:06PM

A. No. 12:46:09PM

Q. Did you review any materials from that IPR proceeding besides the institution decision? 12:46:09PM 12:46:13PM 12:46:18PM

A. Not that I recall. 12:46:19PM

Q. And similar question with respect to this institution decision: Do you recall when in the drafting process of your declaration that you reviewed that? 12:46:20PM 12:46:25PM 12:46:28PM 12:46:31PM

A. I don't. 12:46:32PM

Q. And did it also inform your opinions that are rendered here? 12:46:32PM 12:46:37PM

A. I found -- 12:46:38PM

MR. SUMMERS: Objection, form. 12:46:39PM

THE WITNESS: -- I found it to be 12:46:40PM

consistent with my opinions. 12:46:41PM

BY MR. BRAUSA: 12:46:42PM

Q. And, again, why did you review 12:46:42PM

the institution decision and the different 12:46:44PM

proceeding as a part of the process of rendering 12:46:47PM

your opinions in this proceeding? 12:46:49PM

A. So my understanding from counsel 12:46:52PM

was that it was relevant to this proceeding. 12:46:54PM

Q. Okay. Did you find it to be 12:46:57PM

relevant? 12:46:58PM

A. Yes. 12:46:59PM

Q. In what way? 12:46:59PM

A. Well, if you show it to me, I can 12:47:00PM

go through it and show you the areas that I think 12:47:02PM

were relevant. 12:47:04PM

Q. Okay. But without looking at the 12:47:05PM

institution decision, you can't tell me why you 12:47:06PM

thought it was relevant? 12:47:08PM

A. I can tell you, if I review it, 12:47:09PM

the parts that were relevant. 12:47:11PM

Q. Okay. But I just want to 12:47:13PM

confirm: Without going through it line-by-line, 12:47:15PM

you can't tell me at a high level what you found 12:47:17PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 161

to be relevant? 12:47:20PM

A. Again, it was a while ago. I 12:47:20PM

don't -- I haven't reviewed the document in a 12:47:22PM

while, so I -- I can't answer your question. 12:47:24PM

Q. Okay. So you didn't review the 12:47:25PM

document as part of your Zoom meetings with 12:47:26PM

counsel to prepare for this deposition? 12:47:30PM

A. Not for this deposition, no. 12:47:31PM

Q. For your prior deposition, did 12:47:32PM

you? 12:47:34PM

A. I don't recall. 12:47:35PM

Q. A few moments ago you were 12:47:36PM

looking at a -- the discussion that you provide in 12:48:04PM

your report of obviousness, which I think was on 12:48:09PM

page 20 and it started at paragraph 32, correct? 12:48:12PM

A. Yes. 12:48:15PM

Q. And this is -- Obviousness is 12:48:21PM

listed as Subsection D or Subheading D under a 12:48:26PM

Heading 4 that appears on page 16 entitled: "The 12:48:30PM

Relevant Legal Standard"? 12:48:34PM

A. Yes. 12:48:36PM

Q. And in paragraph 19 on page 16, 12:48:37PM

you say that you're relying on certain legal 12:48:40PM

principles, but that counsel's explained those 12:48:43PM

legal principles -- principles to you, correct? 12:48:46PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 162

A. Yes. 12:48:47PM

Q. Okay. And so if the explanation 12:48:51PM
you received of the legal principles or the 12:48:53PM
relevant legal standard was incomplete or 12:48:56PM
inaccurate in any way, that -- that's on your 12:48:59PM
counsel, right? 12:49:01PM

A. I'm not sure I understand how to 12:49:04PM
answer that question. 12:49:05PM

Q. You don't have any independent 12:49:06PM
knowledge of the proper legal standard for 12:49:09PM
evaluating the obviousness of a patent, beyond 12:49:11PM
what counsel told you, right? 12:49:14PM

A. That's correct. 12:49:15PM

Q. And, in fact, for all of the 12:49:16PM
legal standards that you've included here, you 12:49:18PM
don't have any independent knowledge of what the 12:49:20PM
legal standard is beyond how it was explained to 12:49:22PM
you by counsel? 12:49:24PM

A. That's correct. 12:49:25PM

Q. And, similarly, there may be 12:49:26PM
other legal standards that are not included in 12:49:27PM
your report because they weren't identified as 12:49:29PM
being relevant to your opinions, by counsel? 12:49:32PM

A. I -- I don't know how to answer 12:49:34PM
that question. Can you break it down for me? 12:49:37PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 163

Q. Sure. 12:49:39PM

Are all the relevant legal 12:49:40PM

standards for the validity of the patent set forth 12:49:43PM

in your report? 12:49:47PM

A. I do not know. I only know the 12:49:47PM

ones that were provided for coun- -- by counsel. 12:49:51PM

Q. Okay. In paragraph 23 on page 12:49:53PM

17, you identify a -- a definition of the relevant 12:50:01PM

POSA. 12:50:12PM

Do you see that? 12:50:12PM

A. Yes. 12:50:13PM

Q. And as of the earliest date that 12:50:13PM

we referred to, January 13th, 2011, the 12:50:15PM

provisional filing date, how did your skillset 12:50:18PM

compare to this hypothetical POSA that's defined 12:50:24PM

in paragraph 23 on page 17 of Exhibit 1002? 12:50:25PM

A. I believe that I can answer 12:50:30PM

questions relevant to a way a person of ordinary 12:50:32PM

skill in the art would because I'm an experienced 12:50:36PM

practitioner. And as I say, I -- I -- I practice 12:50:38PM

retinal medicine. I have patients whom I care for 12:50:45PM

who have angiogenic diseases, and I'm 12:50:48PM

knowledgeable about the use of those agents. And 12:50:51PM

so although I'm not a hypothetical construct, I 12:50:56PM

can -- I can answer questions regarding what a 12:50:58PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 164

hypothetical construct will -- would do. 12:51:02PM

Recall, also, that at that time 12:51:05PM

frame when these drugs were being developed, all 12:51:08PM

retina specialists were in essence POSAs. We were 12:51:12PM

learning about those -- the use of those 12:51:17PM

medications, so.... 12:51:18PM

Q. Okay. And when you say that you 12:51:19PM

were learning about it, that's because this is a 12:51:22PM

-- a newer field at the time? 12:51:24PM

A. It was at that time, yes. 12:51:26PM

Q. Okay. Now, in reality, though, 12:51:27PM

you'd been -- I think you said a clinician since 12:51:30PM

1987? 12:51:33PM

A. Yes. 12:51:34PM

Q. And so you had 14 years of 12:51:34PM

experience as a clinician prior to January 13th of 12:51:36PM

2011; is that fair? 12:51:40PM

A. Yes. 12:51:43PM

Q. Okay. And then we're sitting 12:51:43PM

here in 2023, so -- or 2024, excuse me, and so in 12:51:46PM

addition to those 14 years, you have another 15 12:51:50PM

years of experience from 2011 to sitting here 12:51:54PM

today, right? 12:51:58PM

A. I do. 12:51:59PM

Q. Okay. And so do you consider 12:51:59PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 165

yourself a POSA figure today, or do you consider yourself an expert? 12:52:03PM 12:52:06PM

A. I believe I can answer and do answer relevant questions from the perspective of a person of ordinary skill in the art, having been a person of ordinary skill in the art and understanding what the perspective of a person of ordinary skill in the art would be. 12:52:07PM 12:52:09PM 12:52:14PM 12:52:17PM 12:52:20PM 12:52:24PM

Q. If I can direct you to paragraph 42 of your report, page 24, this refers to hindsight. 12:52:25PM 12:52:30PM 12:52:41PM

Do you see that? 12:52:42PM

A. Yes. 12:52:44PM

Q. What's your understanding of what "hindsight" is in the context of rendering your opinions? 12:52:45PM 12:52:47PM 12:52:50PM

A. I'm sorry, your -- your question is confusing to me. Are you asking me what my understanding of the word "hindsight" means? 12:52:51PM 12:52:54PM 12:52:57PM

Q. Let's start there, sure. 12:52:59PM

A. On. Hindsight means the use of information looking -- looking back and making a determination based upon some information that has been gleaned subsequently. 12:53:01PM 12:53:04PM 12:53:07PM 12:53:11PM

Q. Okay. And in the context of 12:53:13PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 166

paragraph 42 and your opinions in this case, do you have an understanding of what "hindsight" refers to? 12:53:16PM 12:53:18PM 12:53:20PM

A. Yes. 12:53:20PM

Q. What is that understanding? 12:53:21PM

A. Well, similarly to using subsequent information that became available after the time frame in which the proceedings relate to. 12:53:22PM 12:53:25PM 12:53:29PM

Q. Okay. And, again, when you refer to "the time frame after which the proceedings relate to," what's the time frame relevant to this patent? 12:53:32PM 12:53:34PM 12:53:42PM 12:53:45PM

A. Again, we're talking 2013, July of 2013. 12:53:45PM 12:53:47PM

Q. Okay. And so did you consider the prior art from the perspective of a POSA in July 2013 or January 2011? 12:53:48PM 12:53:49PM 12:53:53PM

A. Well, my review of the documents here relates to 20- -- to the date 2013. The -- as I -- so I would have to include that information with respect to my overall declaration. 12:53:56PM 12:53:59PM 12:54:07PM 12:54:12PM 12:54:15PM

Q. Okay. And so you didn't -- you didn't conduct any independent evaluation if the earliest priority date was deemed to be January 12:54:15PM 12:54:17PM 12:54:22PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 167

2011. You included information from between January 2011 and July 2013 in your analysis?

MR. SUMMERS: Objection, form.

THE WITNESS: Could you rephrase the question, please?

BY MR. BRAUSA:

Q. Sure.

Did you conduct any analysis of the prior art as of January 13th, 2011?

A. I included in my analysis -- the examp- -- the information or the Example 7 that were included in the '601 patent subsequent to that.

Q. Okay. Beyond Example 7 that was included in the patent application filed in July 2013, did you include in your analysis or consider in your analysis any additional material that became available after January 13th, 2011?

A. Not that I'm aware of, no.

Q. Photograph 42 says: "I understand that hindsight must not be used when comparing the prior art to the invention for obviousness," correct?

A. Yes.

Q. What's your understanding of what

that means? 12:55:28PM

A. My understanding of that 12:55:28PM

paragraph is that in putting myself in the 12:55:31PM

position of a person of ordinary skill in the art, 12:55:34PM

that I would have an understanding and would make 12:55:38PM

decisions and make determinations and understand 12:55:42PM

what the art was and what was -- what the art was 12:55:51PM

prior to that particular date. 12:55:59PM

Q. Okay. Do you think that in 12:56:01PM

rendering your opinions, you used any hindsight at 12:56:04PM

any point in time? 12:56:08PM

A. I don't think so, no. 12:56:10PM

Q. Okay. And you yourself testified 12:56:11PM

you're not a hypothetical construct. And in 12:56:12PM

reality how can you be sure? 12:56:16PM

A. Well, what I was asked to do was 12:56:17PM

to put myself in the position of a person of 12:56:19PM

ordinary skill at that time, and I was practicing 12:56:23PM

and developing uses for these new medications in 12:56:29PM

my practice at that time. 12:56:32PM

So I'm not looking back at some 12:56:34PM

period of time in hypothetical context and saying 12:56:38PM

what might I have done and how that might be 12:56:42PM

potentially colored by hindsight. Rather, I'm 12:56:46PM

looking back into who I was and how I was 12:56:51PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 169

practicing and what I was thinking at that time. 12:56:55PM

So in addition to -- to being -- 12:56:57PM

intellectually being able to put myself in the 12:57:00PM

context of that time frame and the introduction of 12:57:04PM

these drugs for use in that time frame, I was 12:57:07PM

living in that time frame and applying those early 12:57:09PM

-- applying the thought process to the application 12:57:14PM

of those medications in my practice. 12:57:19PM

So I have both intellectual 12:57:21PM

understanding of what a person in the ordinary 12:57:25PM

skill in the art would do and a personal 12:57:27PM

understanding of what I was doing at that time. 12:57:30PM

Q. Okay. And with respect to the 12:57:32PM

personal understanding of what you were doing at 12:57:33PM

that time, I think you previously testified that 12:57:37PM

you weren't familiar with the 2009 Regeneron press 12:57:38PM

release at that point in time. Right? 12:57:42PM

A. I don't recall whether I had seen 12:57:44PM

it or not, no. 12:57:46PM

Q. Okay. And, similarly, you 12:57:47PM

testified that you weren't familiar with the Shams 12:57:49PM

publication that you rely on in your report until 12:57:52PM

it was provided to you by counsel, correct? 12:57:55PM

A. I had not reviewed it, no. 12:57:57PM

Q. And so from your personal 12:57:59PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 170

experience, you didn't have any experience dealing with those references and making determinations about what they would or would not teach, correct? 12:58:01PM 12:58:03PM 12:58:07PM

A. You'll have to rephrase that question. 12:58:09PM 12:58:11PM

Q. Sure. 12:58:11PM

As of the earliest priority date, January 13th, 2011, you weren't familiar with the Regeneron 2009 press release or the Shams patent litigation, right? 12:58:11PM 12:58:14PM 12:58:17PM 12:58:23PM

A. Well, I may or may not have seen the Regeneron press release. But at that time, the -- there was, in the -- in the clinical practice in the retina community, there was general knowledge about these drugs that were being developed. So I was certainly aware of the -- the -- the drug at that time. 12:58:24PM 12:58:27PM 12:58:29PM 12:58:36PM 12:58:38PM 12:58:41PM 12:58:44PM

Again, these early clinical studies were being presented at meetings, and so there -- I certainly had awareness of that. But if you're asking me did I read that particular Regeneron press release at that time, I can't tell you if I did or not. 12:58:47PM 12:58:52PM 12:58:56PM 12:58:59PM 12:59:03PM 12:59:06PM

Q. Okay. If we can go back to paragraph 32 of your report on page 20 -- 12:59:07PM 12:59:09PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 171

A. Yes. 12:59:19PM

Q. -- the first part of the sentence 12:59:20PM

says that you understand that even if a patent 12:59:22PM

claim is not anticipated.... 12:59:24PM

Do you see that? 12:59:29PM

A. Yes. 12:59:30PM

Q. What does it mean to be 12:59:30PM

"anticipated"? 12:59:32PM

A. (Witness reviews documents.) 12:59:33PM

I would say in this context, what 01:00:09PM

it means is that the patent claim would have 01:00:14PM

followed on from another claim. 01:00:20PM

Q. Okay. Maybe -- maybe I'm not 01:00:27PM

understanding. What do you mean when you say: 01:00:28PM

"The patent claim would have followed on from 01:00:30PM

another claim"? 01:00:33PM

A. Again, I -- I think I've said it 01:00:55PM

as -- as well as I can. That -- that a claim 01:01:05PM

would be expected or would be -- follow on from 01:01:09PM

another claim that's -- another patent claim 01:01:17PM

that's related or relevant to it. 01:01:20PM

Q. Okay. And so that's what your 01:01:22PM

understanding of anticipation is? 01:01:24PM

A. Best as I can describe it to you 01:01:27PM

at this point, yes. 01:01:30PM

Q. Okay. And do you know whether anticipation is a basis for invalidity in the patent context? 01:01:30PM 01:01:33PM 01:01:38PM

A. I'm -- I'm not -- I'm not a patent attorney. As I understand it, it may be. 01:01:38PM 01:01:42PM

Q. Okay. And in the Relevant Legal Standards section of your report, which starts on page 16 and goes up to page 24 -- 01:01:45PM 01:01:47PM 01:01:51PM

A. (Witness reviews documents.) 01:01:51PM

Q. -- do you see any subheading that explains what anticipation is? 01:02:09PM 01:02:10PM

A. (Witness reviews documents.) 01:02:14PM

I'm sorry. You're referring to paragraphs? To -- to what extent? I mean, to which paragraph on this -- 01:03:06PM 01:03:07PM 01:03:17PM

Q. Yeah, I'm just looking to see if any of the relevant legal standards that were provided to you by counsel identified in paragraphs 19 to 42 of your report explain what the legal standard, if any, is of "anticipation," which you refer to in paragraph 32 of your report. 01:03:18PM 01:03:20PM 01:03:22PM 01:03:25PM 01:03:28PM 01:03:31PM

A. (Witness reviews documents.) 01:03:38PM

So I don't see a definition of "application," but I was asked to opine on validity related to obviousness. 01:04:05PM 01:04:08PM 01:04:15PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 173

Q. Okay. 01:04:18PM
A. And so that's where the focus of 01:04:18PM
my opinion is based. 01:04:20PM
Q. Okay. Do you know if 01:04:21PM
paragraph 32 appears in your declarations in any 01:04:22PM
of the other cases you've been retained by Quinn 01:04:25PM
Emanuel on behalf of Samsung for? 01:04:28PM
A. I don't know. I'd have to look. 01:04:35PM
Q. Okay. Do you know whether it was 01:04:36PM
copied over from any of those par- -- 01:04:38PM
declarations? 01:04:40PM
A. I have no idea. 01:04:40PM
Q. How was the declaration in this 01:04:41PM
proceeding drafted? 01:04:43PM
MR. SUMMERS: I'm just going to 01:04:45PM
caution the witness not to reveal the 01:04:47PM
substance of any attorney-client 01:04:49PM
communication. 01:04:51PM
THE WITNESS: So counsel and I 01:04:52PM
had discussed the -- the approach to -- 01:04:56PM
or what the understanding of obviousness 01:05:03PM
was with respect to patent in -- in 01:05:06PM
patent law, and the obviousness -- 01:05:11PM
which, again, I've laid out different 01:05:14PM
aspects of what -- what is -- what would 01:05:17PM

be considered obviousness or obvious, that that approach to understanding this issue was -- was -- was an area that was -- that they wanted me to opine about. 01:05:22PM 01:05:25PM 01:05:30PM 01:05:37PM

BY MR. BRAUSA: 01:05:40PM

Q. Okay. 01:05:40PM

A. And so I looked at various aspects about my understanding of obviousness to determine and just generate an opinion about whether or not the claims that were here in patent '601 would have been considered obvious. 01:05:40PM 01:05:43PM 01:05:46PM 01:05:51PM 01:05:56PM

Q. Okay. And if we focus again on the first part of paragraph 32 -- and you wrote the sentence: "I understand that even if a patent claim is not anticipated," do you recall, is that language you decided to include in the report? 01:05:59PM 01:06:01PM 01:06:04PM 01:06:07PM 01:06:10PM

A. I don't recall. 01:06:13PM

Q. Okay. And do you have any understanding of why that statement is in your report? 01:06:13PM 01:06:18PM 01:06:22PM

A. I would have to defer to counsel. 01:06:24PM

Q. Okay. If we go to paragraph 35, as -- as you noted, this further expands on your understanding of obviousness and it says that: The obviousness -- your understanding is that the 01:06:27PM 01:06:31PM 01:06:34PM 01:06:37PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 175

obviousness determination can be based on a single prior art reference or a combination of multiple prior art references. Correct? 01:06:40PM 01:06:44PM 01:06:46PM

A. Yes. 01:06:48PM

Q. Okay. I want to focus on the single prior art reference example you provide in paragraph 35, okay? 01:06:48PM 01:06:51PM 01:06:54PM

A. Okay. 01:06:55PM

Q. If we're considering a single prior art reference, do you have an understanding of when that prior art reference could be said to anticipate a claim? 01:06:56PM 01:06:59PM 01:07:02PM 01:07:06PM

MR. SUMMERS: Objection to form. 01:07:07PM

THE WITNESS: Yeah, I didn't generate an opinion based upon anticipation -- 01:07:09PM 01:07:10PM 01:07:12PM

BY MR. BRAUSA: 01:07:13PM

Q. Okay. 01:07:13PM

A. -- so I can't comment. 01:07:14PM

Q. And do you have any understanding of when the prior art reference would be said to render the claim obvious, standing alone, that prior art reference? 01:07:15PM 01:07:16PM 01:07:20PM 01:07:23PM

A. I don't understand your question. 01:07:24PM

Q. Sure. 01:07:25PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 176

It sounds like you don't have an understanding of when the prior art reference would anticipate the claim, correct? 01:07:26PM 01:07:28PM 01:07:30PM

MR. SUMMERS: Objection, mischaracterizes his testimony; form. 01:07:31PM 01:07:32PM

THE WITNESS: I think I've answered your question is that -- my understanding of anticipation. 01:07:35PM 01:07:36PM 01:07:38PM

BY MR. BRAUSA: 01:07:39PM

Q. Okay. So let me -- maybe I misunderstood. 01:07:40PM 01:07:41PM

If we consider the 2009 press release from Regeneron that you offer obviousness opinions about, right? 01:07:42PM 01:07:47PM 01:07:50PM

A. Yes. 01:07:51PM

Q. You don't have any opinion that that 2009 press release anticipates the claim, do you? 01:07:51PM 01:07:52PM 01:07:56PM

A. I only provided an opinion related to obviousness. 01:07:59PM 01:08:01PM

Q. Okay. My question is: Do you have any understanding of what the reference would have to disclose in order for it to be considered an anticipating reference? 01:08:04PM 01:08:06PM 01:08:10PM 01:08:14PM

MR. SUMMERS: Objection to form, 01:08:18PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 177

calls for a legal conclusion. 01:08:19PM

THE WITNESS: I can't answer the 01:08:20PM

question. I don't know. 01:08:21PM

BY MR. BRAUSA: 01:08:21PM

Q. Okay. So when you say in 01:08:21PM

paragraph 32: "I understand that even if a patent 01:08:24PM

claim is not anticipated," you can't tell me what 01:08:26PM

that means with respect to the 2009 press release? 01:08:30PM

A. I'd have to think about that. 01:08:35PM

Q. Okay. And so can you tell me 01:08:37PM

again, if we have a single prior art reference, 01:08:42PM

what the difference is between saying that prior 01:08:45PM

art reference makes the claim obvious versus 01:08:49PM

anticipating the claim? 01:08:53PM

MR. SUMMERS: Objection: Calls 01:08:53PM

for a legal conclusion, form. 01:08:54PM

THE WITNESS: I'm sorry, can you 01:08:56PM

rephrase the question, please? 01:08:58PM

BY MR. BRAUSA: 01:09:00PM

Q. Sure. 01:09:00PM

I guess my question is: Do you 01:09:00PM

have any understanding of the difference between 01:09:04PM

obviousness and anticipation? 01:09:06PM

MR. SUMMERS: Objection: Calls 01:09:07PM

for a legal conclusion, form. 01:09:08PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 178

THE WITNESS: Yeah, I'm -- I'm not -- I'm not in a position to answer that question. I'm not an attorney. 01:09:09PM 01:09:10PM 01:09:13PM

BY MR. BRAUSA: 01:09:14PM

Q. Okay. So is the answer to that question today, no, you don't know the difference? 01:09:14PM 01:09:18PM

MR. SUMMERS: Same objections. 01:09:20PM

THE WITNESS: So I've answered, I think, your question regarding my understanding of anticipation. 01:09:21PM 01:09:23PM 01:09:24PM

BY MR. BRAUSA: 01:09:25PM

Q. What's the difference between anticipation and obviousness? 01:09:25PM 01:09:27PM

MR. SUMMERS: Objection: Calls for a legal conclusion, form. 01:09:29PM 01:09:31PM

THE WITNESS: I can't answer your question. 01:09:32PM 01:09:33PM

BY MR. BRAUSA: 01:09:34PM

Q. Okay. So just to confirm, the difference between anticipation and obviousness wasn't explained to you by counsel? 01:09:34PM 01:09:38PM 01:09:41PM

A. I was not asked to review the documents with the perspective of providing an opinion regarding anticipation. I was asked to review the documents to provide an opinion 01:09:42PM 01:09:48PM 01:09:52PM 01:09:57PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 179

regarding obviousness. 01:10:00PM

Q. Okay. And when you say you "were not asked to review the documents for anticipation, you were asked to review the documents for obviousness," you were asked by counsel, correct? 01:10:01PM 01:10:04PM 01:10:06PM 01:10:08PM 01:10:11PM

A. Yes. 01:10:11PM

Q. Okay. Paragraph 34 sets forth -- this is on page 20 of Exhibit 1002 -- sets forth your understanding that: "Obviousness includes a consideration of various factors such as" -- and then you provide four factors. 01:10:11PM 01:10:26PM 01:10:31PM 01:10:36PM 01:10:38PM

Do you see that? 01:10:40PM

A. Yes. 01:10:40PM

Q. Are those the only factors that the obviousness determination includes consideration of? 01:10:41PM 01:10:43PM 01:10:46PM

A. No, but those are the ones that I considered. 01:10:51PM 01:10:53PM

Q. Okay. What other factors could be included in the obviousness determination? 01:10:53PM 01:10:55PM

A. I'm not a patent attorney. I don't know. 01:10:57PM 01:10:59PM

Q. Okay. So you considered each one of these factors, listed in paragraph 34, in 01:11:00PM 01:11:03PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 180

rendering your opinions? 01:11:07PM

A. Yes. 01:11:08PM

Q. The second one is the differences between the prior art and the asserted claims. 01:11:09PM 01:11:13PM

Do you see that? 01:11:17PM

A. Yes. 01:11:17PM

Q. What's your understanding of what that factor means? 01:11:18PM 01:11:21PM

MR. SUMMERS: Objection, form. 01:11:22PM

THE WITNESS: I would -- my understanding is based upon the language itself. Differences between the prior art, what's in the public domain and literature and the asserted claims. 01:11:23PM 01:11:28PM 01:11:30PM 01:11:32PM 01:11:35PM

BY MR. BRAUSA: 01:11:37PM

Q. Okay. And would you agree that there are differences between the prior art that you considered and the asserted claims in this case? 01:11:37PM 01:11:40PM 01:11:42PM 01:11:45PM

A. There are some, yes. 01:11:46PM

Q. Okay. And you considered those differences? 01:11:47PM 01:11:50PM

A. Yes. 01:11:51PM

Q. If we now go to paragraph 35 on page 21, it also refers to a combination of -- or 01:11:53PM 01:12:01PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 181

withdraw that. 01:12:12PM

So the first sentence provides 01:12:12PM

your understanding that obviousness determination 01:12:15PM

can be based on a single prior art reference, 01:12:18PM

right? 01:12:21PM

A. Yes. 01:12:21PM

Q. Or a combination of multiple 01:12:22PM

prior art references, right? 01:12:24PM

A. Correct. 01:12:27PM

Q. Or the knowledge of one of 01:12:27PM

ordinary skill in the art. 01:12:30PM

Do you see that? 01:12:31PM

A. Yes. 01:12:32PM

Q. Okay. And so it's your opinion 01:12:32PM

that obviousness can be based on the knowledge of 01:12:36PM

one of ordinary skill in the art on its own 01:12:41PM

without any other references? 01:12:44PM

MR. SUMMERS: Objection: Form, 01:12:45PM

calls for a legal conclusion, scope. 01:12:47PM

THE WITNESS: Yeah, I -- can you 01:12:48PM

break that down? 01:12:51PM

BY MR. BRAUSA: 01:12:51PM

Q. Sure. 01:12:51PM

Can obviousness be based solely 01:12:53PM

on the knowledge of one of ordinary skill in the 01:12:56PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 182

art? 01:12:59PM

MR. SUMMERS: Objection: Form, 01:13:00PM

calls for a legal conclusion, scope. 01:13:01PM

THE WITNESS: I used all three, 01:13:11PM

so I'd have to think about that. 01:13:12PM

BY MR. BRAUSA: 01:13:14PM

Q. Okay. So you used a single prior 01:13:15PM

art reference, a combination of the prior art 01:13:21PM

references, and a knowledge of ordinary skill in 01:13:24PM

the art to arrive at your obviousness conclusion? 01:13:26PM

A. Yes. 01:13:30PM

Q. Why did you rely on multiple 01:13:30PM

prior art references instead of just a single 01:13:32PM

prior art reference? 01:13:36PM

MR. SUMMERS: Objection, form. 01:13:37PM

THE WITNESS: Well, multiple 01:13:41PM

prior art references are still relevant 01:13:43PM

to the conclusion. 01:13:45PM

BY MR. BRAUSA: 01:13:48PM

Q. Okay. And -- and did you 01:13:48PM

determine which multiple prior art references to 01:13:51PM

rely on, or were those provided to you by counsel? 01:13:53PM

A. Some of them were provided by 01:13:55PM

counsel and some I have knowledge of. 01:13:57PM

Q. Okay. Are -- are you familiar 01:13:58PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 183

with the terminology of the grounds in an IPR proceeding? 01:14:07PM 01:14:04PM

A. No. 01:14:05PM

Q. The second sentence in paragraph 35 sets forth your understanding that the prior art may provide a suggestion, motivation, or reason to combine or modify the teachings of the prior art. 01:14:08PM 01:14:10PM 01:14:14PM 01:14:17PM 01:14:19PM

Do you see that? 01:14:20PM

A. Yes. 01:14:20PM

Q. And then it says that: "Such a reason can come from other sources, such as the knowledge of a person having ordinary skill in the art, common sense, and market forces." 01:14:21PM 01:14:24PM 01:14:26PM 01:14:29PM

Do you see that? 01:14:33PM

A. Yes. 01:14:33PM

Q. So I think I understand what you mean when you say "knowledge of a person having ordinary skill in the art." How does common sense differ from that, if at all? 01:14:33PM 01:14:35PM 01:14:37PM 01:14:41PM

A. Well, I think it's similar in the sense that a person of -- having ordinary skill in the art would make decisions, for the care of the patient, that were based upon clinical experience and common sense considerations. 01:14:45PM 01:14:48PM 01:14:53PM 01:14:56PM 01:15:00PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 184

Q. Okay. What does "market forces" refer to in that statement? 01:15:01PM 01:15:06PM

A. Just potentially -- well, let's see. (Witness reviews documents.) 01:15:07PM 01:15:09PM

I think just knowledge about a particular -- the way that you -- strike that. 01:15:16PM 01:15:35PM

I think what I meant here is just interest in -- in that particular -- in a particular drug or its awareness in the common -- in -- you know, in the field. 01:15:49PM 01:16:24PM 01:16:29PM 01:16:37PM

Q. How is that different from the knowledge of a person of ordinary skill in the art? 01:16:38PM 01:16:42PM 01:16:46PM

A. Well, it's not necessarily specifically related to the practice of medicine. 01:16:47PM 01:16:48PM

Q. Okay. So can you give me an example of when market forces would give a POSA reason to combine or modify teachings of the prior art? 01:16:50PM 01:16:51PM 01:16:56PM 01:16:59PM

MR. SUMMERS: Objection to form; calls for a legal conclusion. 01:17:00PM 01:17:02PM

THE WITNESS: Can you just rephrase the question for me? 01:17:03PM 01:17:04PM

BY MR. BRAUSA: 01:17:05PM

Q. Sure. 01:17:06PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 185

You say that in paragraph 35 that 01:17:06PM
the reason to combine or modify the teachings of 01:17:08PM
prior art may be provided by other sources, 01:17:11PM
including market forces -- 01:17:14PM
A. Uh-huh. 01:17:16PM
Q. -- right? 01:17:16PM
And I'm just wondering what's an 01:17:18PM
example of that, where a reason to combine is 01:17:20PM
motivated by market forces? 01:17:24PM
A. Well, for example, with -- 01:17:25PM
related to anti-VEGF agents, the use of anti-VEGF 01:17:27PM
agents was in the treatment of -- validated in the 01:17:32PM
treatment of neovascular macular degeneration. 01:17:38PM
But there's obviously an 01:17:39PM
awareness and an interest in a -- on the part of 01:17:41PM
the community -- medical community to apply those 01:17:44PM
medi- -- that type of medication to clinical 01:17:50PM
entities. And so that would be in -- an example 01:17:53PM
of there's an -- there's an interest and a need 01:18:00PM
in -- in potentially using those agents for other 01:18:02PM
treatments. 01:18:05PM
And so that's -- that's the kind 01:18:05PM
of thing that I'm talking about. 01:18:06PM
Q. Paragraph 35, you go on to say 01:18:08PM
that in the list in bullet point form, several 01:18:11PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 186

rationales that you understand may support a finding of obviousness. 01:18:15PM 01:18:17PM

A. Yes. 01:18:18PM

Q. Which of these rationales, in your view, support your opinion on obviousness? 01:18:19PM 01:18:22PM

MR. SUMMERS: Objection, form. 01:18:26PM

THE WITNESS: Well, I say combining prior art elements according to known methods to yield predictable results. 01:18:28PM 01:18:38PM 01:18:39PM 01:18:42PM

BY MR. BARUSA: 01:18:42PM

Q. Okay. 01:18:42PM

A. I included that. 01:18:42PM

Q. So that's Bullet Point 1, right? 01:18:43PM

A. Substitution of one known element for another to obtain predictable results. 01:18:45PM 01:18:47PM

Q. Okay. 01:18:50PM

A. I would include that. The use of a known technique to improve similar methods in the same way, I would use that. Applying a known technique to -- a known method to -- to yield improvements in results, I would apply that. 01:18:50PM 01:18:52PM 01:18:54PM 01:18:58PM 01:19:01PM

And also from the perspective of a person of ordinary skill in the art, that it would obviously try different variations in the 01:19:04PM 01:19:07PM 01:19:09PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 187

process of routine experimentation to -- to improve clinical outcomes. 01:19:13PM 01:19:17PM

Q. Okay. 01:19:19PM

A. In addition, I write here: "No work in one field may prompt variations for use either in the same field or a different one based upon design," such as in this is, again, the issue of market forces as I mentioned -- "if the variations are predictable to one of ordinary skill in the art." 01:19:19PM 01:19:23PM 01:19:27PM 01:19:29PM 01:19:34PM 01:19:35PM 01:19:38PM

This gets to the question of expanding the use of anti-VEGF agents for other applications -- 01:19:39PM 01:19:41PM 01:19:45PM

Q. Okay. And -- 01:19:45PM

A. -- and then, also, I write some teaching suggestion or modification in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine it to arrive at the claimed invention -- invention. 01:19:46PM 01:19:47PM 01:19:50PM 01:19:54PM 01:19:57PM

Q. And so by reading each of the bullets, I take it your view is that you applied each of these rationales of your obviousness determination? 01:19:58PM 01:20:00PM 01:20:02PM 01:20:06PM

A. I applied all of them in one form of another or in combination. 01:20:06PM 01:20:08PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 188

Q. Okay. There's a bullet on page 21 that refers to "obvious to try" in quotes. 01:20:10PM 01:20:14PM

A. Uh-huh, yes. 01:20:20PM

Q. Why is "obvious to try" in quotes? 01:20:21PM 01:20:24PM

A. Just a simple phrase. 01:20:24PM

Q. Okay. And it refers to "choosing from a finite number of identified predictable solutions"? 01:20:26PM 01:20:29PM 01:20:33PM

A. Yes. As written, yes. 01:20:34PM

Q. Okay. And what -- in your view, is there a number that you can put on that in terms of a finite number of predictable solutions? 01:20:35PM 01:20:37PM 01:20:39PM

MR. SUMMERS: Objection, calls for a legal conclusion. 01:20:42PM 01:20:44PM

THE WITNESS: I would not put a number. I don't think there's a specific number that would be appropriate. 01:20:45PM 01:20:47PM 01:20:49PM 01:20:50PM

BY MR. BRAUSA: 01:20:50PM

Q. Okay. It would depend on the context; is that fair? 01:20:50PM 01:20:52PM

A. The context, the patient, the disease being treated, the response of the patient to -- to the intervention and other features -- 01:20:53PM 01:20:56PM 01:20:58PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 189

Q. Okay. 01:21:01PM

A. -- other factors. 01:21:02PM

Q. And it also refers to in the 01:21:03PM
Obvious to Try section -- or bullet, rather, to a 01:21:07PM
reasonable expectation of success? 01:21:10PM

A. Yes. 01:21:12PM

Q. What's your understanding of what 01:21:12PM
a "reasonable expectation of success" is? 01:21:14PM

A. Well, I -- I think the language 01:21:15PM
is -- as written is -- is clear, that a person of 01:21:18PM
ordinary skill in the art would expect -- would 01:21:22PM
have, based on their knowledge, based on their 01:21:24PM
understanding of the disease process, based on 01:21:26PM
their understanding of the medication, that the 01:21:28PM
intervention, if you will, would be successful in 01:21:32PM
terms of the desired management of that patient. 01:21:36PM

Q. Okay. So if we look at claim 10 01:21:39PM
of the '601 patent, which is designated 01:21:42PM
Exhibit 1001, when you were analyzing whether this 01:21:47PM
claim is obvious or not in view of the prior art, 01:21:59PM
what did you view as a POSA's reasonable 01:22:03PM
expectation of success with respect to this claim 01:22:06PM
dosing regimen? 01:22:09PM

A. I'm sorry, can -- yeah, can you 01:22:10PM
break down your question for me, please? 01:22:11PM

Q. Sure. 01:22:14PM

As -- as part of your obviousness 01:22:15PM

analysis, you consider whether a POSA would have a 01:22:17PM

reasonable expectation of success? 01:22:19PM

A. Yes. 01:22:21PM

Q. And I think you just provided 01:22:21PM

what your understanding of a reasonable 01:22:23PM

expectation of success may be, in some context, 01:22:26PM

correct? 01:22:29PM

A. Yes. 01:22:29PM

Q. Okay. In the context of your 01:22:29PM

analysis of claim 10 in this proceeding, what is 01:22:31PM

the reasonable expectation of success that you 01:22:35PM

applied? 01:22:39PM

MR. SUMMERS: Objection, form; 01:22:40PM

foundation. 01:22:43PM

THE WITNESS: Yeah, I -- again, 01:22:44PM

I'm not quite sure I'm understanding 01:22:45PM

your -- your question. 01:22:47PM

BY MR. BRAUSA: 01:22:48PM

Q. Sure. When evaluating the prior 01:22:49PM

art, did you have any guide as to what you 01:22:51PM

considered a -- a reasonable expectation of 01:22:54PM

success to be? 01:22:57PM

MR. SUMMERS: Objection, form; 01:22:58PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 191

foundation. 01:23:00PM

THE WITNESS: Well, the prior art 01:23:01PM
is instructive in terms of understanding 01:23:04PM
how patients responded to anti-VEGF 01:23:05PM
agents. And so a person of ordinary 01:23:09PM
skill in the art would understand how 01:23:13PM
modifications of those dosing regimens 01:23:16PM
would impact the patient's clinical 01:23:21PM
status. 01:23:25PM

BY MR. BRAUSA: 01:23:25PM

Q. Okay. And is it your opinion 01:23:26PM
that a POSA would have had a reasonable 01:23:27PM
expectation of success in making the modifications 01:23:29PM
you suggest in your report? 01:23:33PM

A. Which modifications are you 01:23:36PM
talking about specifically? 01:23:39PM

Q. Well, for instance, using EYLEA 01:23:40PM
instead of ranibizumab. 01:23:42PM

A. So the -- a person of ordinary 01:23:44PM
skill in the art, if the patient didn't respond to 01:23:48PM
ranibizumab, might have a reasonable expectation 01:23:52PM
of success that an alternative anti- -- anti-VEGF 01:23:54PM
agent may be beneficial for that patient. 01:23:59PM

Q. Okay. And so my question is when 01:24:01PM
you say that they might have a reasonable 01:24:03PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 192

expectation of success, how would a POSA define "success"? 01:24:05PM 01:24:10PM

MR. SUMMERS: Objection to form. 01:24:11PM

THE WITNESS: So, again, a person of ordinary skill in the art practicing would be providing the medication to a patient for the purpose of improving their clinical status. 01:24:13PM 01:24:20PM 01:24:23PM 01:24:27PM 01:24:30PM

BY MR. BRAUSA: 01:24:31PM

Q. Uh-huh. 01:24:31PM

A. And, therefore, their definition of success, again, success is -- is -- is a jargon term. It can mean anything. 01:24:32PM 01:24:34PM 01:24:38PM

But from the perspective of a retina specialist, it might include improvement in vision. It might include improvement in the anatomical status of the macula. It might include improvement in visual function. It might include regression of disease. It might include deferral of disease progression. Success can be defined in any number of ways with respect to the care of a patient. 01:24:41PM 01:24:45PM 01:24:49PM 01:24:53PM 01:24:57PM 01:25:01PM 01:25:04PM 01:25:08PM 01:25:12PM

So, you know, that's what I would say. 01:25:12PM 01:25:15PM

Q. Okay. Did you define success in 01:25:16PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 193

any particular way when rendering your obviousness opinions? 01:25:17PM 01:25:23PM

A. I looked at, from my perspective or the perspective of a person of ordinary skill in the art, all of the potential definitions of success. 01:25:27PM 01:25:30PM 01:25:32PM 01:25:35PM

Q. Okay. And so those were all included in your opinions where you say a POSA would have a reasonable expectation of success? 01:25:35PM 01:25:38PM 01:25:39PM

A. They were considered, yes. 01:25:42PM

Q. Okay. When -- when you say "they were considered," what's -- what's the distinction you're drawing? 01:25:43PM 01:25:45PM 01:25:48PM

A. As I understood your question, did -- I interpreted your question to mean you included everything for all patients. And I -- I would -- I would say that they were considerations, but not necessarily for every patient. 01:25:49PM 01:25:50PM 01:25:56PM 01:25:58PM 01:26:03PM 01:26:04PM

Q. Okay. So success in one patient might vary in terms of what success is con- -- deemed successful in another patient? 01:26:05PM 01:26:08PM 01:26:10PM

A. Again, success is jargon. Yeah, if we wanted to understand a definition of success, then you'd have to identify it in more 01:26:12PM 01:26:14PM 01:26:17PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 194

specifics. 01:26:19PM

Q. Okay. And in your report, did 01:26:19PM

you identify or define success any more 01:26:21PM

specifically? 01:26:24PM

A. I -- 01:26:25PM

MR. SUMMERS: Objection, form. 01:26:27PM

THE WITNESS: -- I didn't -- I 01:26:28PM

didn't define success in a specific way 01:26:28PM

in my report, that I recall. 01:26:33PM

BY MR. BRAUSA: 01:26:35PM

Q. Okay. If we go to paragraph -- 01:26:35PM

MR. SUMMERS: I'm just going to 01:26:40PM

let you know -- not suggesting a 01:26:41PM

break -- but since you don't have a 01:26:44PM

watch, it's been about an hour and 01:26:47PM

three. 01:26:50PM

MR. BRAUSA: Okay. 01:26:50PM

MR. SUMMERS: I'm totally fine 01:26:50PM

with Dr. Chaum to keep going for the -- 01:26:51PM

MR. BRAUSA: Let me ask two more 01:26:51PM

questions. 01:26:53PM

MR. SUMMERS: Yeah. Yeah. 01:26:53PM

MR. BRAUSA: Famous last words. 01:26:53PM

BY MR. BRAUSA: 01:26:54PM

Q. Paragraph 37 of your report, 01:26:56PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 195

1002. And this, again, provides further expansion on your understanding of obviousness and it says that you understand that the content of the patent or other printed publication, i.e., a reference, could be interpreted by a POSA as of the effective filing date of the patent application for the '601 patent. 01:26:57PM 01:27:07PM 01:27:10PM 01:27:14PM 01:27:18PM 01:27:21PM 01:27:24PM

Do you see that? 01:27:25PM

A. Yeah. 01:27:25PM

Q. And do you have any understanding of whether there's a difference between the effective filing date which you refer to in paragraph 37 of your report and the earliest priority date which you refer to in paragraph 2 of your report? 01:27:26PM 01:27:29PM 01:27:33PM 01:27:35PM 01:27:37PM 01:27:40PM

A. I have no opinion regarding that. 01:27:42PM

Q. Okay. And so when you say effective filing date here, do you know whether that's referring to July 12th, 2013 or January 11th, 2011? 01:27:43PM 01:27:47PM 01:27:49PM 01:27:53PM

A. I don't recall. 01:27:54PM

Q. And when you interpreted the prior art for rendering your obviousness opinions, do you recall whether you used January 13th, 2011 as the date or July 12th, 2013? 01:27:55PM 01:28:00PM 01:28:04PM 01:28:08PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 196

A. I actually used both, because I considered the Example 7 that was added to the '601 patent as part of my discussion regarding obviousness. 01:28:12PM 01:28:18PM 01:28:24PM 01:28:27PM

Q. Okay. A -- a third question -- I realized I shouldn't have promised you. 01:28:27PM 01:28:32PM

This paragraph also refers to -- it says a person of ordinary skill is not an automaton? 01:28:34PM 01:28:36PM 01:28:38PM

A. Automaton. 01:28:39PM

Q. There you go. 01:28:41PM

Is that a term you're familiar with? 01:28:42PM 01:28:44PM

A. Yes. 01:28:44PM

Q. What does it mean? 01:28:45PM

A. Mechanical machine. 01:28:46PM

Q. Okay. 01:28:47PM

MR. BRAUSA: We can take a break. 01:28:47PM

THE VIDEOGRAPHER: We are going off the record at approximately 1:28 p.m. 01:28:50PM 01:28:51PM 01:28:54PM

(Brief recess observed.) 01:46:29PM

THE VIDEOGRAPHER: We are going back on the record at approximately 1:46 p.m. 01:46:29PM 01:46:33PM 01:46:36PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 197

BY MR. BRAUSA: 01:46:36PM

Q. Dr. Chaum, are you familiar with 01:46:39PM

a concept or term of "individualized therapy"? 01:46:40PM

A. I would have my own 01:46:45PM

interpretation of it. I think people might have 01:46:47PM

different personalized invitations -- excuse me -- 01:46:49PM

definitions for -- for theirselves [sic]. 01:46:53PM

Q. Okay. What's your definition of 01:46:56PM

"individualized therapy"? 01:46:59PM

A. Well, I think every physician 01:47:00PM

wants to treat a patient in a manner that is best 01:47:03PM

for them, for the -- for the patient, and a 01:47:07PM

concept of individualizing therapy, to me, means 01:47:12PM

that the decisions that I make are going to be 01:47:16PM

based upon the patient's response to medication. 01:47:20PM

Other factors as well, but if 01:47:25PM

we're talking about therapeutics, potentially 01:47:27PM

modifying the way that that patient is -- is 01:47:31PM

treated in order to maximize the benefit for that 01:47:34PM

patient. 01:47:38PM

Q. Okay. And -- and you're familiar 01:47:39PM

with a concept called "pro re nata" or PRN 01:47:40PM

treatment strategy? 01:47:46PM

A. Yes. 01:47:47PM

Q. And what does that mean? 01:47:47PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 198

A. Are you asking in the context of anti-VEGF treatments? 01:47:49PM 01:47:54PM

Q. Yes. 01:47:55PM

A. Okay. So the concept of pro re nata, as needed, arose from the difficulty that we have in managing patients with this disease with, for example, macular degeneration, using monthly dosing regimens. We know, for example, that a certain -- that three initial doses of a medication for age-related macular degeneration can reduce the therapy benefit. And then the question becomes for patients how often do they need to be treated after that initial thera- -- presumably therapeutic response. 01:47:55PM 01:47:59PM 01:48:04PM 01:48:08PM 01:48:14PM 01:48:17PM 01:48:20PM 01:48:25PM 01:48:29PM 01:48:31PM 01:48:35PM

The original studies with ranibizumab and Avastin as well, utilized monthly doses. And so the clinical efficacy was seen, and based upon patients being treated on a monthly basis. But treating patients on a monthly basis is difficult. It's difficult for the patient to come in on a monthly basis; it's difficult for the physician to manage. There are risks associated with monthly dosing for anti-VEGF agents. 01:48:37PM 01:48:45PM 01:48:50PM 01:48:53PM 01:48:55PM 01:48:59PM 01:49:01PM 01:49:04PM 01:49:08PM

And so in the context of what we're talking about, anti-VEGF therapy, the -- 01:49:12PM 01:49:14PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 199

there are many physicians who have developed an approach which is to treat the patient, demonstrate that the patient has responded, and then predicate future treatments, not on a time schedule, but on a response schedule and determine whether or not that patient requires treatment as needed at some future point in time. 01:49:17PM 01:49:21PM 01:49:25PM 01:49:28PM 01:49:34PM 01:49:39PM 01:49:42PM

And there are -- there is good rationale for considering that type of therapy. We know some patients respond well and -- and do incredibly well for a long period of time on -- after, you know, a few doses of a medication. Others do not. 01:49:45PM 01:49:48PM 01:49:51PM 01:49:54PM 01:49:57PM 01:50:01PM

And so physicians and persons of ordinary skill in the art at that time were looking at alternatives that would maximize the benefit to a patient and yet reduce the number of interactions that might be problematic for the patient in terms of risk and reduce the burden of providing care for these blinding diseases. 01:50:02PM 01:50:08PM 01:50:12PM 01:50:16PM 01:50:20PM 01:50:23PM 01:50:26PM

Q. Okay. And in your own practice, for a period of time, my understanding is that you employed a PRN approach? 01:50:28PM 01:50:29PM 01:50:31PM

MR. SUMMERS: Objection to form. 01:50:33PM

THE WITNESS: I -- I did and 01:50:34PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 200

still do in some patients. 01:50:36PM

BY MR. BRAUSA: 01:50:37PM

Q. Okay. My understanding from your 01:50:37PM

prior deposition, though, is that in -- on or 01:50:39PM

around 2018, you switched more primarily to what's 01:50:42PM

called a Treat and Extend strategy? 01:50:45PM

A. Yes. 01:50:47PM

Q. What's a Treat and Extend 01:50:48PM

strategy? 01:50:50PM

A. The Treat and Extend strategy is 01:50:50PM

a -- sort of a variation of -- of as-needed in the 01:50:55PM

sense that it's an attempt to extend the dosing 01:50:59PM

regimen, to reduce the dosing regimen to a more 01:51:05PM

manageable one, demonstrate that the patient has 01:51:09PM

the appropriate response and can maintain that 01:51:11PM

appropriate response, and then try and extend that 01:51:15PM

to a longer interval and maintain patients on a 01:51:19PM

longer interval regimen. 01:51:23PM

Q. Okay. And so Treat and Extend is 01:51:25PM

-- it sounds like is a little different than PRN? 01:51:28PM

A. Yep. 01:51:30PM

Q. Is that fair? 01:51:31PM

A. It's a little different, yes. 01:51:31PM

Q. And can you just articulate what 01:51:32PM

the difference is? 01:51:34PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 201

A. Again, it's -- it is -- it's a little bit more intensive in my practice. The idea is that you -- as -- as you treat patients, you -- and you try and extend the dosing interval, it requires that you examine them and determine that they are responding, on a -- on a more regular basis -- although the PRN is similar. You have to -- you have to decide the time frame in which you want to re-examine the patient to make sure that they're doing well and don't require retreatment. 01:51:35PM 01:51:39PM 01:51:42PM 01:51:48PM 01:51:54PM 01:51:57PM 01:52:01PM 01:52:04PM 01:52:07PM 01:52:10PM 01:52:12PM

It's a -- it's a way to -- let me think about the right way to describe this. 01:52:12PM 01:52:19PM

It's a little bit more efficient in terms of practice management. Because once -- for most patients, once you demonstrate that they can get onto a longer schedule, a longer -- a reduced schedule -- injection and schedule, if I made myself clear there -- once you've done that and the patient has demonstrated that they can maintain a healthy retina and don't have a new disease, then you can more easily manage them going forward and perhaps examine them less frequently down the road. 01:52:22PM 01:52:24PM 01:52:29PM 01:52:32PM 01:52:37PM 01:52:41PM 01:52:44PM 01:52:48PM 01:52:51PM 01:52:55PM 01:52:58PM

On a PRN schedule, you're 01:53:02PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 202

obligated to continue to see the patient on a more regular basis because you don't know how they're responding. Once you -- once they've demonstrated that they can respond effectively at a particular schedule, then you can maintain them on a schedule that might reduce the number of clinic visits. 01:53:04PM 01:53:06PM 01:53:10PM 01:53:12PM 01:53:15PM 01:53:17PM

The other rationale for doing -- a couple other rationales for doing Treat and Extend, another rationale is that to the extent that you can extend them, you can carry them out to longer and longer intervals, which again reduces the treatment burden. 01:53:20PM 01:53:22PM 01:53:25PM 01:53:28PM 01:53:30PM 01:53:32PM

And the last is that if you can demonstrate that they can maintain the retina in a healthy state, what we've seen compared to PRN regimens is that if a -- if patients begin to have new leakage and lose vision on a PRN schedule, that it's not always possible to recover all of that vision loss. 01:53:35PM 01:53:37PM 01:53:41PM 01:53:45PM 01:53:48PM 01:53:52PM 01:53:55PM

So there is theoretically a risk of vision loss longer term on a PRN relative to a Treat and Extend schedule. 01:53:56PM 01:54:01PM 01:54:05PM

Q. Okay. Are PRN -- or -- or PRN was around and being used in January of 2011 with respect to VEGF antagonists, right? 01:54:06PM 01:54:12PM 01:54:15PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 203

A. Yes. 01:54:19PM

Q. And Treat and Extend, was that a strategy that some clinicians used in January of 2011? 01:54:20PM 01:54:22PM 01:54:25PM

A. It probably was, but I don't know that there was general awareness with respect to that being a common practice. 01:54:26PM 01:54:27PM 01:54:31PM

Q. Okay. And so if I understand it correctly, if we're thinking about PRN, most patients that you would see would still need to come in for regular visits monthly. 01:54:33PM 01:54:35PM 01:54:39PM 01:54:43PM

Is that fair? 01:54:45PM

MR. SUMMERS: Objection, form. 01:54:46PM

THE WITNESS: Not necessarily, no. 01:54:46PM 01:54:47PM

BY MR. BRAUSA: 01:54:47PM

Q. How often would a patient, that you're employing PRN with, for an anti-VEGF antagonist come in for visits? 01:54:48PM 01:54:50PM 01:54:56PM

A. That would be individual for the patient. 01:54:58PM 01:55:00PM

Q. Have you -- are you familiar with the PRONTO clinical study? 01:55:00PM 01:55:01PM

A. I am. 01:55:03PM

Q. And that was a study involving 01:55:03PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 204

PRN, right? 01:55:06PM

A. It was. 01:55:07PM

Q. And do you know how frequent the 01:55:08PM

office visits were in the PRN study? 01:55:09PM

A. You know, I haven't reviewed that 01:55:10PM

study for the declaration, so I'd have to look at 01:55:12PM

it. 01:55:14PM

Q. You were asked about the PRONTO 01:55:14PM

study in your prior deposition. Do you remember 01:55:16PM

that? 01:55:18PM

A. I believe so, yes. 01:55:18PM

Q. And you hadn't reviewed it at 01:55:19PM

that time either? 01:55:21PM

A. No. 01:55:22PM

Q. Okay. And you didn't review it 01:55:22PM

at any time between October, when you were 01:55:24PM

previously deposed, and now? 01:55:26PM

A. I'm aware of the study, but I 01:55:28PM

haven't reviewed it in detail. 01:55:29PM

Q. Okay. You'd agree that office 01:55:31PM

visits, though, are part of the treatment burden 01:55:34PM

for a patient receiving anti-VEGF antagonists, 01:55:36PM

correct? 01:55:39PM

A. Yes. 01:55:39PM

Q. Okay. And in PRN, the as-needed 01:55:39PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 205

means that you'd have a patient come in, you'd look to see if their, for example, DME had reactivated, and if it had, you'd provide a dose of VEGF [sic] antagonist. And if it hadn't, you'd schedule another visit, right? 01:55:46PM 01:55:49PM 01:55:53PM 01:55:56PM 01:56:00PM

MR. SUMMERS: Objection, form. 01:56:01PM

THE WITNESS: I'm sorry, just rephrase the question for me. 01:56:02PM 01:56:04PM

BY MR. BRAUSA: 01:56:05PM

Q. I -- I'm trying to -- I think I'm -- I'm just trying to make sure I understand the difference between PRN on the one hand and Treat and Extend on the other. 01:56:05PM 01:56:07PM 01:56:09PM 01:56:13PM

In PRN, your dosing decisions are based on whether you're observing reactivation of the disease, right? 01:56:13PM 01:56:18PM 01:56:20PM

A. Correct. 01:56:21PM

Q. Okay. Whereas on Treat and Extend, you have a schedule where you're -- and it may be an extended schedule -- where you're treating regardless of whether you see disease reactivation, correct? 01:56:21PM 01:56:25PM 01:56:30PM 01:56:34PM 01:56:37PM

A. Correct. 01:56:37PM

Q. And as you extend further and further out or to longer and longer durations in 01:56:38PM 01:56:39PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 206

Treat and Extend, you may hit a point where someone comes in and you see their disease has reactivated, right? 01:56:43PM 01:56:46PM 01:56:48PM

A. Correct. 01:56:49PM

Q. In that instance, what do you do? 01:56:50PM

MR. SUMMERS: Objection, form. 01:56:54PM

THE WITNESS: It depends on the disease that you're treating. So give me a -- give me a specific example. 01:56:55PM 01:56:56PM 01:56:57PM

BY MR. BRAUSA: 01:56:59PM

Q. So let's focus on DME. 01:56:59PM

A. Okay. 01:57:01PM

Q. If you have a treat -- actually, why don't you walk me through the -- for a given patient, do you have an ordinary practice with respect to how many initial treatments you provide and then what period you extend to with respect to DME? 01:57:02PM 01:57:04PM 01:57:07PM 01:57:10PM 01:57:11PM 01:57:14PM

MR. SUMMERS: Objection, form. 01:57:15PM

THE WITNESS: So for my own practice for diabetic macular edema, if I make a decision to initiate a patient on an anti-VEGF agent, I will treat them for -- on a monthly schedule for -- for three injections. 01:57:16PM 01:57:18PM 01:57:20PM 01:57:22PM 01:57:25PM 01:57:28PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 207

BY MR. BRAUSA: 01:57:29PM

Q. Okay. 01:57:29PM

A. And then I will start to examine -- I'll examine the patient and then determine what is next indicated. So if the patient still has edema, they haven't responded fully, if I haven't been able to dry the retina, then I would continue them on a monthly injection. So I'd give that patient another monthly injection. I'd see them a month later. If they're still not dry, then I would give them another injection at that time. 01:57:29PM 01:57:33PM 01:57:36PM 01:57:40PM 01:57:44PM 01:57:47PM 01:57:49PM 01:57:53PM 01:57:56PM 01:57:58PM

At the point at which I feel that I've been able to successfully -- or maybe "success" is -- that's not the right word. 01:57:58PM 01:58:02PM 01:58:04PM

At the point at which I've been able to demonstrate on my clinical exam and on imaging studies that the retina is dry, then I will consider and make a decision to extend the dosing schedule. 01:58:07PM 01:58:08PM 01:58:11PM 01:58:16PM 01:58:19PM

And my own practice is just my own practice. Other physicians do it in a different way. Some physicians do it -- extend for four weeks to eight weeks. Other physicians extend longer. Some physicians extend shorter. 01:58:21PM 01:58:22PM 01:58:25PM 01:58:27PM 01:58:30PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 208

My own practice is that I extend to six weeks. And the purpose of doing that is to demonstrate that I have an understanding of the dynamics of the macular edema, for that patient, under control. 01:58:34PM 01:58:36PM 01:58:39PM 01:58:45PM 01:58:48PM

And, again, we know that we want to keep the retina dry. If I extend arbitrarily to two months instead of one month, I don't know for sure at that point in time whether or not the patient will actually do well on that regimen. 01:58:50PM 01:58:52PM 01:58:55PM 01:58:58PM 01:59:01PM

So my own practice is to see them again in six weeks. If they are dry, then I would give them another injection and I would consider either another cycle of six weeks or extending beyond six weeks to -- to a reduced injection frequency. 01:59:05PM 01:59:07PM 01:59:10PM 01:59:12PM 01:59:15PM 01:59:19PM

And that's just my own practice. I think if you ask ten retina doctors how they did it, you'd get ten different answers. 01:59:20PM 01:59:22PM 01:59:25PM

Q. Okay. And -- and so with both Treats and Extends and PRN, it's fair to say there are quite a few potential dosing schedules a -- a physician might use? 01:59:27PM 01:59:30PM 01:59:32PM 01:59:35PM

A. Yeah, again, I think a physician has the opportunity to make a decision based upon 01:59:36PM 01:59:39PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 209

1	the patient and the individualized care of that	01:59:44PM
2	patient. The physician can also make a decision	01:59:47PM
3	based upon their practice requirements and their	01:59:50PM
4	practice patterns. And -- and the decision as to	01:59:52PM
5	how -- how a particular physician injects a	01:59:56PM
6	medication and the dosing regimen is a combination	01:59:59PM
7	of a number of different factors.	02:00:02PM
8	Q. Okay. How do you -- when you're	02:00:04PM
9	in the Treat and Extend world, you've extended to	02:00:06PM
10	six weeks. You said they come back. If they're	02:00:10PM
11	still, in your determination, dry or it's been	02:00:12PM
12	successful, it's -- they haven't had reactivation	02:00:15PM
13	of the disease, how do you determine when you	02:00:18PM
14	extend further? You push it to seven, eight,	02:00:22PM
15	nine, ten weeks or what have you?	02:00:26PM
16	MR. SUMMERS: Objection, form.	02:00:29PM
17	THE WITNESS: So just -- just	02:00:29PM
18	rephrase the question for me.	02:00:30PM
19	BY MR. BRAUSA:	02:00:31PM
20	Q. Sure. I think you identified	02:00:32PM
21	that in your practice, after you have successfully	02:00:33PM
22	dried out a patient's retina, so to speak, using	02:00:38PM
23	monthly dosing of the anti-VEGF antagonist, in	02:00:42PM
24	your practice, you extend it to six weeks?	02:00:47PM
25	A. If I can. Once the retina is dry	02:00:48PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 210

after however many initial monthly doses they get. 02:00:52PM

Q. Sure. And that can vary? 02:00:55PM

A. Yes. 02:00:56PM

Q. Is it ever less than three 02:00:56PM

initial monthly doses in your practice? 02:00:59PM

A. Typically, not for diabetic 02:01:00PM

macular edema. It can be for other neovascular 02:01:03PM

diseases, but typically not for diabetic macular 02:01:06PM

edema. 02:01:09PM

Q. Okay. Have you observed any 02:01:09PM

differences in your patients between the number of 02:01:11PM

monthly doses necessary to dry out the retina from 02:01:13PM

DME using Avastin as compared to EYLEA? 02:01:20PM

A. I -- I don't have any information 02:01:23PM

on that. 02:01:24PM

Q. Okay. If we are now thinking 02:01:25PM

about having done those monthly doses, we have the 02:01:30PM

extended dosing after six weeks -- are you with 02:01:34PM

me? 02:01:38PM

A. So we've extended to six weeks? 02:01:39PM

Q. Correct. 02:01:41PM

A. Okay. 02:01:41PM

Q. So the patient has come back 02:01:42PM

after six weeks, in Treat and Extend, you're going 02:01:44PM

to give them a dose at six weeks regardless of the 02:01:47PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 211

examination, correct? 02:01:52PM

A. If they -- correct. If they -- 02:01:52PM

if I'm on a Treat and Extend regimen or if they 02:01:53PM

reactivate and have diabetic macular edema, I'm 02:01:56PM

going to treat them also. 02:01:59PM

Q. Okay. But in -- in all 02:02:01PM

instances, you're going to administer a dose of 02:02:02PM

the anti-VEGF antagonist? 02:02:04PM

A. That's my -- that's my plan for 02:02:06PM

that patient, yes. 02:02:07PM

Q. And if they haven't reactivated, 02:02:08PM

how do you determine when they come back? 02:02:10PM

A. It's -- 02:02:12PM

MR. SUMMERS: Objection, form. 02:02:13PM

THE WITNESS: So, again, it's 02:02:15PM

based on my own experience -- 02:02:16PM

BY MR. BRAUSA: 02:02:17PM

Q. Uh-huh. 02:02:18PM

A. -- my own interaction with that 02:02:18PM

patient and understanding of that patient's 02:02:20PM

disease. So my own pattern is to be confident 02:02:22PM

that at each extension interval, I have an 02:02:30PM

understanding of the dynamics, the disease, and am 02:02:33PM

confident that I've controlled that disease at 02:02:40PM

that regimen, at that interval. 02:02:41PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 212

Q. Okay. 02:02:42PM

A. So in a -- in a routine example 02:02:44PM in my practice -- so if I've extended the patient 02:02:46PM to six weeks and that patient's retina is dry, 02:02:48PM typically I would give them another six-week cycle 02:02:52PM and demonstrate that the retina is dry after -- 02:02:56PM after that additional six-week cycle. 02:02:58PM

Q. Uh-huh. 02:03:00PM

A. And then at that point, I would 02:03:01PM consider extending to eight weeks; do two cycles 02:03:02PM at eight weeks and then ten weeks; two cycles at 02:03:07PM ten weeks; then 12 weeks, et cetera. 02:03:10PM

Q. Okay. And -- and do you 02:03:12PM typically move in two-week extension increments? 02:03:14PM

A. Depends on the patient, depends 02:03:17PM on the nature of the disease. So some patients, 02:03:19PM for example, have mild macular edema and they 02:03:21PM respond well. And in those patients who have a 02:03:25PM mild level of disease and good control and good 02:03:29PM control of their blood sugars and hypertension, 02:03:32PM those patients may be able to be extended more 02:03:36PM fully more quickly. 02:03:38PM

For other patients -- and we have 02:03:40PM a relatively high morbidity in terms of disease, 02:03:42PM diabetic disease in particular in our practice -- 02:03:42PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 213

Q. Uh-huh. 02:03:42PM

A. -- a lot of patients come in with severe macular edema, and it's very clear that they've had macular edema for a long time. 02:03:48PM 02:03:51PM 02:03:53PM

Q. Sure. 02:03:53PM

A. And it's very clear they're not going to respond to a quick taper. And so I'm -- I try to be judicious about how I do Treat and Extend, because, again, I'm making a decision specifically for that patient based upon their level of disease and their response as I understand it. 02:03:55PM 02:03:57PM 02:03:59PM 02:04:04PM 02:04:07PM 02:04:10PM 02:04:11PM

Q. Okay. And in your response, you just referred to a "quick taper." That taper, you're referring to extending -- 02:04:12PM 02:04:14PM 02:04:17PM

A. Extending -- 02:04:19PM

Q. -- out the intervals? 02:04:20PM

A. -- extending, correct. 02:04:21PM

Q. Do you recall or do you know what the -- is there a maximum interval you'd extend to in any of your patients? 02:04:22PM 02:04:24PM 02:04:28PM

A. I -- I don't think that -- I don't think that there is a maximal interval in the context that you're thinking about. 02:04:31PM 02:04:34PM 02:04:38PM

Q. Uh-huh. 02:04:40PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 214

A. So, again, the goal is to mitigate the disease. So for some patients, again, you can't get them past ten weeks or 12 weeks and that would be the maximum for them if they -- the -- the disease recrudescences and they -- they require that medication on, you know, every 12 weeks; otherwise, the disease is going to get worse. 02:04:41PM 02:04:44PM 02:04:48PM 02:04:51PM 02:04:53PM 02:04:59PM 02:05:02PM 02:05:04PM

But for many patients, the -- the -- the disease gets better, the macular edema goes away, and their disease is in better control. The goal is always -- is off -- is always to get them off the injections, right? That's the goal. And these medications are useful in controlling disease, but we're always trying to optimize the treatment regimen for that patient, reduce the treatment burden, and then ultimately get them off. 02:05:05PM 02:05:08PM 02:05:12PM 02:05:15PM 02:05:18PM 02:05:21PM 02:05:24PM 02:05:30PM 02:05:34PM 02:05:37PM

So if you asked is there some maximal interval, the best outcome for any patient is get off the medication, right, and then the interval's, you know, the future. 02:05:37PM 02:05:40PM 02:05:44PM 02:05:47PM

Q. Sure. 02:05:48PM

A. So.... 02:05:49PM

Q. Do you have a lot of patients in 02:05:50PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 215

your practice that stop taking anti-VEGF antagonists? 02:05:53PM 02:05:57PM

MR. SUMMERS: Objection, form. 02:05:58PM

THE WITNESS: I mean, I have a lot of patients in my practice, and the disease severity varies. I have many patients who have been on the anti-VEGF medications for a long time. I have some patients for a much shorter period of time, and I have everything in between. 02:05:59PM 02:06:00PM 02:06:02PM 02:06:04PM 02:06:07PM 02:06:09PM 02:06:12PM 02:06:13PM

BY MR. BRAUSA: 02:06:13PM

Q. Okay. So you do have some patients that have taken anti-VEGF antagonists for a longer period of time and no longer need them? 02:06:13PM 02:06:14PM 02:06:19PM

A. Yes. 02:06:21PM

Q. Okay. If we can turn back to 1001, the '601 patent, I want to direct you to Column 16, which is on -- I guess, are you -- do you see the column numbers are at the top of the patent? 02:06:21PM 02:06:24PM 02:06:29PM 02:06:34PM 02:06:37PM

A. Yes. 02:06:37PM

Q. So I'll refer to Column 16 and then line 33 to 38. 02:06:37PM 02:06:43PM

A. Yes. 02:06:52PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 216

Q. And my understanding is that this is referring to a PRN dosing strategy. Correct? 02:06:52PM 02:06:55PM

MR. SUMMERS: Objection, form. 02:07:01PM

THE WITNESS: Yes. 02:07:03PM

BY MR. BRAUSA: 02:07:14PM

Q. Okay. And then just above it in Column 16, lines 27 to 32, there's a description of a dosing strategy that's a little bit different, but the amounts and initial duration of injections are the same, right? 02:07:15PM 02:07:19PM 02:07:26PM 02:07:30PM 02:07:33PM

MR. SUMMERS: Objection, form. 02:07:35PM

THE WITNESS: Yes. 02:07:36PM

BY MR. BRAUSA: 02:07:46PM

Q. And if I understood our discussion correctly, this would be describing, at lines 28 to 32, a potential Treat and Extend dosing strategy. Is that fair? 02:07:47PM 02:07:49PM 02:07:51PM 02:07:58PM

MR. SUMMERS: Objection, form. 02:07:59PM

THE WITNESS: Well, I don't think that describes what you are defining as Treat and Extend. It -- it defines just reducing the intravitreal injection frequency based upon examination. 02:08:10PM 02:08:12PM 02:08:15PM 02:08:17PM 02:08:22PM

BY MR. BRAUSA: 02:08:25PM

Q. All right. And you'd agree with 02:08:25PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 217

me that the dosing strategy referenced at Column 16, lines 28 to 32 is not a predetermined dosing schedule. Correct? 02:08:26PM 02:08:29PM 02:08:32PM

MR. SUMMERS: Objection, form. 02:08:33PM

THE WITNESS: Just if you can rephrase the question, please. 02:08:35PM 02:08:36PM

BY MR. BRAUSA: 02:08:38PM

Q. You'd agree with me that the dosing strategy referenced at Columns 16, lines 28 to 32 is not a predetermined schedule. Correct? 02:08:40PM 02:08:42PM 02:08:49PM

MR. SUMMERS: Objection. 02:08:52PM

THE WITNESS: Again, just define "predetermined" for me. 02:08:52PM 02:08:54PM

BY MR. BRAUSA: 02:08:55PM

Q. Do you have an understanding of what "predetermined" means? 02:08:55PM 02:08:56PM

A. I want to understand what you mean by it. 02:08:57PM 02:08:58PM

Q. Well, I'm -- I'm interested in your understanding. 02:08:59PM 02:09:00PM

A. Well, so "predetermined" can mean determined in advance. But predetermined can also be determined based upon, for example, the clinical exam. Right? So pre- -- so in your -- if I predetermined that treatment was going to be 02:09:01PM 02:09:05PM 02:09:07PM 02:09:10PM 02:09:13PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 218

based upon the patient's outcome -- or the patient's clinical exam, then by -- by that definition, the -- the -- the phrase -- the paragraph "administered every -- once every four weeks for the first 20 weeks followed by an intravitreal injection on a less frequent basis based upon visual and anatomical outcomes" could be predetermined for that feature, which is a change in the patient's exam. 02:09:17PM 02:09:19PM 02:09:23PM 02:09:28PM 02:09:33PM 02:09:36PM 02:09:38PM 02:09:42PM 02:09:44PM

Is that -- is that -- I'm -- I'm just trying to be very specific in my understanding of how you're using the word. 02:09:46PM 02:09:49PM 02:09:51PM

Q. Okay. I think I understand your testimony. 02:09:53PM 02:09:56PM

What's the difference between the strategy described at lines 28 to 32 of Column 16 of the '601 patent and the strategy described at lines 33 to 38 in the same column? 02:09:56PM 02:09:59PM 02:10:04PM 02:10:08PM

A. Well, you're asking my opinion or you're asking the -- the person who wrote the application? 02:10:13PM 02:10:15PM 02:10:18PM

Q. I'm -- I'm asking your opinion, based on your analysis of the patent for this proceeding. 02:10:19PM 02:10:21PM 02:10:23PM

MR. SUMMERS: Objection to form. 02:10:24PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 219

THE WITNESS: I think they can be construed as being the same. 02:10:24PM 02:10:45PM

BY MR. BRAUSA: 02:10:47PM

Q. Okay. There's another dosing strategy that's identified at lines 23 to 26. 02:10:47PM 02:10:50PM

Do you see that? 02:10:59PM

A. Yes. 02:10:59PM

Q. Do you consider that to be a predetermined dosing schedule? 02:10:59PM 02:11:03PM

MR. SUMMERS: Objection to form. 02:11:07PM

THE WITNESS: If your definition of "predetermined" is based upon a timing frequency, then that could be considered predetermined. 02:11:16PM 02:11:18PM 02:11:22PM 02:11:25PM

BY MR. BRAUSA: 02:11:26PM

Q. Okay. In your opinion as a clinician and as someone offering opinions from the perspective of a POSA in this case, is that dosing regimen at lines 23 to 26 of Column 16 of the '601 patent a predetermined dosing schedule? 02:11:26PM 02:11:30PM 02:11:34PM 02:11:37PM 02:11:41PM

MR. SUMMERS: Objection, form. 02:11:44PM

THE WITNESS: I think that dosing schedule could be considered to be predetermined, based upon your definition. 02:11:46PM 02:11:53PM 02:11:56PM 02:11:58PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 220

BY MR. BRAUSA: 02:11:58PM

Q. Okay. Do you consider it to be predetermined, is my question, Doctor. 02:11:58PM 02:12:02PM

MR. SUMMERS: Objection, form, scope. 02:12:04PM 02:12:06PM

THE WITNESS: It appears to be, yes. 02:12:06PM 02:12:25PM

BY MR. BRAUSA: 02:12:25PM

Q. Okay. If we take ourselves back to January of 2011, were you aware of any clinical studies that were studying anti-VEGF antagonists in patients with DR that did not also have DME? 02:12:25PM 02:12:34PM 02:12:41PM 02:12:47PM

A. I find it difficult to answer your question because as a -- well, let me take -- let me take that back. Are you ask- -- rephrase the question. Just ask the question again. 02:12:56PM 02:12:57PM 02:13:02PM 02:13:04PM

Q. Sure. 02:13:06PM

In January of 2011, my understanding is that there were various clinical trials looking at anti-VEGF antagonists in patients with DME. 02:13:07PM 02:13:09PM 02:13:12PM 02:13:18PM

A. Yes. 02:13:19PM

Q. Do you recall whether there were any clinical trials underway that were looking at studying anti-VEGF antagonists in patients that 02:13:20PM 02:13:21PM 02:13:26PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 221

had DR but without DME? 02:13:30PM

A. I'm -- I'm not aware, but I'd 02:13:33PM
have to look at the literature. 02:13:38PM

Q. Sitting here today, are you aware 02:13:40PM
of any such studies of anti-VEGF antagonists in 02:13:42PM
patients with DR, without DME? 02:13:45PM

A. I know that anti-VEGF agents have 02:13:47PM
been used and patients have -- with -- without 02:13:49PM
diabetic macular edema have been followed to see 02:13:54PM
the impact of that treatment with -- for example, 02:13:57PM
for proliferative diabetic retinopathy. 02:14:00PM

But I'd have to look at the 02:14:03PM
literature. 02:14:05PM

Q. Okay. And remind me, in your 02:14:05PM
practice, do you ever prescribe anti-VEGF agents 02:14:07PM
to patients that you don't observe DME in? 02:14:12PM

MR. SUMMERS: Objection to form. 02:14:15PM

THE WITNESS: Yes. 02:14:16PM

BY MR. BRAUSA: 02:14:18PM

Q. Okay. Do you ever prescribe 02:14:19PM
anti-VEGF agents to patients -- the only 02:14:23PM
complication they have is DR without any other 02:14:28PM
issues? 02:14:30PM

A. So -- 02:14:31PM

MR. SUMMERS: Objection, form. 02:14:32PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 222

THE WITNESS: -- again -- again, 02:14:32PM
diabetic retinopathy is an umbrella 02:14:33PM
term, so you'd have to tell me the 02:14:36PM
features of the disease that you would 02:14:38PM
include or exclude if I may answer your 02:14:40PM
question. 02:14:42PM
The presence of diabetic 02:14:42PM
retinopathy in and of itself is not an 02:14:46PM
indication for anti-VEGF treatment. But 02:14:48PM
patients who have diabetic retinopathy 02:14:52PM
who have manifestations of the disease 02:14:55PM
at various levels of severity are 02:14:57PM
considered or would be considered for 02:14:59PM
anti-VEGF treatment. 02:15:03PM
Not all of those patients have 02:15:04PM
diabetic macular edema. 02:15:06PM
BY MR. BRAUSA: 02:15:08PM
Q. Okay. 02:15:08PM
A. I'm trying to -- I hope I'm -- 02:15:08PM
Q. I think -- 02:15:08PM
A. -- answering your question. 02:15:10PM
Q. -- I think I understand. 02:15:11PM
In patients that you see that 02:15:12PM
have diabetic retinopathy but no other 02:15:15PM
manifestations of the disease, do you ever 02:15:17PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 223

prescribe VEGF therapy? 02:15:19PM

A. So what level of diabetic 02:15:21PM

retinopathy are you talking about? 02:15:23PM

Q. Okay. Are there any levels of 02:15:24PM

diabetic retinopathy without any other 02:15:26PM

manifestations of it, for which you'd describe 02:15:29PM

VEGF therapy? 02:15:32PM

A. So you're -- you're -- this is 02:15:33PM

where we're getting into difficulty. 02:15:33PM

Q. Uh-huh. 02:15:33PM

A. You're saying diabetic 02:15:35PM

retinopathy and you're saying without 02:15:38PM

manifestations. 02:15:40PM

So diabetic retinopathy by 02:15:41PM

definition has manifestations, so what 02:15:43PM

manifestations are you talking about? 02:15:46PM

Q. Okay. So I may have 02:15:46PM

misunderstood. I thought earlier you were talking 02:15:49PM

about manifestations of diabetic retinopathy may 02:15:51PM

lead you to prescribe VEGF therapy. Is that fair? 02:15:56PM

A. Correct. 02:16:00PM

Q. Okay. Are there instances where 02:16:00PM

there are not any manifestations of diabetic 02:16:03PM

retinopathy? 02:16:08PM

A. Your -- your -- I'm sorry, 02:16:08PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 224

Counsel, your question doesn't make any sense to me. 02:16:09PM 02:16:10PM

Q. Because diabetic retinopathy always has some manifestations? 02:16:11PM 02:16:13PM

A. Right. 02:16:15PM

Q. Okay. 02:16:15PM

A. You're all -- you're asking me, you know, talk about a broken bone, but you don't have a broken bone. 02:16:15PM 02:16:17PM 02:16:19PM

Q. Right. Talking about -- right. 02:16:19PM

A. Right. But I've got -- 02:16:19PM

Q. Let's -- 02:16:19PM

A. -- diabetic retinopathy by its plain and ordinary meaning is retinal disease associated with diabetes. So there -- there must be a manifestation; otherwise, the disease doesn't exist. 02:16:20PM 02:16:22PM 02:16:27PM 02:16:30PM 02:16:34PM

Q. Okay. In -- in -- in your practice, how do you characterize the degree of diabetic retinopathy that a patient has? Do you refer to stages of diabetic retinopathy? 02:16:34PM 02:16:35PM 02:16:38PM 02:16:40PM

A. Not formally, but informally. So there -- there are a number of different ways to cate- -- classify disease severity. 02:16:42PM 02:16:44PM 02:16:47PM

Q. Uh-huh. 02:16:47PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 225

A. In routine clinical practice, it's -- patients are generally diagnosed in -- for diagnostic coding as having mild, moderate, severe, or proliferative disease. 02:16:49PM 02:16:52PM 02:16:55PM 02:16:59PM

Q. Okay. In someone with mild diabetic retinopathy and no other manifestations beyond those associated with mild diabetic retinopathy do you prescribe VEGF therapy? 02:17:02PM 02:17:06PM 02:17:09PM 02:17:11PM

MR. SUMMERS: Objection, form. 02:17:14PM

THE WITNESS: It depends on the feature of the disease, because mild diabetic retinopathy can be associated with diabetic macular edema. 02:17:15PM 02:17:16PM 02:17:18PM 02:17:23PM

BY MR. BRAUSA: 02:17:24PM

Q. Okay. Okay. I think I understand. 02:17:24PM 02:17:26PM

MR. BRAUSA: And, Counsel, for the record, I don't think it's intentional, but if you could avoid shaking your head or nodding in response to answers to questions, I'd appreciate it. 02:17:33PM 02:17:34PM 02:17:35PM 02:17:38PM 02:17:40PM 02:17:41PM

MR. SUMMERS: Oh. I don't think I am, for the record, but I will try to monitor that. 02:17:42PM 02:17:44PM 02:17:46PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 226

MR. BRAUSA: Great. Thank you. 02:17:48PM

BY MR. BRAUSA: 02:17:53PM

Q. So if we can turn back to 02:17:53PM

Exhibit 1002, which is your report, and Section 9 02:17:56PM

that you referred to a little earlier today. It's 02:18:35PM

on page 46. 02:18:38PM

This is the section called 02:18:49PM

Priority Date that we discussed a bit earlier 02:18:53PM

today. 02:18:55PM

A. Yes. 02:18:55PM

Q. And in paragraph 110, which is on 02:18:55PM

page 49, you refer to an Exhibit 1056 that is 02:19:10PM

called the Yancopoulos PCT Application. 02:19:19PM

Do you see that? 02:19:22PM

A. Yes. 02:19:22PM

Q. Do you know what that document 02:19:22PM

is? 02:19:24PM

A. That's the '601 patent. 02:19:24PM

Q. Okay. 02:19:28PM

A. Or what became the '601 patent. 02:19:40PM

Q. Let me hand you what's been 02:19:46PM

marked Exhibit 1056 in this proceeding. 02:19:48PM

(Exhibit 1056 was tendered.) 02:19:56PM

MR. SUMMERS: Do you have another 02:19:58PM

one for me as well? 02:20:00PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 227

MR. BRAUSA: Oh, sorry 02:20:02PM

(tendering). 02:20:03PM

MR. SUMMERS: Thanks. 02:20:04PM

BY MR. BRAUSA: 02:20:07PM

Q. And for the record, Exhibit 1056 02:20:07PM

is designated U.S. Patent 9,254,338, correct? 02:20:11PM

A. Yes. 02:20:15PM

Q. And is your understanding that 02:20:16PM

this is the Yancopoulos PCT Application referred 02:20:19PM

to in paragraph 110? 02:20:24PM

A. (Witness reviews documents.) 02:20:39PM

Yes, I see it there, but I -- I 02:22:02PM

may have also seen it in the '601. 02:22:04PM

Q. Okay. Is your understanding that 02:22:07PM

Exhibit 1056 in the record is the Yancopoulos PCT 02:22:09PM

Application as referenced in paragraph 110 of your 02:22:16PM

report? 02:22:19PM

A. Yes, I see. 02:22:21PM

Q. Okay. Maybe you can help me out. 02:22:25PM

This refers to a bracketed number. It's 0019. 02:22:28PM

Do you see that? 02:22:31PM

A. Yes. 02:22:32PM

Q. Where is that in Exhibit 1056 in 02:22:34PM

front of you? 02:22:37PM

A. (Witness reviews documents.) 02:24:13PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 228

I don't see the 0019. 02:24:30PM

Q. Okay. Do you know what citation 02:24:31PM
this refers to or what this citation is 02:24:34PM
referencing in paragraph 110? 02:24:36PM

A. It's referencing Column 4 at the 02:25:00PM
top. 02:25:03PM

Q. Column 4 at the top. 02:25:05PM

Line 1, you mean? 02:25:07PM

A. Yeah. The methods of the 02:25:09PM
invention may comprom- -- comprise administering 02:25:10PM
to a patient any number of secondary or tertiary 02:25:12PM
doses of a VEGF agent antagonist. For example, in 02:25:16PM
certain embodiments, only a single secondary dose 02:25:21PM
is administered to the patient; in other 02:25:24PM
embodiments, two or more; for example, two, three, 02:25:26PM
four, five, six, seven, eight or more secondary 02:25:30PM
doses are administered to the patient. 02:25:32PM

Q. Okay. And am I correct that if I 02:25:35PM
look at that language, the reference to four 02:25:41PM
secondary doses in combination with an initial 02:25:45PM
dose would be five monthly doses? 02:25:48PM

A. Yes. 02:25:53PM

Q. Okay. And then in the paragraph 02:25:53PM
that follows at line 20, it refers to tertiary 02:25:55PM
doses being administered to the patient eight 02:26:06PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 229

weeks after the immediately preceding dose, correct? 02:26:09PM 02:26:12PM

A. Well, it says each tertiary dose may be administered to the patient eight weeks after the immediately preceding dose. 02:26:17PM 02:26:19PM 02:26:21PM

Q. Right. And so if I combine those two paragraphs, this is a description or -- or could be a description of five monthly doses followed by doses every eight weeks, correct? 02:26:24PM 02:26:28PM 02:26:32PM 02:26:36PM

MR. SUMMERS: Objection to form. 02:26:39PM

THE WITNESS: Well, it's a description of what could be any particular regimen. Two, three, four, five, six, seven, eight or more. 02:26:41PM 02:26:44PM 02:26:47PM 02:26:51PM

BY MR. BRAUSA: 02:26:51PM

Q. Right. One of them, you'd agree, would be five initial doses monthly, followed by doses every eight weeks, right? 02:26:51PM 02:26:53PM 02:26:57PM

A. One of them would be five, yes. 02:26:59PM

Q. Okay. And just so I confirm, it's your testimony that this document, Exhibit 1056, is the Yancopoulos PCT Application you're citing in paragraph 110? 02:27:03PM 02:27:05PM 02:27:08PM 02:27:15PM

MR. SUMMERS: Objection, form. 02:27:17PM

THE WITNESS: Yes, this is the 02:27:18PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 230

'338 patent. 02:27:27PM

BY MR. BRAUSA: 02:27:29PM

Q. And is that the same or different 02:27:30PM
from the Yancopoulos PCT Application that you 02:27:31PM
refer to in paragraph 110? 02:27:34PM

MR. SUMMERS: Objection, form. 02:27:40PM

THE WITNESS: Well, this is -- 02:27:41PM
this is the patent. 02:27:42PM

BY MR. BRAUSA: 02:27:43PM

Q. Okay. Do you know what the 02:27:43PM
Yancopoulos PCT Application is that you're 02:27:46PM
referring to in paragraph 110? 02:27:48PM

MR. SUMMERS: Objection, form. 02:27:51PM

THE WITNESS: Well, it would have 02:27:51PM
been the predicate to the patent. 02:27:55PM

BY MR. BRAUSA: 02:27:56PM

Q. Okay. I think we can put that 02:27:56PM
aside for now. If we can turn to page 69 of your 02:27:59PM
report -- 02:28:38PM

A. (Witness complies.) 02:28:38PM

Q. -- there's a Subsection 3 listed 02:28:40PM
there, right before paragraph 159 in Exhibit 1002. 02:28:42PM

Do you see that? 02:28:51PM

A. Yes. 02:28:52PM

Q. And this subsection is where you 02:28:52PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 231

offer your opinion that the Regeneron September 14th, 2009 press release, in combination with Elman 2010, renders obvious claims 10, 18, and 26? 02:28:56PM 02:28:58PM 02:29:02PM

A. Yes. 02:29:09PM

Q. And so in this section, you're not relying on the Regeneron press release alone for obviousness; you're combining it with the Elman reference; is that fair? 02:29:09PM 02:29:11PM 02:29:14PM 02:29:18PM

A. Yes. 02:29:20PM

Q. Okay. Why are you combining it with Elman instead of relying on it by itself? 02:29:20PM 02:29:26PM

MR. SUMMERS: Objection, form. 02:29:29PM

THE WITNESS: So in any determination of obviousness related to this claim, the Elman study provides relevant information to me with respect to the use of at least five initial monthly loading doses for the treatment of diabetic retinopathy and diabetic macular edema. 02:29:50PM 02:29:53PM 02:29:55PM 02:30:08PM 02:30:11PM 02:30:20PM 02:30:25PM 02:30:28PM

So in my opinion, based upon the press release and Elman's teaching, a POSA would have found it obvious to use a dosing regimen under the anti-VEGF injection administered to patients every 02:30:29PM 02:30:33PM 02:30:37PM 02:30:38PM 02:30:42PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 232

four weeks for potentially five injections. 02:30:43PM 02:30:45PM

BY MR. BRAUSA: 02:30:46PM

Q. Okay. 02:30:46PM

A. And therefore that regimen -- and that regimen -- for that regimen, they would have a reasonable expectation of -- of some success in treating the patient. 02:30:47PM 02:30:52PM 02:30:55PM 02:30:59PM

Q. Okay. You held up your hands and put quotes around success. Why did you do that? 02:31:00PM 02:31:03PM

A. Well, we've gone back and forth about what "success" means, so... 02:31:05PM 02:31:07PM

Q. And I think your testimony is that it's a jargon term. Is that fair? 02:31:08PM 02:31:10PM

A. Yeah. Yeah. 02:31:14PM

Q. Let me hand you the Elman reference. It's referred to as Elman 2010. In your report, it's Exhibit 1006. 02:31:15PM 02:31:17PM 02:31:21PM

MR. SUMMERS: Thank you, Counsel. 02:31:35PM

(Exhibit 1006 was marked.) 02:31:37PM

BY MR. BRAUSA: 02:31:40PM

Q. And I -- I think you testified earlier The University of Tennessee and -- and yourself may have participated in some of the work that Dr. Elman did as part of the DRCR Network? 02:31:47PM 02:31:48PM 02:31:55PM 02:31:56PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 233

A. Yeah. We may have been part of the work that he was involved in. 02:32:01PM 02:32:04PM

Q. Okay. Do you know whether you personally were involved in the work reported in this reference -- 02:32:06PM 02:32:09PM 02:32:12PM

A. I do not -- 02:32:13PM

Q. -- Exhibit 1006? 02:32:13PM

A. -- I do not believe we were, no. 02:32:13PM

Q. Do you remember when you first read this particular reference? 02:32:14PM 02:32:15PM

A. I was familiar with it when it came out and I reread it. 02:32:17PM 02:32:18PM

Q. Okay. And you reread it for the purposes of this proceeding or for other purposes? 02:32:20PM 02:32:25PM

A. Yes. 02:32:27PM

Q. Okay. I guess just to clarify: After you read it when it came out, did you reread it again before this proceeding, or did you reread it for the first time in the context of this proceeding? 02:32:27PM 02:32:29PM 02:32:32PM 02:32:35PM 02:32:40PM

A. I don't recall rereading it before -- 02:32:41PM 02:32:42PM

Q. Okay. 02:32:42PM

A. -- in this context. 02:32:43PM

Q. Got it. 02:32:44PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 234

I will say from my perspective 02:32:45PM
and maybe that's not an appropriate perspective, 02:32:47PM
this is a fairly complicated study. 02:32:50PM
Do you agree with that? 02:32:52PM
MR. SUMMERS: Objection to form. 02:32:54PM
THE WITNESS: I would -- I'm not 02:32:55PM
sure how I should respond to that. 02:32:57PM
BY MR. BRAUSA: 02:32:58PM
Q. How would you respond to it? 02:32:58PM
A. It's a clinical study that was 02:33:00PM
reported in the peer-review literature. 02:33:01PM
Q. Okay. Do you recall when you 02:33:04PM
first read it whether you had any thoughts on how 02:33:05PM
complicated it was or not? 02:33:07PM
A. I didn't reference it with 02:33:08PM
respect to it was complicated or not. I just read 02:33:13PM
it. 02:33:15PM
Q. Okay. What's your comfort level 02:33:15PM
in interpreting statistics in your daily practice? 02:33:17PM
A. We use statistics for our 02:33:20PM
research, and I'm comfortable with it. 02:33:22PM
Q. Okay. 02:33:25PM
A. I understand statistics. I'm not 02:33:26PM
a statistician, but I understand statistics. 02:33:27PM
Q. Okay. As part of your team at 02:33:29PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 235

Vanderbilt, do you have any biostatisticians or statisticians on the team? 02:33:32PM 02:33:34PM

A. We do. 02:33:34PM

Q. Okay. How many? 02:33:34PM

A. There's a department at Vanderbilt that provides support for our research. 02:33:35PM 02:33:36PM

Q. Okay. Have you talked with any of those statisticians about the Elman 2010 reference? 02:33:39PM 02:33:40PM 02:33:43PM

A. No. 02:33:43PM

Q. Why do you have statisticians on the team at Vanderbilt? 02:33:43PM 02:33:49PM

A. Well, because the interpretation of data and different types of data can be complex. 02:33:50PM 02:33:52PM 02:33:56PM

Q. Do you consider the interpretation of the data in the Elman 2010 reference to be complex? 02:33:57PM 02:33:57PM 02:34:00PM

A. Well, I'm not -- I -- I haven't opined about the interpretation of data in -- in this publication. 02:34:02PM 02:34:08PM 02:34:13PM

I've opined in the previous deposition about how to interpret data that's presented in the figures that were presented to me at the previous deposition. 02:34:15PM 02:34:19PM 02:34:22PM 02:34:26PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 236

Q. Okay. Now, just to confirm a few things: El- -- Elman 2010 is studying ranibizumab. This is Lucentis, right? 02:34:28PM 02:34:34PM 02:34:41PM

A. Yes. 02:34:42PM

Q. It doesn't have any data disclosing results for aflibercept or EYLEA, does it? 02:34:43PM 02:34:46PM 02:34:50PM

A. No. 02:34:50PM

Q. Okay. And does any portion of the Elman 2010 reference explicitly disclose a patient that received five and only five loading doses of Lucentis? 02:34:50PM 02:34:56PM 02:35:00PM 02:35:03PM

A. Well, there's data in this paper that demonstrates that at least some of the patients received five doses. 02:35:05PM 02:35:09PM 02:35:11PM

Q. Okay. And -- and so it's your testimony today that Elman 2010 discloses results where necessarily some patients received five and only five loading doses? 02:35:13PM 02:35:14PM 02:35:19PM 02:35:22PM

MR. SUMMERS: Objection, form. 02:35:25PM

THE WITNESS: Just rephrase the question for me. 02:35:25PM 02:35:26PM

BY MR. BRAUSA: 02:35:27PM

Q. Sure. 02:35:27PM

It's your testimony today that 02:35:27PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 237

Elman 2010 -- based on Elman 2010, a POSA would conclude that there were some patients that received five and only five loading doses? 02:35:28PM 02:35:34PM 02:35:36PM

A. A POSA could conclude that there were some patients that received five loading doses, yes. 02:35:39PM 02:35:42PM 02:35:45PM

Q. They could conclude that. Would they necessarily conclude that? 02:35:46PM 02:35:47PM

A. I think the data in Elman shows that at least some patient received five loading doses. 02:35:49PM 02:35:51PM 02:35:54PM

Q. Okay. My question's a little different: Does the data in Elman show that at least some patients received five and only five loading doses, not, for instance, six loading doses, seven loading doses, eight loading doses? 02:35:54PM 02:35:57PM 02:36:00PM 02:36:03PM 02:36:06PM

MR. SUMMERS: Objection, form. 02:36:09PM

THE WITNESS: Again, just rephrase the question, please. 02:36:10PM 02:36:11PM

BY MR. BRAUSA: 02:36:12PM

Q. Sure. 02:36:13PM

Could a POSA conclude, based on Elman 2010, that any of the patients studied received five and only five loading doses of Lucentis? 02:36:13PM 02:36:16PM 02:36:20PM 02:36:25PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 238

A. So they can't definitively 02:36:25PM
because the data is not presented in that way. 02:36:28PM
But the data suggests that at least some patients 02:36:30PM
can and did or might. 02:36:33PM
Q. Okay. If we can turn to page 4, 02:36:35PM
I guess, of the exhibit. We'll continue using 02:36:43PM
those page numbers. 02:36:45PM
And on the right-hand column in 02:36:50PM
the middle of the page, there's a bolded sentence 02:36:52PM
that says: Retreatments are relative to success 02:36:57PM
and failure criteria? 02:36:59PM
A. Yes. 02:37:03PM
Q. And I believe your opinion is 02:37:04PM
that the most relevant cohort in this study is the 02:37:05PM
eyes that received ranibizumab plus deferred 02:37:10PM
laser? 02:37:17PM
A. In the context of our 02:37:17PM
understanding of the disease. And at that time, 02:37:19PM
that was the most relevant to interpreting the 02:37:27PM
potential benefit of ranibizumab for the 02:37:32PM
treatment. 02:37:35PM
Q. Okay. And why was that the most 02:37:35PM
relevant cohort? 02:37:37PM
A. Because laser treatment can also 02:37:37PM
impact the clinical response to diabetic macular 02:37:43PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 239

edema, and therefore, there were -- there were four cohorts. There was one cohort that was treated with ranibizumab and got -- and got laser treatment at that time. So the laser treatment could have impacted the -- the clinical results, right? 02:37:48PM 02:37:51PM 02:37:54PM 02:37:59PM 02:38:02PM 02:38:06PM

Similarly, there was a cohort of patients who were treated with triamcinolone, who also got prompt laser treatment, which could have affected it. And then obviously the -- the sham group was just laser treatment. 02:38:07PM 02:38:12PM 02:38:14PM 02:38:20PM 02:38:22PM

So in terms of understanding whether or not ranibizumab might have an impact on the clinical status of patients with macular edema, the deferred laser group was the one that would permit, at least initially, an assessment of clinical efficacy without the confounding features of having treated the patient with laser. 02:38:23PM 02:38:26PM 02:38:30PM 02:38:33PM 02:38:37PM 02:38:42PM 02:38:46PM

Again, this is a real-world study, and the authors, as I interpret it, wanted to make sure that the patients were appropriately treated based upon the current standard of care at that time. 02:38:48PM 02:38:50PM 02:38:54PM 02:38:56PM 02:38:59PM

Q. If we look at that particular group -- and it's on page 4 -- it says that: 22 02:39:02PM 02:39:05PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 240

percent of the eyes in the ranibizumab plus deferred laser group met success criteria and did not receive an objection -- an injection, correct? 02:39:11PM 02:39:16PM 02:39:19PM

A. Did not receive an additional injection after the initial treatment. 02:39:23PM 02:39:25PM

Q. Okay. And so my understanding is the way that this study was designed was that there were four monthly dosings to start. Right? 02:39:26PM 02:39:29PM 02:39:31PM

A. Yes. 02:39:36PM

Q. And then at the fifth month, based on whether they met the success criteria defined in the protocol, the patients would or would not receive an additional injection, correct? 02:39:37PM 02:39:40PM 02:39:44PM 02:39:47PM 02:39:49PM

MR. SUMMERS: Objection, form. 02:39:50PM

THE WITNESS: That's a fair assessment of the protocol, yes. 02:39:51PM 02:39:53PM

BY MR. BRAUSA: 02:39:55PM

Q. Okay. And do you know, is the decision at that fifth-month visit, if, for instance, a patient met the success criteria in the protocol, did the doctor have a -- have discretion whether to treat or not, at week -- or at Month 5. 02:39:55PM 02:39:57PM 02:40:01PM 02:40:05PM 02:40:09PM 02:40:11PM

A. That's -- so I'd have to go back 02:40:13PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 241

and look at treatment protocol. I haven't reviewed that in detail. 02:40:15PM 02:40:17PM

Q. Okay. And so in your report, you offer the opinion that 22 percent of the patients in this group met the success criteria and did not receive an injection. And so that means that 70 -- 78 percent did not meet success criteria and did receive the injection, correct? 02:40:18PM 02:40:20PM 02:40:27PM 02:40:31PM 02:40:32PM 02:40:36PM

MR. SUMMERS: Objection, form. 02:40:39PM

THE WITNESS: So did receive injection or were eligible to receive an injection. Again, I have to look at the protocol. 02:40:40PM 02:40:42PM 02:40:44PM 02:40:46PM

BY MR. BRAUSA: 02:40:46PM

Q. Okay. And so maybe this can help clear it up. If you turn to figure 6 in the protocol -- I can give you a page number in a moment. 02:40:47PM 02:40:50PM 02:40:54PM 02:40:57PM

Figure 6 is on -- well, maybe it's mistaken. One moment, I may have identified the wrong figure in the record. 02:41:10PM 02:41:22PM 02:41:38PM

Forgive me, I'm finding a figure 5 and a figure 7, but not a figure 6. Maybe it's because I need an appendix. Apologies. 02:41:41PM 02:42:03PM 02:42:09PM

Figure 6, now that I've found it 02:42:20PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 242

on page 10, the Y axis is the percentage of patients that have an OCT central subfield thickness of less that 250 microns, correct? 02:42:28PM 02:42:39PM 02:42:43PM

A. Yes. 02:42:46PM

Q. And this is one of the success criteria in the study? 02:42:46PM 02:42:49PM

A. Again, I have to go look at the -- that, but I believe so, yes. 02:42:50PM 02:42:52PM

Q. Okay. And here, at Week 16 in the ranibizumab plus deferred laser group -- these are the black squares, correct? 02:42:54PM 02:42:59PM 02:43:02PM

A. Yes. 02:43:05PM

Q. And it looks to me like the number of people that satisfied that criteria is about 37 percent, correct? 02:43:05PM 02:43:07PM 02:43:10PM

MR. SUMMERS: Objection, form. 02:43:12PM

THE WITNESS: Yes, I guess. Yep. 02:43:13PM

BY MR. BRAUSA: 02:43:23PM

Q. Okay. Do -- and do you have any understanding of why it shows 37 percent of people at Week 16 in the deferred laser group receiving ranibizumab with an OCP central subfield thickness of less than 250 microns, but earlier we looked at the data in 22 percent people who met success criteria received an injec- -- injection? 02:43:23PM 02:43:25PM 02:43:29PM 02:43:33PM 02:43:38PM 02:43:43PM 02:43:47PM

MR. SUMMERS: Objection, form. 02:43:50PM

THE WITNESS: Well, again, I 02:43:52PM

think I'd have to look at the specific 02:43:52PM

criteria. My interpretation of this is 02:43:54PM

that this was not the only metric that 02:43:57PM

was considered for determination of 02:44:01PM

success. 02:44:03PM

BY MR. BRAUSA: 02:44:03PM

Q. Okay. Let's go back to the -- 02:44:03PM

let's see if we can find the metrics for success. 02:44:22PM

Did you -- did you review this 02:44:25PM

paper in preparation for your deposition today? 02:44:27PM

A. I did review it, but I didn't -- 02:44:29PM

I didn't recall reviewing the specific metrics for 02:44:31PM

success. 02:44:36PM

Q. All right. I don't know the page 02:44:37PM

number. Give me just a minute. In the portion 02:44:53PM

that we were discussing on page 1067 under the 02:45:11PM

Retreatment Heading.... 02:45:14PM

A. I'm sorry. Where are you, sir? 02:45:19PM

Q. Page 1067 where the 22 percent 02:45:20PM

appears. 02:45:22PM

A. Yes. 02:45:23PM

Q. It refers to another success 02:45:36PM

criteria beyond a central subfield thickness of 02:45:38PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 244

less than 250 microns, right? 02:45:44PM

A. What are you referring to? 02:45:46PM

Q. Where it says Success Criteria. 02:45:47PM

A. Yes. 02:45:53PM

Q. And what's the other success criteria beyond the OTC central subfield? 02:45:54PM 02:45:56PM

A. A visual acuity letter score. 02:45:59PM

Q. Okay. And that's identified in the alternative to OCP central subfield thickness of less than 250 microns? 02:46:02PM 02:46:03PM 02:46:06PM

MR. SUMMERS: Objection, form. 02:46:08PM

THE WITNESS: Yes, I -- I'm not sure I understand what you mean by "alternative." 02:46:08PM 02:46:09PM 02:46:11PM

BY MR. BRAUSA: 02:46:11PM

Q. I guess what I'm saying is the success criteria wasn't OCP central subfield of less than 250 microns and this improvement in visual acuity or the visual acuity score. It's either/or was deemed a success, right? 02:46:11PM 02:46:13PM 02:46:17PM 02:46:21PM 02:46:24PM

A. I haven't reviewed it, so I'd have to look at it. 02:46:26PM 02:46:29PM

Q. Okay. So why don't we turn to page 25. And this provides the definition of the success criteria used in the study, right? 02:46:30PM 02:46:35PM 02:47:06PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 245

MR. SUMMERS: Objection, form. 02:47:09PM

THE WITNESS: Yes, I see that. 02:47:10PM

BY MR. BRAUSA: 02:47:49PM

Q. Okay. And so my understanding is the success criteria relative to retreatment decisions, correct, that it's either a visual acuity letter score of greater than 84 or 20/20 or an OCT central subfield thickness of less than 250 microns? 02:47:49PM 02:47:53PM 02:47:55PM 02:47:58PM 02:48:02PM 02:48:08PM

THE COURT REPORTER: Can you slow down, please?

MR. BRAUSA: Sorry.

THE COURT REPORTER: I'm sorry, I can't....

BY MR. BRAUSA:

Q. -- of less than 250 microns?

A. Since the last non-sham injection or since the baseline for the sham plus prompt laser treatment. 02:48:10PM 02:48:12PM 02:48:15PM

Q. Uh-huh. 02:48:16PM

A. Yes. 02:48:16PM

Q. Okay. And so with that definition in mind, does that give you any insight as to why 37 percent of the patients in the deferred laser group met one of the success 02:48:17PM 02:48:19PM 02:48:24PM 02:48:30PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 246

criteria at Week 16 but only 22 percent of them did not receive an injection at Week 20? 02:48:35PM 02:48:40PM

A. Well -- well, I'd have to think about that. The data that presented in figure 6 is just a mean for a cohort and doesn't include all of the data from that clinical trial. 02:48:43PM 02:48:47PM 02:48:52PM 02:49:01PM

Q. Right. Understood. 02:49:05PM

"Mean" is one of the statistical concepts that blends the individual data together? 02:49:07PM 02:49:09PM

A. Correct. 02:49:11PM

Q. "Median" is the same type of thing? 02:49:11PM 02:49:15PM

A. Correct. 02:49:15PM

Q. Okay. And so from figure 6, I can't tell exactly what the individual -- or what the number of individuals that had less than 250 microns in central retina subfield thickness -- 02:49:15PM 02:49:18PM 02:49:25PM 02:49:28PM

A. Start over. 02:49:33PM

Q. Yeah, sorry. That was -- 02:49:34PM

A. We both realized that that was not going anywhere. 02:49:36PM 02:49:38PM

Q. Fair enough. Fair enough. 02:49:39PM

Why don't I ask it this way: 02:49:42PM

You'd agree with me that at Week 16 for the deferred laser group, it looks like the number 02:49:43PM 02:49:50PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 247

corresponds to 37 percent, roughly, in figure 6, right? 02:49:53PM 02:49:57PM

MR. SUMMERS: Objection, form. 02:49:57PM

THE WITNESS: Well, again, I -- if you'll permit me, I think your interpretation of that data is -- is not correct. As I read this, if you look at the Y axis, it says the -- the Y axis is the OTC central subfield thickness less than 250 microns with at least a 25 micron decrease in thickness from the baseline. 02:49:58PM 02:49:59PM 02:50:01PM 02:50:04PM 02:50:06PM 02:50:11PM 02:50:16PM 02:50:17PM 02:50:18PM

So that is not the cohort of patients who had an OCP thickness of less than 250 microns. That is a cohort of patients who had a specific change that they are quantifying. And I -- I just think your interpretation and how you're presenting that cohort is not correct. 02:50:19PM 02:50:21PM 02:50:24PM 02:50:27PM 02:50:30PM 02:50:32PM 02:50:34PM 02:50:37PM

BY MR. BRAUSA: 02:50:37PM

Q. Okay. So you don't think that figure 6 shows that 37 percent of that cohort -- cohort met the success criteria at Week 16? 02:50:39PM 02:50:40PM 02:50:44PM

A. That's not what I -- 02:50:48PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 248

MR. SUMMERS: Objection, form. 02:50:49PM

THE WITNESS: That's not what it 02:50:49PM

says to me as I look at this data. 02:50:53PM

BY MR. BRAUSA: 02:50:56PM

Q. Okay. Let's go to page 3 of this 02:50:56PM

reference. 02:51:33PM

A. (Witness complies.) 02:51:33PM

Q. There's a subheading or a 02:51:53PM

heading, rather, in the left-hand column called 02:51:55PM

Treatment Protocol. 02:51:58PM

Do you see that? 02:51:59PM

A. Yes. 02:51:59PM

Q. And then there's a discussion 02:51:59PM

that follows as an Overview section. 02:52:02PM

Do you see that? 02:52:17PM

A. Yes, I do. 02:52:18PM

Q. Okay. And at the bottom of the 02:52:20PM

left-hand column on page 3 of Exhibit 1006, it 02:52:22PM

says: "From the 16-week study visit and 02:52:25PM

thereafter, a retreatment algorithm for study drug 02:52:28PM

injections and sham injections was designed to 02:52:32PM

require retreatments unless a study visit was 02:52:35PM

deemed a success, at which point retreatment was 02:52:39PM

at investigator discretion. 02:52:42PM

Do you see that? 02:52:44PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 249

A. Yes. 02:52:45PM

Q. Okay. First of all, what's a sham injection? 02:52:45PM 02:52:48PM

A. A sham injection is an injection into the eye in which there's no drug. 02:52:50PM 02:52:57PM

Q. Is it similar to a placebo? 02:53:00PM

A. Not really because you're actually doing an invasive procedure to the eye. 02:53:01PM 02:53:03PM

Q. Okay. 02:53:05PM

A. But there are responses to invasive procedures in the eye in terms of inflammation and other things that can impact the interpretation of data. 02:53:05PM 02:53:07PM 02:53:09PM 02:53:12PM

Q. Okay. 02:53:13PM

A. So it's not a placebo in the way you think about a pill that doesn't have any medicine, because -- otherwise, they just wouldn't do the injection. 02:53:13PM 02:53:16PM 02:53:18PM 02:53:23PM

Q. Right. Okay. I assume that you don't consider a sham injection to be a standard of care at any point in time? 02:53:25PM 02:53:26PM 02:53:29PM

A. A sham injection is required for clinical trials to demonstrate clinical efficacy, but it's not -- I wouldn't stick a needle in someone's eye that didn't have medicine in it. 02:53:30PM 02:53:32PM 02:53:37PM 02:53:39PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 250

Q. Okay. By this point in time, Avastin had been approved -- Avastin was, rather, in use off label for the treatment of AMD, DME, correct? 02:53:42PM 02:53:46PM 02:53:48PM 02:53:54PM

A. Certainly for AMD and -- and, again, physicians were exploring its use for other clinical diseases. 02:53:55PM 02:53:58PM 02:54:02PM

Q. Okay. And -- and as a clinician, would you have any concern with the study being designed in the sense as they used the sham injection? 02:54:03PM 02:54:06PM 02:54:08PM 02:54:10PM

A. Prospective clinical trials require an appropriate control arm, and, again, because an injection -- a use of a needle in the eye incites an inflammatory reaction response -- albeit ideally a mild one -- that inflammatory response can have an impact on the status of the eye in terms of retina, retinal anatomy, complications that need to be established for a prospective clinical trial. 02:54:11PM 02:54:13PM 02:54:18PM 02:54:22PM 02:54:26PM 02:54:29PM 02:54:34PM 02:54:37PM 02:54:41PM

And so in this setting at that time -- because we didn't know whether or not the injection of an anti-VEGF agent would be efficacious for the treatment of this disease -- inclusion of a sham arm that included an 02:54:43PM 02:54:45PM 02:54:50PM 02:54:53PM 02:54:57PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 251

intraocular injection was appropriate clinical trial design. 02:55:02PM 02:55:04PM

Q. Okay. Looking back at this statement, it says that: "Retreatment is at investigator discretion" even when a study visit was deemed a success, right? 02:55:04PM 02:55:09PM 02:55:13PM 02:55:17PM

MR. SUMMERS: Objection, form. 02:55:18PM

THE WITNESS: I say that the study visit was deemed a success at which point retreatment was at investigator discretion. 02:55:19PM 02:55:30PM 02:55:33PM 02:55:36PM

BY MR. BRAUSA: 02:55:37PM

Q. Okay. And so does that -- does that shed any light on whether there were people or patients in the cohort that satisfied the success criteria that nonetheless received an injection at 16 weeks? 02:55:37PM 02:55:38PM 02:55:41PM 02:55:44PM 02:55:48PM

A. I'm not understanding your question as you asked it. 02:55:51PM 02:55:52PM

Q. Sure. 02:55:53PM

I guess what I'm trying to understand is the 22 percent we talked about that had it -- that were deemed a success and did not receive an injection at Week 16 -- correct? 02:55:54PM 02:55:55PM 02:55:59PM 02:56:01PM

A. Correct. 02:56:05PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 252

Q. Is that the entirety of the patients that were deemed a success, or were there some patients that were deemed a success, but the investigator discretion was we're going to go ahead and administer a dose at Week 16 anyway? 02:56:06PM 02:56:09PM 02:56:12PM 02:56:15PM 02:56:18PM

A. I don't think that's clear from the data that's here. 02:56:20PM 02:56:21PM

Q. Okay. And it goes on to say: "From the 24-week study visit and thereafter, retreatment was at investigator discretion if the study visit was deemed no improvement," correct? 02:56:22PM 02:56:26PM 02:56:29PM 02:56:32PM

A. Yes. 02:56:36PM

Q. And that clinical trial provides a definition for what no improvement was as well, correct? 02:56:36PM 02:56:38PM 02:56:42PM

A. Yes. 02:56:42PM

Q. Okay. And so based on the data, it's fair to say that everyone in the study received four injections, correct? 02:56:42PM 02:56:47PM 02:56:50PM

A. Yes. 02:56:53PM

Q. And thereafter, the data doesn't tell you what specific dosing schedules were used in any specific patient? 02:56:54PM 02:56:57PM 02:57:00PM

MR. SUMMERS: Objection, form. 02:57:02PM

THE WITNESS: Yeah, that's not 02:57:03PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 253

entirely true. If you look at the data 02:57:04PM
-- get back to where we were. So on -- 02:57:13PM
in the area that we have previously been 02:57:27PM
discussing retreatments relative to 02:57:29PM
success and failure criteria, the second 02:57:31PM
sentence says: A total of 17 eyes or 9 02:57:36PM
percent of the ranibizumab plus prompt 02:57:41PM
laser treatment group, laser -- in 15 02:57:43PM
eyes, 8 percent in the ranibizumab plus 02:57:48PM
deferred laser group, met success 02:57:50PM
criteria at 16 weeks and did not receive 02:57:53PM
an additional injection before the 02:57:57PM
one-year period. 02:57:59PM
So we know from this study that 02:58:00PM
at least 17 eyes in the prompt group, if 02:58:04PM
we just talk about the deferred group, 02:58:07PM
we know that at least 15 eyes in 02:58:10PM
patients did not receive any additional 02:58:12PM
injections even though they met success 02:58:14PM
criteria. 02:58:17PM
So from my perspective in the 02:58:18PM
seat of a person of ordinary skill in 02:58:22PM
the art, what I would take away from 02:58:25PM
that data is that some patients, 15 of 02:58:28PM
that group, did not receive any 02:58:32PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 254

additional injections. And if the goal 02:58:34PM
was to identify patients who were 02:58:37PM
success -- for whom there was success 02:58:42PM
and I had the discretion to not treat, 02:58:44PM
as 15 patients were not treated, that 02:58:47PM
the data suggests that at least one 02:58:51PM
patient, perhaps more, but certainly at 02:58:55PM
least one patient would have gotten a 02:58:57PM
fifth dose and then not received 02:58:59PM
additional injections. 02:59:01PM
BY MR. BRAUSA: 02:59:02PM
Q. Okay. But I -- I understand your 02:59:03PM
point that this does refer to 15 eyes in the 02:59:06PM
deferred laser group that you can say received 02:59:11PM
four and only four injections for that year, 02:59:15PM
correct? 02:59:17PM
A. Correct. 02:59:17PM
Q. Okay. The data does not 02:59:18PM
definitively show that of the balance, the 92 02:59:21PM
percent that are not in that 8 percent, that any 02:59:24PM
of those patients received five and only five 02:59:28PM
loading doses, correct? 02:59:31PM
MR. SUMMERS: Objection, form. 02:59:33PM
THE WITNESS: The -- the data as 02:59:33PM
presented doesn't definitively show 02:59:35PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 255

that, but there is additional information here that I think is useful. I just need to identify it. Hold on a second. 02:59:38PM 02:59:44PM 02:59:46PM 02:59:49PM

(Witness reviews documents.) 02:59:49PM

THE WITNESS: I'm sorry, Counsel, I'm trying to find some specific text. 02:59:49PM 03:01:25PM

BY MR. BRAUSA: 03:03:41PM

Q. Any luck? 03:03:41PM

A. What I'm looking for -- and I'm sorry I'm not -- I'm not finding it here in this -- in this quick review. But what I do recall seeing in this document is that it said that patients -- that patients who received -- that -- that patients recei- -- the patients who had additional treatments received greater than or equal to one additional injection. 03:03:46PM 03:03:49PM 03:03:52PM 03:03:55PM 03:04:01PM 03:04:06PM 03:04:08PM 03:04:12PM

And I'm trying to find that reference here in the -- in the document. And I'll -- I can -- I can track it down, because I recall seeing it. 03:04:15PM 03:04:17PM 03:04:18PM 03:04:22PM

Q. Okay. 03:04:23PM

A. And in that setting -- my point being that in that language, the authors imply that there was at least one patient and maybe more 03:04:23PM 03:04:27PM 03:04:32PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 256

who received one additional dose of the injection. 03:04:35PM

Q. Okay. I think we can look for 03:04:38PM

that at another time. Let me -- 03:04:44PM

MR. SUMMERS: I'll just let you 03:04:47PM

know you've been going right at an hour 03:04:49PM

and 20. 03:04:51PM

(Simultaneous overlapping 03:04:51PM

speakers.) 03:04:51PM

MR. SUMMERS: But I know you're 03:04:52PM

on a line here, so I don't want to take 03:04:53PM

you off. 03:04:55PM

MR. BRAUSA: I think we can take 03:04:58PM

a break. 03:05:00PM

MR. SUMMERS: Okay. 03:05:00PM

THE VIDEOGRAPHER: We are going 03:05:01PM

off record at approximately 3:05 p.m. 03:05:01PM

(Brief recess observed.) 03:21:44PM

THE VIDEOGRAPHER: We are going 03:21:44PM

back on the record at approximately 3:22 03:22:08PM

p.m. 03:22:12PM

BY MR. BRAUSA: 03:22:12PM

Q. Welcome back, Dr. Chaum. 03:22:13PM

During the break, did you find 03:22:15PM

the disclosure in the Elman 2010 reference that 03:22:18PM

you're looking for? 03:22:24PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 257

A. I didn't, but I've asked counsel to provide it. 03:22:24PM 03:22:26PM

Q. Okay. Why don't we switch gears, go to Exhibit 1000 -- or before we get there, actually, let's go back to your report, Exhibit 1002. And we were talking about the combination of the 2009 Regeneron press release with Elman 2010 and -- and talking about the Elman 2010 reference specifically, right? 03:22:27PM 03:22:32PM 03:22:34PM 03:22:38PM 03:22:46PM 03:22:50PM 03:22:54PM

A. Yes. 03:22:55PM

Q. And if we flip forward from paragraph 159, page 69 to page 71, there's a subheading that says: "A POSA would have been motivated to combine the press release with Elman's 2010 disclosure," right? 03:22:56PM 03:22:59PM 03:23:05PM 03:23:08PM 03:23:12PM

A. With Elman's 2010 dosing regimen. Are you talking about above 164? 03:23:14PM 03:23:18PM

Q. Yes, Subheading A. Sorry. 03:23:20PM

A. Yes. 03:23:22PM

Q. Okay. And then if we go forward to page 66 -- page 76, excuse me, just above paragraph 120 -- 173, there's a subheading talking about your view that a POSA would have a reasonable expectation of success in making the combination of September 14th, 2009 press release 03:23:22PM 03:23:25PM 03:23:30PM 03:23:34PM 03:23:36PM 03:23:39PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 258

with Elman's 2010 dosing regimen. 03:23:43PM

Do you see that? 03:23:46PM

A. I'm sorry, on -- oh, which page? 03:23:46PM

Q. Page 76 just above paragraph 173. 03:23:50PM

A. Yes. 03:24:08PM

Q. And -- and in both these 03:24:09PM

subheadings, you refer to Elman 2010 dosing 03:24:11PM

regimen, correct? 03:24:16PM

A. Yes. 03:24:17PM

Q. But I think we discussed, Elman 03:24:17PM

actually describes various potential dosing 03:24:22PM

regimens and schedules, right? 03:24:25PM

A. Well, Elman describes, you know, 03:24:26PM

for that clinical trial, four initial doses 03:24:29PM

followed by one or more additional doses. 03:24:32PM

Q. Right. Or just four initial 03:24:34PM

doses, right? 03:24:37PM

A. Or four at the discretion of the 03:24:37PM

investigator, yes. 03:24:40PM

Q. Okay. Did you make any effort, 03:24:41PM

in rendering your opinions, to figure out how many 03:24:43PM

potential dosing schedules could be encompassed by 03:24:46PM

the general dosing regimen set forth in Elman 03:24:51PM

2010? 03:24:54PM

A. I didn't, although I believe 03:24:54PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 259

there was -- there may have been a -- a graph that laid out the doses that were provided to patients. 03:24:59PM 03:25:04PM

Q. Okay. And did that graph provide the dosing intervals or just the number of doses? 03:25:06PM 03:25:08PM

A. Just the number of doses. 03:25:11PM

Q. Okay. And so do you have any information or -- or knowledge about how many different dosing schedules were actually tested in the Elman 2010 study? 03:25:12PM 03:25:14PM 03:25:17PM 03:25:20PM

A. Not directly, no. 03:25:21PM

Q. If we now turn to your opinion under Subheading 2 on page 63, just above paragraph 146 of Exhibit 1002 -- let me know when you're there. 03:25:23PM 03:25:29PM 03:25:37PM 03:25:43PM

A. Yes. 03:25:44PM

Q. This is talking about your opinion that claims 10, 18, and 26 of the '601 patent are obvious, by the press release, either alone or in view of Shams, right? 03:25:53PM 03:25:56PM 03:26:03PM 03:26:05PM

A. Yes. 03:26:08PM

Q. And in this section -- I just want to confirm I'm not missing it -- you don't have any subsections talking about motivation to combine Shams with the press release, do you? 03:26:08PM 03:26:12PM 03:26:15PM 03:26:17PM

A. Not with respect to Shams, no. 03:26:19PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 260

Q. Okay. And similarly in this section, you don't have any subheading that deals with a POSA's reasonable ex- -- expectation of success with respect to the proposed combination of Shams in the September 14th, 2009 press release? 03:26:32PM 03:26:35PM 03:26:39PM 03:26:41PM 03:26:44PM 03:26:48PM

A. I'm sorry, Counsel. Could you just repeat the question for me? 03:27:05PM 03:27:06PM

Q. Sure. In your section of your report, it's talking about your obviousness opinion based on the September 14th, 2009 press release. In view of Shams, you set forth in the analysis of whether a POSA would have a reasonable expectation of success in combining Shams with the September 14th, 2009 press release. 03:27:07PM 03:27:10PM 03:27:13PM 03:27:16PM 03:27:19PM 03:27:22PM 03:27:28PM

A. Well, what -- what I say in my declaration is, again, under 155 here, I say that Shams confirms this understanding, monthly dosing of a therapeutically effective amount of VEGF antagonist followed by less frequent dosing of a therapeutically effective amount of VEGF antagonist as described in Shams in 2016 explains the treatment schedule comprising an initial interval of administration of a therapeutic compound, an anti-VEGF antagonist, followed by 03:27:33PM 03:27:36PM 03:27:42PM 03:27:44PM 03:27:49PM 03:27:53PM 03:27:53PM 03:27:57PM 03:28:00PM 03:28:02PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 261

subsequent less frequent interval of 03:28:06PM
administration of the therapeutic compound, allows 03:28:08PM
one to decrease subsequent doses of the 03:28:12PM
therapeutic compound, while at the same time 03:28:15PM
maintaining the therapeutic efficacy. 03:28:17PM
It further explains that the 03:28:20PM
specific time schedule for administered doses 03:28:22PM
could be readily determined by a physician having 03:28:25PM
ordinary skill in administering the therapeutic 03:28:27PM
compound by routine adjustments of the dosing 03:28:29PM
schedule within the method of present invention. 03:28:33PM
So -- and I further say that a 03:28:36PM
person of ordinary skill in the art would have had 03:28:39PM
a reasonable expectation of success in pursuing 03:28:42PM
such optimization. 03:28:46PM
Q. And that's -- and that's based on 03:28:46PM
the portion of the Shams reference that you just 03:28:47PM
read into the record? 03:28:49PM
A. The Shams and also the -- the 03:28:51PM
press release. 03:28:55PM
Q. Okay. 03:28:56PM
MR. BRAUSA: And let's actually 03:28:57PM
mark the press release at this point, or 03:28:59PM
identify it for the record. It was 03:29:02PM
previously marked as Exhibit 1009. 03:29:04PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 262

(Exhibit 1009 was marked.) 03:29:14PM

MR. SUMMERS: Thank you. Thanks. 03:29:16PM

BY MR. BRAUSA: 03:29:22PM

Q. And this document is a press release put out by Regeneron, correct? 03:29:23PM 03:29:25PM

A. Yes. 03:29:27PM

Q. In September of 2009? 03:29:28PM

A. Yes. 03:29:32PM

Q. And in total, front and back, it's a page-and-a-half long? 03:29:32PM 03:29:36PM

A. Yes. 03:29:37PM

Q. Which portions of Exhibit 1009 are you relying on for your obviousness opinions in this case? 03:29:39PM 03:29:44PM 03:29:47PM

MR. SUMMERS: Objection to form. 03:29:47PM

THE WITNESS: So this press release describes the VEGF Trap-eye under development for diabetic macular edema and discloses the VEGF Trap-eye dosed at a half milligrams or two milligrams monthly, two milligrams every eight weeks after three monthly doses -- monthly loading doses or two milligrams on an as-needed basis after three monthly loading doses compared to focal 03:29:48PM 03:30:08PM 03:30:12PM 03:30:17PM 03:30:20PM 03:30:23PM 03:30:25PM 03:30:27PM 03:30:30PM 03:30:33PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 263

laser treatment. 03:30:36PM

BY MR. BRAUSA: 03:30:39PM

Q. Okay. And you're reading from 03:30:39PM

the last full paragraph at the bottom of page 1? 03:30:41PM

A. Yes. 03:30:44PM

Q. Above the: About what AMD 03:30:44PM

heading? 03:30:47PM

A. Yes. 03:30:48PM

Q. Okay. And so it's those three 03:30:48PM

sentences that you relied upon as par of your 03:30:51PM

opinions in this case? 03:30:53PM

A. No, I read the entire press 03:30:54PM

release, but that is the most relevant part of it. 03:30:55PM

Q. Okay are there any other portions 03:30:58PM

of the press release that are relevant to your 03:31:00PM

obviousness opinions? 03:31:02PM

A. Well, the discussion of the 03:31:03PM

clinical trials in general are relevant. 03:31:05PM

Q. Okay. And do any of those 03:31:07PM

clinical trials that are referenced in this 03:31:09PM

Exhibit 1009 involve five loading doses? 03:31:12PM

A. Not that I'm aware of, no. 03:31:16PM

Q. Okay. And at the end of the 03:31:25PM

paragraph you were reading from about the Phase 2 03:31:26PM

development for the treatment of diabetic macular 03:31:31PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 264

edema, it says: Patient enrollment is completed -- has been completed with additional data expected in the first half of 2010. Correct? 03:31:34PM 03:31:37PM 03:31:39PM

A. Yes. 03:31:41PM

Q. So at this point in time, there was not data from these studies available to Regeneron or anyone else, correct? 03:31:42PM 03:31:43PM 03:31:47PM

MR. SUMMERS: Objection, form. 03:31:49PM

THE WITNESS: I'm -- I'm -- I'm not aware whether or not any data had been presented publicly or in meetings. 03:31:51PM 03:31:52PM 03:31:53PM

BY MR. BRAUSA: 03:31:53PM

Q. Okay. Well, certainly this doesn't include any results, correct? 03:31:56PM 03:31:58PM

A. Correct. 03:31:59PM

Q. But it's nonetheless your opinion that the 2009 press release alone is sufficient to render the claims of the '601 patent obvious? 03:31:59PM 03:32:02PM 03:32:06PM

A. I'm using them in combination with Shams. 03:32:12PM 03:32:14PM

Q. Okay. So you're not relying on the Regeneron press release alone for obviousness purposes? 03:32:14PM 03:32:17PM 03:32:21PM

MR. SUMMERS: Objection, form. 03:32:21PM

THE WITNESS: I'm using the press 03:32:21PM

release together with other documents as 03:32:23PM
listed in the declaration. 03:32:27PM
BY MR. BRAUSA: 03:32:28PM
Q. Okay. I just want to be clear. 03:32:28PM
If we go back to your declaration, on page 63, 03:32:30PM
above 146 -- above paragraph 146, it refers to 03:32:37PM
claims 10, 18, and 26 and you state that they're 03:32:43PM
"rendered obvious by the September 14th, 2009 03:32:46PM
press release, either alone or in view of Shams." 03:32:49PM
Do you see that? 03:32:53PM
A. I -- I do. 03:32:54PM
Q. And so is your testimony that 03:32:55PM
you're not in fact relying on the press release 03:32:57PM
alone? 03:33:00PM
A. I am not relying on the press 03:33:01PM
release alone, rather in combination with Shams. 03:33:03PM
Q. Okay. And so the only opinion 03:33:07PM
you're offering in this case and in your report 03:33:09PM
with respect to what's under Subheading 2 is the 03:33:13PM
combination of the press release from 2009 with 03:33:19PM
Shams? 03:33:23PM
MR. SUMMERS: Objection to form. 03:33:24PM
THE WITNESS: Just rephrase the 03:33:25PM
question for me, please. 03:33:26PM
BY MR. BRAUSA: 03:33:27PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 266

Q. Sure. 03:33:28PM

I -- I think you testified you're 03:33:28PM

not relying on the September 14, 2009 press 03:33:30PM

release alone as a basis for obviousness, correct? 03:33:34PM

MR. SUMMERS: Objection, form; 03:33:38PM

mischaracterizes testimony. 03:33:40PM

THE WITNESS: I'm relying on 03:33:41PM

multiple documents, including the press 03:33:44PM

release and Shams. 03:33:46PM

BY MR. BRAUSA: 03:33:47PM

Q. Okay. And -- and so is it fair 03:33:47PM

to just cross out the "either alone" in the 03:33:49PM

subheading? That's not accurate? 03:33:53PM

A. Let me just take a look. 03:33:55PM

Q. Sure. 03:33:58PM

MR. SUMMERS: Object to the form. 03:33:58PM

THE WITNESS: Just let me -- let 03:34:23PM

me read my declaration because I think 03:34:25PM

it's -- it's clear how that relates to 03:34:27PM

the press release. 03:34:30PM

So the Regeneron press release 03:34:30PM

teaches that Regeneron was beginning 03:34:32PM

clinical trials studying the efficacy of 03:34:34PM

aflibercept to treat diabetic macular 03:34:37PM

edema via three different dosing 03:34:41PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 267

regimens using -- or from two milligrams of VEGF Trap-eye. 03:34:44PM 03:34:46PM

Specifically, the press release discloses that aflibercept is in Phase 2 development for the treatment of diabetic macular edema with a dose of half a milligram or two milligrams monthly, two milligrams every eight weeks after three monthly loading doses or two milligrams as needed. 03:34:47PM 03:34:48PM 03:34:50PM 03:34:53PM 03:34:54PM 03:34:56PM 03:34:58PM 03:35:00PM

As discussed, the primary problems associated with monthly injection was patient burden and injection complications. Thus a person of ordinary skill in the art reading the press release would have understood that Regeneron was pursuing multiple different dosing regimens with two milligrams of aflibercept to optimize dosing frequency for efficaciously treating diabetic macular edema with aflibercept while minimizing the number of injections so as to minimize potential complications from repeated intravitreal injections. A person of 03:35:02PM 03:35:04PM 03:35:06PM 03:35:08PM 03:35:10PM 03:35:12PM 03:35:14PM 03:35:16PM 03:35:19PM 03:35:21PM 03:35:23PM 03:35:26PM 03:35:28PM 03:35:30PM 03:35:33PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 268

ordinary skill in the art would have had stronger motivation to further optimize these dosing regimens to achieve the same two goals, especially given the success of other anti-VEGF agents in treating diabetic macular edema and knowledge from prior courses of treatment of the diabetic macular edema -- diabetic macular edema with VEGF agents. 03:35:35PM 03:35:37PM 03:35:40PM 03:35:40PM 03:35:43PM 03:35:46PM 03:35:49PM 03:35:50PM 03:35:52PM 03:35:54PM

DME is characterized by leakage of fluid and blood and swelling from damage to blood vessels in the back of the eye -- retina. And the principal way to treat it effectively was to just try and dry the retina to stop the leakage, with a series of VEGF agents or injections. These antagonists are relatively short-acting compared to laser treatment and thus initial injections are required. 03:35:55PM 03:35:58PM 03:36:00PM 03:36:00PM 03:36:06PM 03:36:06PM 03:36:08PM 03:36:11PM 03:36:13PM 03:36:15PM 03:36:17PM

Because there is a -- 03:36:20PM

BY MR. BRAUSA: 03:36:20PM

Q. If I can stop you there. I appreciate you reading your report into the 03:36:20PM 03:36:21PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 269

record. But my question was actually just about the heading. Can we cross out "either alone" in the heading, or no? 03:36:23PM 03:36:25PM 03:36:30PM

MR. SUMMERS: Objection to form. 03:36:31PM

THE WITNESS: I -- I have no opinion regarding that. 03:36:32PM 03:36:32PM

BY MR. BRAUSA: 03:36:33PM

Q. Okay. Do you have any understanding or review as to whether you're relying on the Regeneron September 14th, 2009 press release alone to support your obviousness opinions? 03:36:33PM 03:36:35PM 03:36:37PM 03:36:42PM 03:36:45PM

A. I think my obviousness opinion is relate -- can be -- is -- is, in part, associated with -- or -- excuse me. Is in part predicated on the press release and the concept that a person of ordinary skill in the art would seek to modify the dosing regimen to minimize the number of injections, and therefore the proposed injection regimen of initial dosing followed by eight-week dosing, followed by PRN dosing is in line with reducing the risk of those injections. 03:36:45PM 03:36:49PM 03:36:57PM 03:37:03PM 03:37:09PM 03:37:13PM 03:37:16PM 03:37:20PM 03:37:27PM 03:37:30PM

Q. Okay. In the heading, what did you mean when you said that the "Claims are Rendered Obvious by the September 14th, 2009 Press 03:37:33PM 03:37:38PM 03:37:41PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 270

Release Alone"? 03:37:44PM

A. I think as I -- as I look back on 03:38:01PM
preparing the -- the declaration, that the press 03:38:11PM
release, again, tells me that Regeneron is looking 03:38:16PM
to modify the dosing regimen to reduce the burden 03:38:21PM
on injections for the patient and physician, and 03:38:26PM
therefore a person of ordinary skill in the art 03:38:31PM
would seek also to modify that regimen and would 03:38:34PM
routinely or would, in the normal course of their 03:38:41PM
practice, seek to find ways to minimize the 03:38:45PM
injection frequency for patients; and, therefore, 03:38:47PM
the claim related to the number of injections, in 03:38:54PM
my view, would be obvious to -- to a physician who 03:38:56PM
was seeking to optimize the treatment regimen 03:39:01PM
while minimizing the number of doses. 03:39:06PM

Q. Is it your view that it would be 03:39:07PM
obvious to such a physician, based solely on the 03:39:11PM
three sentences you read from the September 14th, 03:39:16PM
2009 press release, or would that need Shams or -- 03:39:18PM
Shams or the Elman? 03:39:28PM

MR. SUMMERS: Elman. 03:39:34PM

BY MR. BRAUSA: 03:39:35PM

Q. Elman, sorry. I'm not -- having 03:39:35PM
brain freeze. Let me rephrase. 03:39:37PM

Is it your view that the -- it 03:39:37PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 271

would be obvious to such a physi- -- such a physician based solely on the three sentences that you read from the September 14, 2009 press release, or would they also need Shams and Elman to combine with it? 03:39:40PM 03:39:42PM 03:39:45PM 03:39:47PM 03:39:50PM

A. I think those other sources support that concept, but I think that the concept that Regeneron was putting out in the press release that we are -- we are doing clinical trials in an attempt to modify the number of doses required for patients would suggest to a person of ordinary skill in the art that modification would be beneficial for patient and clinical care. 03:39:51PM 03:39:52PM 03:39:57PM 03:40:01PM 03:40:05PM 03:40:08PM 03:40:13PM 03:40:17PM

Q. Okay. If we can turn to Exhibit 1001, the '601 patent, at column 14, line 6, there's an Example 5. 03:40:20PM 03:40:23PM 03:40:38PM

A. Yes. 03:40:55PM

Q. And this is describing this same clinical protocol as is reported in the September 14th, 2009 press release, right? 03:40:55PM 03:40:59PM 03:41:03PM

A. I don't know. I'd have to check and see if it's exactly the same. 03:41:05PM 03:41:08PM

Q. Okay. Well, why don't I direct your attention to line 16 through 23. And if you could, read that to yourself and let me know when 03:41:09PM 03:41:11PM 03:41:19PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 272

you're finished. 03:41:21PM

A. (Witness reviews document.) Yes. 03:41:22PM

Q. Okay. And -- and so this 03:42:03PM

disclosure, applying the same logic that you used 03:42:04PM

with the prior art, would also suggest to a person 03:42:07PM

of ordinary skill that modification would be 03:42:11PM

beneficial for patient and clinical care, right? 03:42:14PM

A. Well, it -- it might, yes, but 03:42:16PM

there's other information in the '601 patent that 03:42:18PM

also addresses that question. 03:42:22PM

Q. Right. There's even more 03:42:24PM

information in the '601 patent than in the press 03:42:25PM

release, right? 03:42:28PM

A. Yes. 03:42:28PM

Q. And a POSA would be able to 03:42:29PM

interpret that information and consider it as 03:42:31PM

well, understanding what the patent describes? 03:42:35PM

A. Rephrase the question for me. 03:42:39PM

Q. Sure. 03:42:40PM

The POSA reads the whole patent, 03:42:41PM

right? 03:42:42PM

A. Yes. 03:42:42PM

Q. It's not just the three lines of 03:42:43PM

the patent that are the same as the portion of 03:42:45PM

Exhibit 1009? 03:42:48PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 273

A. Yes. 03:42:50PM

Q. Okay. And -- and you yourself considered the whole patent as part of your analysis? 03:42:50PM 03:42:52PM 03:42:54PM

A. I did. 03:42:55PM

Q. Okay. Did you consider Example 5? 03:42:55PM 03:42:57PM

A. I looked at it, yes. 03:42:57PM

Q. Okay. Do you know whether Example 5 was in the Provisional Application as filed? 03:42:58PM 03:43:02PM 03:43:04PM

A. I don't know. 03:43:04PM

Q. Okay. Turning back to the press release, Exhibit 1009, in your report on paragraph 147, you say there are three different dosing regimens. Correct? 03:43:05PM 03:43:15PM 03:43:31PM 03:43:34PM

MR. SUMMERS: Objection to form. 03:43:45PM

THE WITNESS: Well, there's -- there's two dosing regimens at a monthly schedule dosing. A dosing regimen at every eight weeks after three months of loading doses and two milligrams as needed after three monthly loading doses. 03:44:06PM 03:44:06PM 03:44:15PM 03:44:18PM 03:44:18PM 03:44:21PM 03:44:23PM

BY MR. BRAUSA: 03:44:23PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 274

Q. Okay. And I think you anticipated my question. 03:44:23PM 03:44:25PM

That's four different regimens, right? 03:44:26PM 03:44:28PM

A. Yes. 03:44:28PM

Q. Okay. And so when your report says in paragraph 147 that Regeneron was beginning clinical trials studying the efficacy of aflibercept to treat the AMD with three different dosing regimens, it's important that that four two milligrams is there, right? 03:44:28PM 03:44:33PM 03:44:37PM 03:44:40PM 03:44:44PM 03:44:48PM

A. I'm sorry. Say it again. 03:44:49PM

Q. Sorry. Actually, we can withdraw that. 03:44:51PM 03:44:53PM

You -- you'd agree with me that the press release describes four dosing regimens, correct, Exhibit 1009 for DME? 03:44:53PM 03:44:55PM 03:44:58PM

MR. SUMMERS: Objection, form. 03:45:04PM

Yeah, okay. 03:45:05PM

MR. BRAUSA: Apologies. Okay. 03:45:07PM

MR. SUMMERS: You might want to ask that again. I talked over you. 03:45:09PM 03:45:10PM

BY MR. BRAUSA: 03:45:11PM

Q. We can agree that Exhibit 1009, the press release describes four different dosing 03:45:12PM 03:45:14PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 275

regimens for DME as part of a Phase 2 trial that's planned, correct? 03:45:16PM 03:45:19PM

A. Yes. 03:45:20PM

Q. Okay. And in none of those four dosing regimens is five loading doses specified, right? 03:45:20PM 03:45:24PM 03:45:28PM

A. Yes. 03:45:29PM

Q. Okay. And the fourth or the last listed dosing regimen has two milligrams on an as-needed or PRN basis after three monthly loading doses, correct? 03:45:29PM 03:45:32PM 03:45:37PM 03:45:42PM

A. Yes. 03:45:42PM

Q. And so within that fourth regimen, there are a variety of dosing schedules that may occur. Correct? 03:45:42PM 03:45:44PM 03:45:47PM

MR. SUMMERS: Objection to form. 03:45:48PM

THE WITNESS: That would be predicated on the patient's response and the physician's decision. 03:45:49PM 03:45:50PM 03:45:52PM

BY MR. BRAUSA: 03:45:53PM

Q. Right. And so in terms of dosing schedules and intervals there are actually more than four described in the 2009 press release Exhibit 1009. Right? 03:45:53PM 03:45:57PM 03:46:00PM 03:46:04PM

MR. SUMMERS: Objection, form. 03:46:05PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 276

THE WITNESS: Again, it depends on -- on your definition of "schedule." 03:46:05PM 03:46:07PM

BY MR. BRAUSA: 03:46:09PM

Q. Sure. 03:46:09PM

If we talk about the schedule in terms of the intervals of dosing, there are more than four potential intervals of dosing disclosed for DME in the 2009 press release, right? 03:46:10PM 03:46:12PM 03:46:16PM 03:46:21PM

A. If you're saying does the description of the PRN regimen permit multiple dosing regimens, the answer is yes. 03:46:24PM 03:46:26PM 03:46:34PM

Q. Okay. And -- and did you make any attempt to calculate how many dosing regimens specifically would be permitted by this PRN arm described in Exhibit 1009? 03:46:39PM 03:46:41PM 03:46:45PM 03:46:49PM

A. Well, I think you can do the math. So the medication is given on a monthly basis, and, therefore, the dosing regimen would be somewhere between every month and some number less than every month for the period of a year. 03:46:54PM 03:46:59PM 03:47:01PM 03:47:07PM 03:47:10PM

Q. Okay. And what's your basis for concluding that medication would be dosed every month on the PRN arm? 03:47:11PM 03:47:15PM 03:47:17PM

A. It -- because it's -- because PRN is as-needed, and so if there wasn't a response 03:47:20PM 03:47:25PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 277

and the physician determined that the patient required treatment, then the treatment could be considered -- continued on a monthly basis, which was the standard of care for anti-VEGF agents in the treatment of neovascular diseases for AMD. 03:47:29PM 03:47:32PM 03:47:35PM 03:47:38PM 03:47:45PM

Q. And -- and you mentioned you could do the math in terms of figuring out how many different schedules of PRN might be possible within a year time period, right? 03:47:51PM 03:47:52PM 03:47:55PM 03:47:58PM

A. For a particular patient. 03:47:58PM

Q. Okay. 03:47:58PM

A. It would be somewhere between every month and less than every month after the three original doses. 03:48:00PM 03:48:02PM 03:48:04PM

Q. Okay. But I guess my question is if it's less than every month, it could be two weeks, three weeks, one week? 03:48:06PM 03:48:10PM 03:48:13PM

A. No, no. A dosing less frequently than every month. 03:48:15PM 03:48:17PM

Q. Okay. 03:48:17PM

A. So that would be two months, every three months, every four months. 03:48:19PM 03:48:20PM

Q. And -- and what's your basis for concluding that the PRN arm described in Exhibit 1009 necessarily requires less frequent 03:48:22PM 03:48:23PM 03:48:26PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 278

dosing rather than more frequent dosing than monthly? 03:48:30PM 03:48:33PM

A. There's no benefit for more frequent dosing of an anti-VEGF agent. 03:48:33PM 03:48:38PM

Q. Okay. And so to the extent a reference taught or disclosed more frequent dosing could be determined by a physician, you'd disagree with that? 03:48:39PM 03:48:41PM 03:48:43PM 03:48:45PM

MR. SUMMERS: Objection, form. 03:48:46PM

THE WITNESS: Not -- not necessarily. The -- the -- at that time, it wasn't known whether or not more frequent dosing was -- would potentially be beneficial, and so the concept of more frequent dosing had been talked about. It's talked about in Shams. But in terms of the clinical studies that had been performed with ranibizumab and with bevacizumab and the initial studies for aflibercept, the Stan- -- the accepted dosing schedule for loading doses of the drug was on a monthly basis. 03:48:46PM 03:48:47PM 03:48:50PM 03:48:54PM 03:48:56PM 03:48:59PM 03:49:02PM 03:49:04PM 03:49:07PM 03:49:10PM 03:49:14PM 03:49:17PM 03:49:20PM 03:49:24PM

BY MR. BRAUSA: 03:49:25PM

Q. And if we now talk about 03:49:25PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 279

extending the dosing or less frequent dosing under this PRN arm, the Exhibit 1009, the 2009 press release, doesn't say whether that occurred after six weeks, seven weeks, eight weeks or any of those. Right? 03:49:27PM 03:49:31PM 03:49:36PM 03:49:39PM 03:49:41PM

MR. SUMMERS: Objection, form. 03:49:42PM

THE WITNESS: The press release does not address that. 03:49:42PM 03:49:44PM

BY MR. BRAUSA: 03:49:45PM

Q. Right. And as needed, that could vary considerably from patient to patient, physician to physician, right? 03:49:45PM 03:49:47PM 03:49:49PM

A. Again, it would depend upon the criteria that were established for the clinical trial and the criteria that were used by the physicians doing the clinical trial. 03:49:50PM 03:49:53PM 03:49:56PM 03:50:00PM

Q. Okay. And -- and the press release doesn't describe any success criteria or guidance for when, quote/unquote, the dosing would be needed under the PRN re- -- regimen, correct? 03:50:02PM 03:50:03PM 03:50:06PM 03:50:10PM

A. No, it does not. 03:50:12PM

Q. Okay. And just to confirm, you haven't done the math to figure out how many different combinations of dosing or how many schedules would be permitted based on the 2009 03:50:13PM 03:50:16PM 03:50:19PM 03:50:22PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 280

press release, correct? 03:50:26PM

A. Well, we can do the math here if you like. 03:50:27PM 03:50:30PM

Q. So just so I understand the math exercise, we have nine months in question, right, if we're talking about a year time frame? 03:50:30PM 03:50:32PM 03:50:35PM

A. Correct. 03:50:38PM

Q. And "as-needed" could be any number of doses at any point in time greater than a month, right? 03:50:38PM 03:50:40PM 03:50:42PM

A. Could be on a monthly -- on a monthly schedule. Could be every month for those nine months or less. 03:50:43PM 03:50:45PM 03:50:47PM

Q. Uh-huh. And it could be after a month and then six weeks then back to a month, then five weeks, correct? 03:50:48PM 03:50:51PM 03:50:54PM

A. I have no comment on that. 03:50:57PM

Q. Well, I'm asking the question. That's permitted certainly by the dosing regimen referenced in Exhibit 1009? 03:51:00PM 03:51:02PM 03:51:07PM

MR. SUMMERS: Objection, form. 03:51:09PM

THE WITNESS: So I -- again, the -- the medications were used on a monthly basis and that was the -- the -- that was the dosing regimen that was -- 03:51:10PM 03:51:11PM 03:51:13PM 03:51:19PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 281

seemed to be beneficial and so some modification of a monthly dosing regimen would be part of a PRN treatment protocol. 03:51:24PM 03:51:28PM 03:51:30PM 03:51:33PM

BY MR. BRAUSA: 03:51:33PM

Q. But -- right. But if I understood your testimony, it's that the modification would be extending the dosing regimen by some period of time after those three monthly doses. Right? 03:51:34PM 03:51:35PM 03:51:37PM 03:51:39PM 03:51:41PM

A. Correct. 03:51:42PM

Q. Okay. And the 2009 press release doesn't specify how long to extend it or for what duration you're extending that dosing period, does it? 03:51:42PM 03:51:45PM 03:51:49PM 03:51:51PM

A. No. 03:51:51PM

Q. Okay. Now, is it fair to say that for your obviousness opinions of the four dosing regimens referenced in the 2009 press release, you focussed on the two milligrams for three months followed by PRN? 03:51:51PM 03:51:59PM 03:52:03PM 03:52:08PM 03:52:11PM

MR. SUMMERS: Objection, form. 03:52:15PM

THE WITNESS: I -- I don't know that I specified the two milligrams dose. 03:52:31PM 03:52:32PM 03:52:34PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 282

BY MR. BRAUSA: 03:52:34PM

Q. Okay. Does the 2009 press release offer any insight to a POSA as to why the different dosing regimens were being considered? 03:52:34PM 03:52:40PM 03:52:45PM

A. Well, so the document itself does not. 03:52:50PM 03:53:04PM

Q. Uh-huh. 03:53:04PM

Are there any other documents that you're aware of that specify why these dosing regimens were considered at the time? 03:53:06PM 03:53:07PM 03:53:11PM

A. Well, a person of ordinary skill in the art would have understood that there was rationale and motivation to extend the dosing regimen because of the clinical burden on the patient and the physician. And so there was motivation to examine alternative dosing regimens other than monthly injections to determine whether or not other dosing scheduling could control the disease and still maintain an appropriate clinical response. 03:53:13PM 03:53:14PM 03:53:19PM 03:53:21PM 03:53:24PM 03:53:28PM 03:53:33PM 03:53:37PM 03:53:44PM 03:53:52PM

Q. The 2009 press release doesn't refer to extending the dosing regimen or the motivation to extend the dosing regimen, does it? 03:53:53PM 03:53:58PM 03:54:02PM

A. It describes it. It describes a dosing regimen in which the -- after the initial 03:54:05PM 03:54:07PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 283

loading doses, the dosing regimen is extended. 03:54:09PM

Q. Where does it talk about 03:54:12PM

extending the dosing regimen? 03:54:13PM

A. It goes from monthly injections 03:54:15PM

for the first three to eight week injections. 03:54:17PM

Q. Okay. And that's in AMD [sic], 03:54:21PM

correct? I'm sorry. I misspoke. 03:54:24PM

A. Yeah, we're talking about 03:54:32PM

diabetic macular edema. 03:54:35PM

(Simultaneous overlapping 03:54:35PM

speakers.) 03:54:35PM

BY MR. BRAUSA: 03:54:35PM

Q. Yeah. Okay. And so extending to 03:54:35PM

eight weeks is what you're talking about, is a 03:54:38PM

POSA would interpret that as being a rationale to 03:54:40PM

extend the dosing regimen? 03:54:43PM

A. That's what I opined to, yes. 03:54:45PM

Q. And to confirm, in the 2009 press 03:54:46PM

release, that extended eight-week regimen is three 03:54:50PM

with three monthly loading doses, not five, right? 03:54:54PM

A. Correct. 03:54:57PM

Q. Okay. You mentioned the Shams 03:54:57PM

reference, and I want to talk about that briefly. 03:55:07PM

It's Exhibit 1010. 03:55:13PM

(Exhibit 1010 was marked.) 03:55:15PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 284

MR. SUMMERS: Thank you, Counsel. 03:55:18PM

BY MR. BRAUSA: 03:56:00PM

Q. And I want to direct you to page 22, line 30. 03:56:00PM 03:56:04PM

A. On which page -- what page are you referring to? 03:56:08PM 03:56:11PM

Q. Sorry. So this one is cut off in my copy of the lower right end, so this is now, to add to the confusion, the central -- center footer, 22, on the document itself. 03:56:12PM 03:56:16PM 03:56:18PM 03:56:21PM

A. And, I'm sorry, which page? 03:56:23PM

Q. 22. 03:56:28PM

A. Okay. 03:56:29PM

Q. And line 30. 03:56:29PM

A. Okay. 03:56:35PM

Q. And this says the doses may be administered according to any time schedule, which was appropriate for treatment of the disease or condition, right? 03:56:35PM 03:56:40PM 03:56:43PM 03:56:46PM

A. Right. Yes, I believe I referred to this previously. 03:56:46PM 03:56:47PM

Q. Yeah. And it says the dosages may be administered on a daily basis? 03:56:48PM 03:56:50PM

A. Well, that's -- that certainly wouldn't be given on a daily basis in clinical 03:56:55PM 03:56:57PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 285

practice, but that's what's written here. 03:57:00PM

Q. Okay. And it -- it also says it might be given on a weekly basis, correct? 03:57:02PM 03:57:04PM

A. Again, same response. 03:57:06PM

Q. And that's the -- no one would dose VEGF agents on a weekly basis? 03:57:07PM 03:57:09PM

A. No. 03:57:11PM

Q. Okay. What about a biweekly basis? That's also disclosed in Shams. Right? 03:57:12PM 03:57:15PM

A. Unlikely. 03:57:17PM

Q. Okay. And biweekly, just to make sure I have it correct, that would be every two weeks? 03:57:17PM 03:57:22PM 03:57:24PM

A. Correct. 03:57:24PM

Q. Okay. And then we get to monthly, which is a dosing regimen that has clinical relevance? 03:57:24PM 03:57:26PM 03:57:29PM

A. Well, that's -- that's the dosing regimen that has been shown to be efficacious for the treatment of the angiogenic diseases in the clinical trials that we're running. 03:57:31PM 03:57:33PM 03:57:37PM 03:57:39PM

Q. Okay. And it actually doesn't describe in this sentence dosing every eight weeks, does it? It stops at monthly? 03:57:40PM 03:57:42PM 03:57:45PM

A. In that sentence, yes. 03:57:51PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 286

Q. Okay. And then in the next sentence it says: "The dosages can be administered before, during, or after the development of the disorder." 03:57:53PM 03:57:55PM 03:57:57PM 03:58:00PM

Do you see that? 03:58:01PM

A. I do. 03:58:02PM

Q. Do you ever administer VEGF agents prophylactically? 03:58:02PM 03:58:06PM

A. No. 03:58:08PM

Q. And so you never do what this is specifying in Shams, right? 03:58:08PM 03:58:11PM

A. I would not administer in advance of knowing the disease is present, no. 03:58:12PM 03:58:16PM

Q. Okay. And based on this paragraph in Shams and the knowledge of a POSA, do you think this paragraph would cause a POSA to question the reliability of the Shams reference overall? 03:58:18PM 03:58:20PM 03:58:24PM 03:58:26PM 03:58:28PM

A. No. I think the reference speaks to a number of important aspects to understanding the -- the disease and the potential to treat the disease with anti- -- to treat diseases with anti-VEGF agents. 03:58:29PM 03:58:31PM 03:58:34PM 03:58:38PM 03:58:42PM

Q. Okay. Does this -- this is a patent application, is your understanding? 03:58:43PM 03:58:46PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 287

A. It's the -- yeah, PCT. 03:58:49PM

Q. Okay. Do you know what "PCT" 03:58:53PM

stands for? 03:58:55PM

A. It's probably a preliminary -- I 03:58:56PM

-- I'd have to look -- look it up. It's a -- it's 03:58:58PM

a -- it's the -- it's an application to -- which 03:59:00PM

is submitted to yield a patent. 03:59:05PM

Q. Okay. Do you know whether this 03:59:06PM

ever issued as a patent? 03:59:09PM

A. I don't know. 03:59:10PM

Q. Did you ask counsel whether this 03:59:11PM

issued as a patent? 03:59:14PM

A. I didn't. 03:59:15PM

Q. Did you do any investigation as 03:59:17PM

to whether Genentech got a patent on the 03:59:19PM

disclosures of Shams? 03:59:23PM

A. I did not. 03:59:24PM

Q. Is there any clinical data in the 03:59:25PM

Shams disclosure? 03:59:37PM

A. (Witness reviews documents.) 03:59:38PM

There is robust references to -- 04:00:08PM

in the -- to the medical literature regarding the 04:00:10PM

use of anti-VEGF agents. 04:00:14PM

Q. Sure. But I'm talking about an 04:00:17PM

actual dosing regimen that was tested. Is there 04:00:24PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 288

any clinical data in the Shams application? 04:00:26PM

MR. SUMMERS: Objection, form. 04:00:31PM

THE WITNESS: So there's clinical data in the references that are within the Shams. 04:00:32PM 04:00:36PM 04:00:39PM

BY MR. BRAUSA: 04:00:40PM

Q. I -- I see. Fair enough. 04:00:41PM

So if we turn to one of the claims in Shams on page 36 -- claim 1, for instance. 04:00:42PM 04:00:45PM 04:01:06PM

A. (Witness complies.) 04:01:06PM

Q. Did you review this when you looked at the Shams reference? 04:01:06PM 04:01:07PM

A. I did. 04:01:08PM

Q. Okay. And so this claim talks about administering to a mammal a number of first individual doses of a VEGF antagonist and then administering to the same mammal a number of second individual doses of the VEGF antagonist where the second individual doses are administered less frequently than the first individual doses, right? 04:01:09PM 04:01:11PM 04:01:14PM 04:01:18PM 04:01:21PM 04:01:23PM 04:01:26PM 04:01:28PM

A. Yes. 04:01:28PM

Q. Does this claim limit itself to any particular mammal? 04:01:29PM 04:01:30PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 289

MR. SUMMERS: Objection, form. 04:01:34PM

THE WITNESS: Well, the second 04:01:35PM

claim does. 04:01:35PM

BY MR. BRAUSA: 04:01:35PM

Q. Sure. I'm talking about claim 1. 04:01:36PM

A. No. 04:01:38PM

Q. Okay. Does claim 1 limit itself 04:01:39PM

to any particular VEGF antagonist? 04:01:42PM

A. No. 04:01:45PM

Q. Does claim 1 even limit where 04:01:45PM

you're injecting the VEGF antagonist? 04:01:47PM

MR. SUMMERS: Objection, form. 04:01:51PM

THE WITNESS: Well, the -- the 04:01:51PM

discussion previously relates to -- to 04:01:54PM

that. This claim 1 does not. 04:01:57PM

BY MR. BRAUSA: 04:01:59PM

Q. Okay. And is there any clinical 04:01:59PM

data provided in the Shams reference that talks 04:02:02PM

about administering the VEGF antagonist in 04:02:05PM

individual doses and then administering individual 04:02:08PM

doses after that less frequently, as the claim 04:02:11PM

states? 04:02:14PM

A. I'm sorry, can you rephrase the 04:02:14PM

question, please? 04:02:16PM

Q. Sure. 04:02:17PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 290

Does any of the -- does any of the clinical data in the Shams reference -- and I mean clinical data presented in the Shams reference, not that might be presented in some reference it cites. But does any of it relate to what is claimed in claim 1? 04:02:17PM 04:02:18PM 04:02:22PM 04:02:25PM 04:02:27PM 04:02:30PM

MR. SUMMERS: Object to the form. 04:02:32PM

THE WITNESS: Again, I'm not -- I'm not understanding your question. 04:02:35PM 04:02:36PM

BY MR. BRAUSA: 04:02:37PM

Q. Okay. So in the PIER study, for example, there was a dosing regimen of three monthly loading doses followed by quarterly maintenance doses, right? 04:02:38PM 04:02:40PM 04:02:46PM 04:02:48PM

A. Yes. 04:02:49PM

Q. Okay. And if we turn to figure 2, which I think is at the back of the document, you see there's something called a Treatment Schema. It's on page -- well, it doesn't have a page. It's behind the claims. If you turn one page and then you turn it over -- do you see that? 04:02:50PM 04:02:53PM 04:03:00PM 04:03:03PM 04:03:06PM 04:03:12PM

A. Are you looking at figure 2? 04:03:15PM

Q. Yes. 04:03:22PM

A. Yes. 04:03:23PM

Q. And this shows three monthly 04:03:23PM

loading doses in Groups 1, 2, and 3, and then the next doses at Months 5 and 8 and 11, correct? 04:03:27PM 04:03:31PM

A. Yes. 04:03:36PM

Q. And that would be quarterly dosing? 04:03:37PM 04:03:38PM

A. Yes. 04:03:38PM

Q. Does the Shams reference describe any data from the clinic that followed this dosing schedule in figure 2? 04:03:38PM 04:03:42PM 04:03:47PM

MR. SUMMERS: Object to the form. 04:03:50PM

THE WITNESS: Are you asking is a specific clinical data that's in the Shams application related to this particular clinical study? 04:03:56PM 04:03:59PM 04:04:01PM 04:04:04PM

BY MR. BRAUSA: 04:04:06PM

Q. Correct. 04:04:06PM

A. No. 04:04:06PM

Q. Okay. And the treatment schema that we see here in figure 2, it was eventually tested in the PIER study, right? 04:04:06PM 04:04:09PM 04:04:12PM

A. Yes. 04:04:14PM

Q. And it didn't work, right? 04:04:15PM

A. I would disagree with that. 04:04:16PM

Q. Okay. And why would you disagree with that? 04:04:17PM 04:04:19PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 292

A. Well, No. 1, I'm not sure what you mean by "work." 04:04:19PM 04:04:21PM

Q. Do you think it worked? 04:04:23PM

A. I think the clinical data from the PIER study actually was relevant, was important for the work that was being done. And the authors themselves described it as a useful study. 04:04:24PM 04:04:27PM 04:04:32PM 04:04:35PM 04:04:40PM

If you -- if you look at the -- if you provide me with the PIER study, I can -- we can go through the conclusions together and you can -- you can determine for yourself what the authors contemporaneously thought the results of the PIER study was. 04:04:41PM 04:04:42PM 04:04:45PM 04:04:48PM 04:04:50PM 04:04:53PM

Q. Do you know whether Dr. Brown was an author on the contemporaneous publications -- 04:04:54PM 04:04:57PM

A. He was. 04:04:59PM

Q. -- about the PIER study? 04:04:59PM

A. He was. 04:04:59PM

Q. Okay. And he'd know whether it was a success or not? 04:04:59PM 04:05:00PM

A. I think he may have an opinion about that, but the results of the PIER 1 study were published in the peer-reviewed literature and are relevant to my opinion here. And if you look 04:05:02PM 04:05:04PM 04:05:08PM 04:05:12PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 293

at the peer-review study, the -- the results actually were -- were meaningful and were described as meaningful by the authors. 04:05:17PM 04:05:22PM 04:05:24PM

Q. Do you know whether, in the PIER study, Genentech stopped dosing patients on a quarterly schedule for Lucentis? 04:05:29PM 04:05:31PM 04:05:34PM

MR. SUMMERS: Objection, form. 04:05:36PM

THE WITNESS: There -- there was a -- as I recall, there was a follow-on study, and additional -- additional treatments were provided to some patients. 04:05:37PM 04:05:38PM 04:05:40PM 04:05:46PM 04:05:48PM

BY MR. BRAUSA: 04:05:48PM

Q. And when you say "additional treatments," you mean treatments more frequently than quarterly? 04:05:48PM 04:05:51PM 04:05:53PM

MR. SUMMERS: Objection, form. 04:05:54PM

THE WITNESS: Yes. 04:05:55PM

BY MR. BRAUSA: 04:05:55PM

Q. Why was that? 04:05:55PM

A. Because the response of patients was less than had been hoped and predicted, and patients required treatment. 04:05:56PM 04:05:58PM 04:06:02PM

Q. If we turn back to your report -- well, actually, before we go there, let's stay 04:06:05PM 04:06:14PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 294

with the Shams reference, and then I think we can -- can put it away. 04:06:18PM 04:06:20PM

If we go to page 35, line 28 -- do you see that? 04:06:21PM 04:06:38PM

A. Yes. 04:06:39PM

Q. And there's a sentence that says: "The specification is considered to be sufficient to enable one skilled in the art to practice the invention," right? 04:06:42PM 04:06:44PM 04:06:46PM 04:06:49PM

A. Yes. 04:06:50PM

Q. And the invention you understand is set forth in the claims that follow? 04:06:50PM 04:06:52PM

A. Yes. 04:06:55PM

Q. Okay. Do you agree with that statement, in Shams? 04:06:55PM 04:06:58PM

MR. SUMMERS: Objection, form. 04:06:59PM

THE WITNESS: I haven't evaluated Shams with respect to that. 04:06:59PM 04:07:03PM

BY MR. BRAUSA: 04:07:04PM

Q. Okay. Have you evaluated whether any of the prior art you considered is sufficient to enable one of ordinary skill had the art? 04:07:04PM 04:07:06PM 04:07:09PM

A. I'm not understanding your question. 04:07:11PM 04:07:12PM

Q. Okay. You said you didn't 04:07:12PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 295

evaluate Shams to determine whether the specification is considered sufficient and enabled one skilled in the art to practice the invention, right? 04:07:14PM 04:07:17PM 04:07:21PM 04:07:25PM

A. With respect to Shams, yes. 04:07:25PM

Q. Do you think the Regeneron 2009 press release is sufficient to enable a person of ordinary skill in the art to practice the invention claimed in the '601 patent in claim 10, for example? 04:07:27PM 04:07:29PM 04:07:32PM 04:07:34PM 04:07:38PM

A. Can you repeat the question for me, please? 04:07:38PM 04:07:45PM

Q. Sure. 04:07:47PM

Do you think that the Regeneron 2009 press release, Exhibit 1009, is sufficient to enable one skilled in the art to practice claim 10 of the '601 patent? 04:07:49PM 04:07:50PM 04:07:56PM 04:08:00PM

A. The Regeneron press release in 2009, in my view, is not specific enough to -- for the practice of the claim -- claim 10. 04:08:03PM 04:08:16PM 04:08:39PM

Q. Okay. With respect to the Elman 2010 reference, is that disclosure specific enough to enable one of skilled in the art to practice claim 10 of the '601 patent? 04:08:42PM 04:08:48PM 04:08:52PM 04:08:55PM

A. Elman would -- I'm sorry , I'd 04:09:14PM

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 296

have -- I'd have to think about that. I just can't -- I can't answer that question right now. 04:09:36PM 04:09:39PM

Q. Okay. And you didn't perform that analysis in rendering your opinions in this case? 04:09:41PM 04:09:44PM 04:09:47PM

A. Well, I -- I used Elman and the press release together to come to a determination opinion regarding obviousness. 04:09:47PM 04:09:49PM 04:09:55PM

Q. Okay. If we can go to paragraph 178 of your report. 04:10:00PM 04:10:06PM

A. (Witness complies.) 04:10:06PM

Q. Here, you say: "Consistent with an understanding, prior art also teaches" -- and then there's a quote about methods for administering therapeutically effective amount of VEGF antagonist followed by less frequent dosing of the VEGF antagonist. 04:10:29PM 04:10:31PM 04:10:34PM 04:10:37PM 04:10:41PM 04:10:45PM

Do you see that quote? 04:10:47PM

A. Yes. 04:10:49PM

Q. And there's a citation here to an Exhibit 1054, which is a U.S. patent application? 04:10:50PM 04:10:52PM

A. Yes. 04:10:56PM

Q. And there's no other citation provided for that statement, right? 04:10:56PM 04:11:00PM

A. Again, not -- not that I'm aware 04:11:14PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 297

of. 04:11:16PM

Q. Okay. And do you know what that 04:11:17PM

U.S. patent application publication is that's 04:11:19PM

referenced in paragraph 178 of your report? 04:11:22PM

A. Well, the language is similar to 04:11:25PM

the language from Shams, but I don't know offhand. 04:11:59PM

Q. Okay. And Shams, we just looked 04:12:02PM

at, was Exhibit 1010? 04:12:08PM

A. Yes. 04:12:11PM

Q. Okay. Let me hand you Exhibit 04:12:11PM

1024 [sic]. 04:12:17PM

(Exhibit 1044 was marked.) 04:12:20PM

MR. SUMMERS: Did you mean 1044? 04:12:38PM

MR. BRAUSA: Yes, apologies. 04:12:41PM

1044 for the record. Thanks for 04:12:43PM

the clarification. 04:12:45PM

BY MR. BRAUSA: 04:12:45PM

Q. And this is the U.S. Patent 04:12:46PM

Publication 2007/0190058-A1 that's referenced in 04:12:48PM

paragraph 178 of your report, correct? 04:12:55PM

A. Yes. 04:12:57PM

Q. And this is the Shams application 04:12:58PM

in a different form, right? 04:13:01PM

A. Yes, it appears to be. 04:13:02PM

Q. Okay. Was this provided to you 04:13:05PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 298

by counsel as well? 04:13:06PM

A. I do not recall seeing this 04:13:07PM

document. 04:13:09PM

Q. Okay. Do you know why you're 04:13:09PM

citing this document in paragraph 178 instead of 04:13:13PM

Shams Exhibit 1010 that we considered previously? 04:13:17PM

A. I do not. 04:13:21PM

Q. Okay. And just to confirm, your 04:13:22PM

testimony is you don't recall seeing this document 04:13:25PM

at all before this deposition? 04:13:26PM

A. Not this document, no. 04:13:28PM

Q. Okay. And this is a U.S. patent 04:13:29PM

application, right? 04:13:34PM

A. Yes. 04:13:35PM

Q. Do you know whether a patent was 04:13:37PM

ever issued from this application? 04:13:39PM

A. I don't. 04:13:41PM

Q. And so you don't have any 04:13:42PM

information about whether Genentech abandoned this 04:13:44PM

patent application? 04:13:47PM

A. I do not. 04:13:48PM

Q. Well, since you haven't seen this 04:13:49PM

document, let's go back to Exhibit 1010. And I 04:13:56PM

want to go back to paragraph 22 -- or, I'm sorry, 04:14:04PM

page 22 that talked about the daily, weekly, 04:14:14PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 299

biweekly, monthly dosing before, during, or after the document of a disorder. 04:14:19PM 04:14:23PM

Are you with me? 04:14:27PM

A. Yes. 04:14:28PM

Q. Okay. In that paragraph, have you attempted to calculate how many dosing schedules would be encompassed? 04:14:29PM 04:14:31PM 04:14:33PM

A. No. 04:14:35PM

Q. Do you have any idea sitting here today how many that would include? 04:14:35PM 04:14:39PM

A. No. 04:14:40PM

Q. Do you consider that to be a laundry list? 04:14:40PM 04:14:43PM

A. I don't know your definition. 04:14:44PM

Q. Okay. Have you ever used the term "laundry list" in your practice? 04:14:47PM 04:14:48PM

A. I don't use it in my practice, no. 04:14:51PM 04:14:54PM

Q. Okay. Have you ever used it in this proceeding? 04:14:54PM 04:14:56PM

A. I believe in my declaration, there's maybe a reference to it, yes. 04:14:57PM 04:15:01PM

Q. Okay. And is that wording that you provided, or was that supplied by counsel? 04:15:03PM 04:15:04PM

A. Probably my language. 04:15:06PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 300

Q. Okay. Well, let's take a look at that if we can go back to your report. And it's at paragraph 106 after your report, page 48. 04:15:09PM 04:15:11PM 04:15:42PM

A. Sorry. Which page? 04:16:06PM

Q. We're now at the -- 04:16:08PM

A. Yeah. 04:16:08PM

Q. -- lower right-hand -- 04:16:09PM

A. Yeah. 04:16:09PM

Q. -- corner again. 04:16:10PM

A. Yeah. 04:16:11PM

Q. It's page 48. 04:16:11PM

A. Yeah. 04:16:11PM

Q. Paragraph 106. 04:16:12PM

A. I see. 04:16:13PM

Q. And here you state that you understand that laundry list disclosures are insufficient to satisfy the written description requirement, correct? 04:16:14PM 04:16:15PM 04:16:17PM 04:16:20PM

A. Yes. 04:16:20PM

Q. What did you mean when you said "laundry list disclosures" in this paragraph of your report? 04:16:21PM 04:16:23PM 04:16:25PM

A. Well, my understanding is that in the context of a patent, that simply listing numbers related to particular aspects of -- of the 04:16:25PM 04:16:31PM 04:16:39PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 301

description of an invention is -- is not, in 04:16:51PM
essence, permitted, if you will, by the -- for -- 04:16:58PM
for the -- to support a claim on a patent. 04:17:02PM
Q. Okay. And so do there have to be 04:17:07PM
specific numbers for it to be a laundry list? 04:17:09PM
A. I don't know what the -- I don't 04:17:12PM
know the -- if there is a requirement in that 04:17:16PM
regard legally. 04:17:18PM
Q. Okay. And so taking your 04:17:19PM
understanding of what a laundry list disclosure 04:17:22PM
is, as you used that term in paragraph 106 of your 04:17:25PM
report, let's go back to Exhibit 1010 in Shams, 04:17:28PM
paragraph 23 -- or, I'm sorry, page 22, line 30. 04:17:38PM
And that paragraph's talking 04:17:41PM
about various dosing frequencies and times. Is 04:17:42PM
that a laundry list or not? 04:17:45PM
A. I -- I have no opinion about 04:17:47PM
whether or not that would be a laundry list or 04:17:50PM
not. 04:17:52PM
Q. Okay. I don't have anything 04:17:52PM
further. 04:17:54PM
Thank you for your time. 04:17:55PM
MR. SUMMERS: Yeah, let me -- let 04:17:56PM
me just take a look and see if I have 04:17:57PM
any redirect. One -- this won't take 04:17:59PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 302

too long. 04:18:05PM

MR. BRAUSA: Sure. 04:18:06PM

MR. SUMMERS: Do you mind if I -- 04:18:06PM

we should -- 04:18:06PM

MR. BRAUSA: Why don't we go off 04:18:09PM

the record? 04:18:10PM

MR. SUMMERS: Oh, yeah. Let's go 04:18:10PM

off the record. 04:18:10PM

THE VIDEOGRAPHER: We are going 04:18:12PM

off the record at approximately 4:18 04:18:13PM

p.m. 04:18:16PM

(Brief recess observed.) 04:24:06PM

THE VIDEOGRAPHER: We are going 04:24:06PM

back on record at approximately 4:24 04:24:20PM

p.m. 04:24:23PM

MR. SUMMERS: I have no further 04:24:24PM

either. 04:24:26PM

Thank you for your time, Dr. 04:24:26PM

Chaum. 04:24:28PM

THE VIDEOGRAPHER: Anything else? 04:24:28PM

Is that it? 04:24:29PM

MR. SUMMERS: That's it. 04:24:29PM

MR. BRAUSA: That's it. Thank 04:24:30PM

you. 04:24:31PM

THE VIDEOGRAPHER: This concludes 04:24:31PM

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 303

today's testimony. We are going off the record at 4:24 p.m. 04:24:32PM 04:24:35PM

(Discussion off the record.) 04:24:35PM

(The following proceedings were held on the stenographic record only.) 04:24:35PM 04:24:57PM

THE COURT REPORTER: I do have an expedite on this, though. 04:24:57PM 04:25:01PM

MR. BRAUSA: That's right. 04:25:03PM

(Discussion off the record.)

FURTHER DEPONENT SAITH NOT.

(Proceedings concluded at 4:25 p.m.)

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 304

REPORTER'S CERTIFICATE

I certify that the witness in the foregoing deposition, EDWARD CHAUM, M.D., PH.D., was by me duly sworn to testify in the within entitled cause; that the said deposition was taken at the time and place therein named; that the testimony of said witness was reported by me, a Shorthand Reporter and Notary Public of the State of Tennessee authorized to administer oaths and affirmations, and said testimony, Pages 5 through 304 thereafter transcribed into typewriting.

I further certify that I am not of counsel or attorney for either or any of the parties to said deposition, nor in any way interested in the outcome of the cause named in said deposition.

IN WITNESS WHEREOF, I have hereunto set my hand this 10th day of January 2024.



Carissa L. Boone, LCR No. 382

My License Expires: 6/30/2024

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 305

E R R A T A

I, EDWARD CHAUM, M.D., Ph.D., having read the foregoing transcript, Pages 5 through 304 do hereby certify said testimony is a true and accurate transcript, with the following changes (if any):

PAGE	LINE	SHOULD HAVE BEEN
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_____
EDWARD CHAUM, M.D., Ph.D.

_____
Notary Public

My Commission Expires: _____

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 306

Adam R. Brausa, Esq.

ABrausa@mofo.com

January 10, 2024

RE: SAMSUNG BIOEPIS CO. vs. REGENERON PHARMACEUTICALS,INC.

January 5, 2024-EDWARD CHAUM, M.D., Ph.D.-JOB NO.6381270

The above-referenced transcript has been completed by Veritext Legal Solutions and review of the transcript is being handled as follows:

__ Per CA State Code (CCP 2025.520 (a)-(e)) – Contact Veritext to schedule a time to review the original transcript at a Veritext office.

__ Per CA State Code (CCP 2025.520 (a)-(e)) – Locked .PDF Transcript - The witness should review the transcript and make any necessary corrections on the errata pages included below, notating the page and line number of the corrections. The witness should then sign and date the errata and penalty of perjury pages and return the completed pages to all appearing counsel within the period of time determined at the deposition or provided by the Code of Civil Procedure.

__ Waiving the CA Code of Civil Procedure per Stipulation of Counsel - Original transcript to be released for signature as determined at the deposition.

__ Signature Waived – Reading & Signature was waived at the time of the deposition.

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 307

__ Federal R&S Requested (FRCP 30(e)(1)(B)) - Locked .PDF Transcript - The witness should review the transcript and make any necessary corrections on the errata pages included below, notating the page and line number of the corrections. The witness should then sign and date the errata and penalty of perjury pages and return the completed pages to all appearing counsel within the period of time determined at the deposition or provided by the Federal Rules.

_X_ Federal R&S Not Requested - Reading & Signature was not requested before the completion of the deposition.

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 308

SAMSUNG BIOEPIS CO. vs. REGENERON PHARMACEUTICALS,INC.

EDWARD CHAUM, M.D., Ph.D.-JOB NO.6381270

E R R A T A S H E E T

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WITNESS Date

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 309

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& 2:3,9 5:18 307:23 308:9

0

0019 228:20 229:1

1

1 3:18 76:2,16 76:22 77:1,4,7 77:16 78:3 79:7,14 80:4 119:8 129:10 187:14 229:8 264:4 289:9 290:5,7,10,15 291:6 292:1 293:1,23 308:1
10 145:14 190:17 191:12 232:3 243:1 260:17 266:7 296:9,16,20,24 307:3
10,000 50:1
10,130,681 8:25
10,888,601 1:5 3:9 6:16
1000 258:4
1001 3:9 151:16,17 153:18 190:19 216:18 272:15
10010 2:5
1002 3:11 116:18 138:10 138:12,25 139:12 141:11 143:25 155:12 155:18 156:22 164:16 180:9 196:1 227:4 231:22 258:6 260:13
1006 3:12 233:18,20 234:7 249:18
1009 3:16 262:25 263:1 263:12 264:21 273:25 274:14 275:17,24 276:24 277:15 278:25 280:2 281:20 296:15
1010 3:18 284:24,25 298:8 299:6,23 302:12
1016 3:8 128:20,21 129:11 135:12 142:9,13
1024 298:11
1025 155:24 157:5
1044 3:20 298:12,13,15
1054 297:21
1056 3:21 227:12,22,23 228:5,15,23 230:22
106 301:3,13 302:11
1067 244:18,21
109 147:17
10:17 82:18
10:34 82:23
10th 305:18
11 144:1 292:2
11,253,572 10:11
110 227:11 228:10,16 229:4 230:23 231:5,12
11:37 143:1
11th 196:20
12 213:12 215:3,7
120 258:22
128 3:8
12:24 143:6
12th 145:17,23 146:2,4,17 147:10,12,20 148:13 150:24 153:3,10 196:19,25
13 3:11,20 21:25 145:13
138 3:11
13th 152:2,15 152:23 153:2 153:17 154:6 164:13 165:16 168:9,18 171:8 196:24
14 3:16 21:25 165:15,21 267:3 272:3,15
1401 4:6
146 260:13 266:6,6
147 274:15 275:7
14th 232:2 258:25 261:5 261:11,15 266:8 270:10 270:25 271:18 272:20
15 114:6 155:17,17 165:21 254:8 254:17,24 255:5,13
151 3:9
155 261:17
159 231:22 258:12
16 145:13 156:2 159:7,14 162:19,22 173:8 216:19 216:23 217:7

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Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 310

218:2,9 219:16 220:19 243:9 243:21 247:1 247:24 248:24 249:19 252:17 252:24 253:5 254:11 272:24
164 258:17
17 3:9 164:8,16 254:6,15
173 258:22 259:4
178 297:10 298:4,20 299:5
18 115:16 232:3 260:17 266:7
180 72:12
19 162:22 173:19
198 48:25
1980s 15:3
1987 20:6 165:13
1994 48:25
1:28 197:20
1:46 197:24
1st 48:21,23,25

2

2 3:16 76:2 77:10,14,17,21 79:8,14 80:6,9 80:14,22 81:3 144:1 145:5,20 146:3,11 147:4 147:25 148:13 148:18 151:1 152:21 196:14 260:12 264:24 266:19 268:4 276:1 291:17 291:22 292:1,9 292:19
2,000 57:16
20 56:15 145:13 162:15 167:19 171:25 180:9 219:5 229:24 247:2 257:6
20/20 246:7
2000 48:23
2002 54:5
2004-2005 33:25
2006 123:16,25
2006/047325 3:19
2007 56:16
2007/0190058 3:20 298:19
2008 56:16
2009 3:16 118:12 170:16 171:9 177:12 177:17 178:8 232:2 258:7,25 261:5,11,15 263:7 265:17 266:8,20 267:3 270:10,25 271:19 272:3 272:20 276:23 277:8 280:2,25 282:12,19 283:2,21 284:18 296:6 296:15,19
2010 118:22 232:3 233:17 236:8,17 237:2 237:10,17 238:1,1,23 257:24 258:8,8 258:15,16 259:1,7,24 260:9 265:3 296:22
2011 20:4,5,8 20:15 21:15 22:12 126:12 128:2 135:13 135:23 136:3,9 152:2,15,23 153:2,18 154:7 164:13 165:17 165:22 167:17 168:1,2,9,18 171:8 196:20 196:24 203:24 204:4 221:10 221:18
2013 123:16,25 145:18,23 146:2,4,18 147:10,12,21 148:13 152:7 153:3,10 167:13,14,17 167:19 168:2 168:16 196:19 196:25
2016 261:22
2018 48:21 201:5
2021-8811 121:7
2022-1226 159:8
2023 165:20
2023-442 8:24
2023-739 6:15
2023-884 10:10
2024 1:16 4:4 5:4 165:20 305:18 307:3,5
2025.520 307:9 307:12
21 3:8,12 181:25 189:2
212.849.7000 2:5
22 139:3 145:14 240:25 242:4 243:24 244:21 247:1 252:22 285:4 285:10,12 299:24,25 302:13

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 311

227 3:21
22nd 2:4
23 3:21 164:7 164:16 220:5 220:19 272:24 302:13
233 3:12
23rd 146:2
24 3:4 145:14 166:10 173:8 253:9
25 245:24 248:10
250 72:10 243:3,23 245:1 245:10,18 246:8,16 247:16 248:10 248:15
26 220:5,19 232:3 260:17 266:7
263 3:16
27 217:7
28 217:16 218:2,9 219:16 295:3
285 3:18
29 145:14
298 3:20

3

3 76:2,8,9 78:12,14,16,25 79:7,8,15 80:11,18 81:4 81:10 140:3 231:21 249:5 249:18 292:1
30 14:5 20:5 101:6 285:4,14 302:13 308:1
304 305:11 306:3
30647 305:24
32 139:12 145:14 162:15 171:25 173:21 174:5 175:13 178:6 217:7,16 218:2,10 219:16
33 216:24 219:18
338 147:13 155:21 156:6,6 156:16,24 157:3 158:1,7 158:8,15,19,24 231:1
34 180:8,25
35 175:22 176:7 181:24 184:5 186:1,24 295:3
350 69:16
36 289:9
37 195:25 196:13 243:15 243:20 246:24 248:1,23
370 147:12
38 216:24 219:18
382 305:24
3:05 257:16
3:22 257:19
3d 32:14 63:9

4

4 162:19 229:5 229:7 239:5 240:25
400 69:16 70:12,25
415.268.6053 2:10
42 166:10 167:1 168:20 173:19
424 4:5
425 2:9
46 144:18 227:6
48 145:11 301:3,11
49 227:12
4:18 303:10
4:24 303:14 304:2

5

5 1:16 3:4 4:4 241:24 242:23 272:16 274:7 274:10 292:2 305:10 306:3 307:5
50 57:20
51 2:4
572 10:11
5th 5:4

6

6 242:16,19,23 242:25 247:4 247:14 248:1 248:23 272:15
6/30/2024 305:25
60 95:4 141:21
601 6:20 117:2 117:18 119:3 120:1 144:8,9 144:11 145:7 145:22 146:14 146:24 147:3 148:2 149:22 150:20 151:5,7 152:5,13 153:19 156:5 158:5,9,20 159:22,24 160:5 168:12 175:11 190:18 196:6 197:3 216:18 219:17 220:20 227:18 227:20 228:13 260:17 265:18 272:15 273:9 273:12 296:9 296:17,24

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 312

61 139:3,12 140:3 141:6,10 141:19 142:5
63 260:12 266:5
66 258:21
681 8:25 10:5
69 231:18 258:12

7

7 147:3,6,13 152:6,16 168:11,14 197:2 242:23
70 242:7
71 258:12
76 258:21 259:4
78 242:7

8

8 254:9 255:20 292:2
84 246:7

9

9 145:1 227:4 254:6
9,254,338 3:21 121:8 228:6
92 255:19
94105 2:10
9:03 4:4 5:2

a

a.m. 4:4 5:2 82:19,23 143:2
a1 3:19,20 298:19
a1c 67:22
abandoned 299:19
ability 58:9 100:19 132:15 133:3
able 32:13 53:4 61:20 69:13 170:3 208:7,14 208:17 213:21 273:15
abnormally 19:11
above 19:13 217:6 258:17 258:21 259:4 260:12 264:6 266:6,6 307:6
abrausa 2:11 307:2
abreast 125:21 126:8,15 127:2 128:5
academic 36:5 36:16 40:4,11 128:4
academy 127:3 127:14
acceptable 45:12
accepted 15:24 42:9,10 279:21
access 53:5,6 58:2 59:6
accolades 124:5
account 70:20
accurate 10:6 142:5 267:13 306:4
achieve 87:9 106:10 269:3
achieved 87:6,7 100:16 107:4
acquired 124:6
acting 269:19
action 68:3,13
actions 116:15
active 20:3,5 22:8 95:10
activity 98:9 102:1 105:21 106:4 107:14 108:13
actual 288:25
actually 10:13 12:7 17:22 56:11 58:22 68:3 74:8,16 104:12 109:7 123:11 125:18 127:4,21,21 134:5 141:5 197:1 207:13 209:10 250:8 258:5 259:11 260:8 262:22 270:1 275:13 276:22 286:22 293:5 294:2,25
acuity 62:24 66:19 74:1,2 245:7,19,19 246:7
adam 2:8 5:15 307:1
add 285:9
added 93:13,16 152:7 197:2
adding 93:21 94:17 147:2,5 147:13
addition 19:19 106:18 145:25 165:21 170:2 188:4
additional 19:23 102:14 112:25 152:5 168:17 213:7 241:4,13 254:12,18 255:1,10 256:1 256:16,17 257:1 259:15 265:2 294:10 294:10,14
address 121:11 145:8,13 280:8

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 313

addressed 117:7 144:16
addresses 273:10
adequate 59:19
adequately 99:4
adjective 25:17
adjustments 262:10
administer 28:19 47:22 91:7,12 212:7 253:5 287:7,12 305:9
administered 61:5,6 104:3 142:21 219:4 229:14,17,25 230:4 232:25 262:7 285:17 285:23 287:3 289:20
administering 16:23 42:15 92:16 229:10 262:9 289:16 289:18 290:19 290:20 297:15
administration 136:25 137:14 137:23,24 142:10,14 261:24 262:2
adopt 62:2
advance 11:16 100:2 101:1 115:20 218:22 287:12
advances 21:14
advent 32:19
affected 240:10
affirmations 305:10
affirmatively 56:5
afford 58:9
aflibercept 50:16 81:14 97:6,10,19 101:22 107:10 141:20 237:6 267:24 268:4 268:19,22 275:9 279:20
age 134:18 199:10
agency 124:6
agent 17:4,6 29:8,15 42:15 43:21 50:23 55:19 56:21 68:8 71:3 84:8 88:8 92:16 99:14,17 102:23,25 112:22,24 131:23 136:20 192:23 207:23 229:12 251:23 279:4
agents 41:1 44:2,2 50:7 51:11,17 52:2 52:6 58:7,21 59:10 61:21 74:4 89:24 91:7 104:4 106:6 131:21 132:1 134:8 140:10 164:23 186:11,12,20 188:12 192:5 199:23 222:7 222:15,21 269:5,10,17 278:4 286:6 287:8,23 288:23
ago 7:8 9:5 11:4 115:16 162:2,12
agree 20:25 98:13 130:6 137:22 140:17 181:16 205:20 217:25 218:8 230:16 235:4 247:24 275:15 275:24 295:14
agreed 4:14
ahead 253:5
albeit 251:16
albini 110:1,3
alexander 110:10
algorithm 249:20
algorithms 64:1
allow 149:18
allows 262:2
alternative 99:15,17 192:22 245:9 245:14 283:16
alternatively 28:5
alternatives 200:16
amd 41:3 60:24 61:10,22 134:6 134:12,24 251:3,5 264:6 275:9 278:5 284:6
america 123:16 123:18,23
american 127:2 127:13
amount 37:16 37:24 63:3,12 63:15,17 67:1 67:10 84:11,25 85:3,7 86:13 86:20 261:19 261:21 297:15

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 314

amounts 137:5 217:9
analyses 33:11
analysis 84:14 97:18 168:2,8 168:10,16,17 191:3,12 219:23 261:13 274:4 297:4
analyzing 190:19
anatomical 193:17 219:7
anatomy 103:23 251:18
anemia 15:8
angiogenic 134:12,14 164:22 286:20
angiography 32:20 60:14
answer 21:23 22:15 38:17 40:21 51:7 57:7 99:11,20 105:2,14 116:12 123:6 131:19 132:14 146:20 162:4 163:8,24 164:17,25 166:3,4 178:2 179:2,5,16 221:13 223:5 277:11 297:2
answered 29:7 177:7 179:8
answering 223:21
answers 209:19 226:21
antagonist 17:3 17:5,6 28:20 28:24 31:2 53:25 54:9 56:9,9 65:12 66:12 68:24 70:15 71:11 204:19 206:4 210:23 212:8 229:12 261:20 261:22,25 289:17,19 290:8,11,19 297:16,17
antagonists 41:1 57:10 61:6 131:14 141:12,18 142:1 203:25 205:22 216:2 216:14 221:11 221:20,25 222:5 269:18
anti 17:3,4 41:1 41:1 43:21 44:1,2 50:23 51:11 56:19 58:7 61:21 68:8 71:3 74:4 74:4 88:8 99:14,17 102:25 104:3 106:5 112:21 112:23 131:21 131:23 132:1 134:14 136:19 186:11,11 188:12 192:4 192:22,22 199:2,23,25 204:18 205:22 207:23 210:23 212:8 216:1,7 216:14 221:11 221:20,25 222:5,7,15,21 223:9,14 232:24 251:23 261:25 269:5 278:4 279:4 287:22,23 288:23
antibodies 97:15,16
antibody 95:19 95:21,25 96:18 96:19,20,23 97:8
anticipate 176:12 177:3
anticipated 172:4,8 175:15 178:7 275:2
anticipates 177:17
anticipating 10:15 177:24 178:14
anticipation 149:1 172:23 173:2,11,20 176:16 177:8 178:23 179:10 179:13,20,24 180:4
anymore 50:24
anyway 253:5
apologies 242:24 275:20 298:14
appeal 1:1 157:14,25
appealed 157:23
appearance 5:9
appearances 2:1
appeared 58:12
appearing 307:18 308:7
appears 162:19 174:5 221:6 244:22 298:24
appendix 242:24
application 3:18 15:14 39:17 112:21

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 315

113:3 118:17 144:11 145:6 145:21 146:14 146:23 147:12 148:2 149:3,21 150:20 151:7 152:1,22,24 153:17,22,25 154:6,10 155:4 168:15 170:7 173:24 196:6 219:21 227:13 228:9,16 230:22 231:4 231:11 274:10 287:25 288:6 289:1 292:13 297:21 298:3 298:22 299:13 299:16,20
applications 188:13
applied 15:24 144:21 188:21 188:24 191:14
apply 15:12 186:16 187:22
applying 125:7 131:20 170:6,7 187:20 273:4
appreciate 27:4 150:13 226:21 269:25
approach 99:15 174:20 175:2 200:2,23
appropriate 42:4,12 45:12 149:1 189:19 201:15,16 235:2 251:13 252:1 283:19 285:18
appropriately 240:21
approval 76:9 79:2 131:3,18 133:21 134:8 135:13,18
approve 79:20
approved 30:9 30:17 44:1 53:25 54:3,9 56:1,5,18,18 79:19 81:11 130:7,19 131:12 132:20 132:21 133:8 133:20,21 134:1,13 135:19,23 136:2,3 251:2
approving 30:21
approximately 82:18,22 143:1 143:5 197:20 197:24 257:16 257:19 303:10 303:14
april 48:21
arbitrarily 209:7
archive 49:25
archived 49:10
area 15:2,4 22:8 63:13,16 63:18 101:17 175:3 254:3
areas 14:25 33:1 64:24 72:25 73:3 127:1 161:16
arm 251:13,25 277:14,23 278:24 280:2
arms 79:9
arose 199:5
arrive 183:10 188:19
arrived 89:1 94:3
art 61:18 117:8 149:15 150:3,4 150:9 164:19 166:5,6,8 167:16 168:9 168:22 169:4,7 169:7 170:11 176:2,3,6,10,11 176:21,23 177:2 178:11 178:13 181:4 181:13,17 182:4,8,11,16 183:1,8,8,10,13 183:14,17,21 184:6,8,14,19 184:23 185:13 185:19 186:3 187:8,24 188:10,17,18 190:11,20 191:22 192:2,6 192:20 193:5 194:5 196:23 200:15 254:23 262:13 268:15 269:1 270:17 271:7 272:12 273:5 283:12 295:8,21,22 296:3,8,16,23 297:13
article 3:12
articles 40:4
articulate 201:24
aside 155:9 231:18
asked 88:22 144:7 169:16 173:24 179:22 179:24 180:3,4 180:5 205:8 215:19 252:19 258:1
asking 11:24 41:23 44:17 60:25 96:1

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 316

111:21 116:4,4 166:18 171:21 199:1 219:19 219:20,22 225:7 281:18 292:11
aspect 66:17,23 95:5 125:10
aspects 31:22 76:5,6 117:6 174:25 175:8 287:20 301:25
asserted 181:4 181:14,18
assessment 65:6 66:6,10 91:14 240:16 241:17
assist 32:8
associated 25:22 77:24 105:20 106:12 199:22 225:15 226:7,12 268:12 270:14
assume 49:13 103:11 250:19
assumption 103:13
attempt 201:12 272:10 277:13
attempted 300:6
attending 128:4
attention 139:2 155:17 272:24
attorney 34:17 38:14 40:20 114:15 116:23 173:5 174:17 179:3 180:22 305:14
attorneys 5:3,5 7:1 11:24
author 12:14 36:15 75:2,11 109:8 125:12 293:16
authorized 305:9
authors 240:20 256:24 293:7 293:13 294:3
automaton 197:9,10
available 49:11 52:15 53:2 55:16,17 57:11 58:21 69:9 70:5 84:9 86:15 90:20 150:18 167:7 168:18 265:6
avastin 50:14 50:15 56:11,13 56:22 57:12 59:25 83:16,22 84:4,21 85:4,9 85:12 86:25 87:17 88:3,4 88:12 89:11 92:7 95:10,11 97:11 98:14,20 99:5,22 100:11 100:18 101:7,9 101:18,23 103:25 104:12 104:15,17,23 105:22 132:4 133:7,14,16,17 133:18,20,24 134:13,23 135:1,5 199:16 211:13 251:2,2
avenue 2:4
avoid 226:19
award 124:4,10 124:15,19 125:2,13
awarded 123:15 124:9
aware 11:1,17 29:3 30:3 36:1 36:4 54:24 75:4,12 101:4 102:10 109:6 136:2,6 150:22 153:11 168:19 171:16 205:18 221:10 222:2,4 264:22 265:10 283:9 297:25
awareness 55:5 81:2 171:20 185:9 186:15 204:6
axis 243:1 248:8,8

b

b 124:10 145:14 308:1
b2 3:10
back 9:10 13:20 16:3 20:8 21:18 33:21,24 38:17 40:3 48:5,15 48:21,23,25 49:21 56:15 75:11 78:23 82:1,22 83:18 88:4,9 95:22 98:6 119:9,19 123:8 126:11 128:2 135:11 138:23 142:8,9 143:5,8,24 145:19 151:1 153:13 155:10 155:11 166:22 169:21,25 171:24 197:24 210:10 211:23 212:12 216:17 221:9,15 227:3 233:11 241:25 244:9 252:3 254:2 257:19 257:22 258:5

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 317

263:9 266:5 269:13 271:2 274:13 281:15 291:17 294:24 299:23,24 301:2 302:12 303:14
background 123:13
bad 103:18
balance 255:19
barusa 187:11
base 72:11
based 28:4 33:11 45:7 47:14 51:18 55:5 59:21 60:12 70:19 73:18 74:10,19 89:8 90:21 92:17 101:15 107:6 120:6 135:3 140:12 140:14 141:8 146:16 148:8 155:8 166:23 174:3 176:1,15 181:11 182:4 182:15,24 184:24 188:6 190:12,12,13 198:15 199:18 206:15 209:25 210:3 212:16 214:10 217:23 218:23 219:1,7 219:23 220:12 220:24 232:21 238:1,22 240:22 241:11 253:17 261:11 262:16 271:17 272:2 280:25 287:14
baseline 246:18 248:12
basically 18:25 77:2
basis 57:18 105:12 107:25 173:2 199:19 199:19,21 202:7 203:2 219:6 263:24 267:4 276:10 277:18,21 278:3,23 279:23 281:24 285:23,25 286:3,6,9
began 33:22 57:10 61:24 62:2
beginning 267:22 275:7
behalf 1:15 8:23 10:9,21 13:6,11 174:7
belief 61:17
believe 7:8 9:6 40:5 51:9 93:11 121:11 132:18 133:5 138:21 144:16 145:8 147:2,4 148:19 159:3 160:2 164:17 166:3 205:11 234:8 239:13 243:8 259:25 285:20 300:21
ben 98:19
beneficial 46:4 54:19 99:16 107:12 192:23 272:13 273:7 279:14 282:1
benefit 26:1 29:15 58:13 71:2 77:18 84:5 87:21 88:6 99:13 100:16 103:5 105:17 106:1 106:10,11 107:4,9 108:25 132:19 133:5 198:19 199:11 200:17 239:20 279:3
benefits 84:22 102:14
benefitting 99:4
beovu 50:17
best 6:4,24 20:24 46:6 47:13 68:3,13 69:11 89:9 107:20 123:15 123:17,22 124:7 172:24 198:11 215:20
betsy 134:15
better 21:1 59:5 68:2,7 83:16,22 86:24 87:1,3,5,9 98:13 99:22 100:11,20 101:7,8,17 102:5,9 215:10 215:11
bevacizumab 50:15 57:13,19 58:11,16 59:15 59:25 60:8,16 97:19 106:9 132:5 136:20 141:20 279:19
beyond 34:4 73:4 121:14,24 163:11,17 168:14 209:15 226:7 244:25 245:6
binding 102:1
binds 101:23

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 318

bioengineering 124:21
bioepis 1:3 5:13 7:21 307:4 309:1
biologic 95:16 95:18 96:16 98:9 134:10
biological 18:18 19:20 21:6 22:2 102:4
biologics 51:2
biology 22:18 74:11
biomicroscopic 31:25
biosimilar 8:7
biosimilars 8:2 8:13,15
biostatisticians 236:1
bit 65:18 68:1 72:12,14 104:8 202:2,14 217:8 227:8
biweekly 286:8 286:11 300:1
black 243:11
bleeding 28:8
blends 247:9
blinded 79:9
blinding 19:18 200:20
block 134:10
blocking 103:3
blood 17:23 18:17,17,19 19:2,2,12,23 21:20 27:25,25 32:25 68:2 103:1 213:20 269:12,13
board 1:1 120:18 134:8 157:11,15 159:3
board's 158:10 158:14,15
body 17:11 18:21 21:22 125:16
bold 139:10
bolded 239:9
bone 15:6,12 15:18 67:5 225:8,9
book 119:19
boone 4:15 305:24
bother 158:6
bottom 139:11 249:17 264:4
bracketed 228:20
brain 271:24
brausa 2:8 3:4 5:15,15,25 14:2 20:21 22:6,11,20 24:17 27:1,21 29:2 30:2,23 31:11 33:5 34:3,16,22 35:11 36:12 37:21 38:6,15 38:24 39:10,19 40:23 41:9 42:23 44:9,21 45:20 47:17 49:19 50:5 52:24 53:18 54:16,25 58:19 60:6 61:2 62:13,25 64:4 65:16 68:15 69:7 71:5,17 72:2,15 73:2 73:11,20 76:20 78:1,10,21 80:20 82:11,16 82:24 84:18 94:14 95:14 98:10 100:8,23 101:13 104:9 112:6 114:19 116:7 117:15 123:9 128:22 130:5 135:10 136:22 138:5 138:14 139:19 139:22,25 141:3 142:23 143:7 146:9 150:14 151:12 151:22 154:12 157:20 161:4 168:6 175:5 176:17 177:9 178:4,19 179:4 179:11,18 181:15 182:22 183:6,19 185:24 189:20 191:20 192:10 193:9 195:10 195:17,20,23 195:24 197:18 198:1 201:2 204:16 206:9 207:10 208:1 210:19 212:17 216:12 217:5 217:13,24 218:7,14 220:3 220:15 221:1,8 222:19 223:17 226:14,17 227:1,2 228:1 228:4 230:15 231:2,9,16 233:3,21 235:8 237:23 238:20 241:18 242:14 243:18 244:8 245:15 246:3 246:12,15 248:21 249:4 252:12 255:11

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 319

256:8 257:12 257:21 262:22 263:3 264:2 265:12 266:3 266:25 267:10 269:23 270:7 271:22 274:25 275:20,23 276:20 277:3 279:24 280:9 282:5 283:1 284:12 285:2 289:6 290:4,16 291:10 292:15 294:13,19 295:19 298:14 298:17 303:2,5 303:23 304:8 307:1
break 36:14 82:12,14,25 101:12 104:7 139:23 142:24 143:9 163:25 182:21 190:25 195:14 197:18 257:13,23
brief 82:20 197:22 257:17 303:12
briefly 284:23
briefs 158:1
broad 44:5 125:15
broader 63:18
broadly 23:6 76:19
broke 83:8
broken 67:5 225:8,9
brought 35:8
brown 109:13 109:16,23 293:15
bullet 186:25 187:14 189:1 190:4
bullets 188:21
burden 58:5 106:21 200:19 203:12 205:21 215:17 268:13 271:5 283:14

c

ca 307:9,12,20
calculate 277:13 300:6
california 2:10
call 17:7 19:16 155:21
called 14:22 23:6 31:15 32:24 50:21 64:25 119:22 198:22 201:6 227:7,13 249:9 291:18
calls 40:17 157:17 178:1 178:15,24 179:14 182:19 183:3 185:21 189:14
camera 18:7
cancer 133:22 134:1,14
caption 4:10
care 41:13,16 42:3,6,8,12,16 43:8,12,17,23 44:8,12,17 45:4,6,9,13 51:5,13,14,18 51:21 79:11 91:3 164:21 184:23 193:21 200:20 210:1 240:22 250:21 272:13 273:7 278:4
career 15:20 16:4,13,14,20
carissa 4:14 305:24
carry 203:10
case 9:10 16:25 18:10 74:23 115:17,19,25 116:6 121:24 122:6 138:11 149:8 156:16 167:1 181:19 220:18 263:14 264:11 266:18 297:5
cases 7:18 23:15 174:6
cataract 106:13
cate 225:24
catt 134:21 135:4
cause 18:12 19:14 70:14 103:2 287:16 305:5,16
caused 18:11
causes 19:20,23 21:3,3
caution 34:14 35:5 114:14 116:21 174:16
ccp 307:9,12
cell 15:8
cells 18:3 19:9 19:10
center 31:14 48:23,25 52:4 57:24 73:13 139:5 285:9
central 72:23 73:1,4,13 74:7 243:2,22 244:25 245:6,9 245:17 246:8 247:17 248:9 285:9
certain 17:13 17:15 21:3,4,4 38:10,19 52:14

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 320

52:15 84:22,25 120:23 149:8 162:23 199:9 229:13
certainly 41:7 48:1 171:16,20 251:5 255:7 265:13 281:19 285:24
certificate 4:10 305:1
certify 305:2,13 306:3
cetera 4:10 149:19 213:12
challenged 12:19,24 13:8
challenging 126:2,3,5
chance 9:17,18 119:15
change 45:5,7 55:25 69:25 219:9 248:16 309:4,7,10,13 309:16,19
changed 20:13
changes 19:14 23:12 306:4
changing 74:14
characterizati... 103:8
characterize 65:9 137:4 225:19
characterized 269:11
chaum 1:14 3:3 3:11 4:2 5:7,20 6:1,7 82:25 128:24 138:17 143:8 195:19 198:2 257:22 303:19 305:3 306:2,20 307:5 309:2
cheaper 88:12
check 272:21
chief 95:7
children 16:8
choice 44:19 90:9 132:4 136:19
choosing 189:7
church 4:5
citation 229:2,3 297:20,23
cite 117:22 148:22 153:21 153:23
cited 121:24 154:20
cites 291:5
citing 230:23 299:5
civil 4:8 307:19 307:20
claim 172:4,11 172:12,15,16 172:18,20,20 175:15 176:12 176:22 177:3 177:17 178:7 178:13,14 190:17,20,22 191:12 232:15 271:12 289:9 289:15,24 290:3,5,7,10,15 290:21 291:6 296:9,16,20,20 296:24 302:3
claimed 150:4 188:19 291:6 296:9
claims 12:18,24 13:7,11 119:14 119:16,17 145:13,16 149:8,9 156:5 158:6 160:4 175:10 181:4 181:14,18 232:3 260:17 265:18 266:7 270:24 289:9 291:20 295:12
clarification 27:5 298:16
clarify 6:13 7:3 65:15 139:4 234:16
class 56:1 57:25 58:1
classify 225:24
clear 6:20,24 11:22 47:6 53:10 79:23 90:10 133:13 159:22 190:10 202:19 214:3,6 242:16 253:6 266:4 267:19
clearer 20:23
clearly 61:22
client 34:17 114:15 116:23 174:17
clinic 203:6 292:8
clinical 14:25 15:4,15 41:13 42:10 44:19,25 45:8,11,24 46:8,10 47:15 48:6,8,12,15,20 48:22,24 49:12 51:22 52:1 58:12 60:13 61:14 62:4,11 64:17 66:3,24 70:20 72:22 75:6,19,21,24 76:5,6,25 77:6 77:15,18 78:14 78:17,18 79:8 79:24 80:1 83:20 94:21 95:5 96:7

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 321

100:13 104:19
105:5,15 106:8
107:4,24
108:12,25
109:4,20 111:4
113:3 117:10
117:12 118:24
124:23,23
127:6,8,8
128:15,17,18
129:20 131:2,6
132:22,23
133:2 134:20
134:21 135:2,9
140:13 171:13
171:18 184:24
186:17 188:2
192:8 193:8
199:17 204:23
208:17 218:24
219:2 221:10
221:19,24
226:1 235:10
239:25 240:5
240:14,17
247:6 250:23
250:23 251:7
251:12,20
252:1 253:13
259:14 264:18
264:20 267:23
272:9,13,19
273:7 275:8
279:17 280:14
280:16 283:14
283:19 285:25
286:17,21
288:18 289:1,3
290:17 291:2,3
292:12,14
293:4

clinician 16:7
20:4,5,6 101:6
133:24 165:12
165:16 220:17
251:8

clinicians 52:15
204:3

close 18:16

code 307:9,12
307:19,20

coding 226:3

coherence
32:11 63:24

cohort 105:16
106:16 239:14
239:23 240:2,7
247:5 248:13
248:15,19,23
248:24 252:15

cohorts 240:2

collaboration
34:2,6

colleague 5:17
60:2 99:6
110:16

colleagues
33:25 74:23
91:7,8,11,15
92:17,18
125:24 126:9
127:22

colored 169:24

column 129:14
216:19,20,23
217:7 218:1
219:16,18
220:19 229:5,7
239:8 249:9,18
272:15

columns 218:9

combination
69:23 176:2
181:25 182:7
183:8 188:25
210:6 229:20
232:2 258:6,25
261:4 265:19
266:16,20

combinations
280:24

combine 184:7
185:18 186:2,8
188:18 230:6
258:14 260:24
272:5

combining
187:8 232:7,10
261:14

come 27:6 28:6
46:11 50:18
155:10 184:12
199:21 204:11
204:19 206:1
210:10 211:23
212:12 214:2
297:7

comes 43:1
47:2 70:4
90:18 155:5
207:2

comfort 235:18

comfortable
133:24 137:12
235:21

coming 52:6
58:10 91:4

commencing
4:4

comment 37:12
176:19 281:17

comments
149:24

commercial
79:2

commission
306:25

common 32:10
41:7 51:14
132:8 184:14
184:19,25
185:9 204:7

commonly
65:24,25

communication
116:23 174:18

communicati...
12:3 34:18
114:16

community 37:6 42:11 60:2 99:7 105:24 127:9 171:14 186:16 186:16
companies 130:18 132:12
compare 104:11 164:15
compared 30:9 36:6 87:15 105:21 115:10 203:15 211:13 263:25 269:19
comparing 168:22
completed 4:18 265:1,2 307:7 307:17 308:6
completely 103:12,17
completion 308:10
complex 236:15,18
complicated 235:3,14,16
complication 222:22
complications 251:19 268:14 268:24
complies 155:19 231:20 249:7 289:11 297:11
compound 261:25 262:2,4 262:10
compounded 57:19,21
comprise 229:10
comprised 57:25
comprising 261:23
comprom 229:10
computer 33:11 34:12,25 35:9
computers 33:23
con 194:21
conceiving 15:1
concept 15:5 24:7 35:24 36:2 198:3,13 198:22 199:4 270:16 272:7,7 279:15
concepts 124:22 125:7 247:9
concern 12:2 251:9
conclude 60:18 238:2,4,7,8,22
concluded 304:11
concludes 303:25
concluding 277:22 278:24
conclusion 40:17 157:17 178:1,16,25 179:15 182:19 183:3,10,18 185:21 189:15
conclusions 293:11
condition 23:3 31:1 42:10 59:11 285:19
conditions 15:9 45:25 55:19 131:11
conduct 167:24 168:8
conducted 110:24
conferences 125:25 126:4,5 127:2 128:5
confident 212:21,24
confirm 26:2 29:7 154:19 161:24 179:19 230:20 237:1 260:22 280:22 284:18 299:8
confirms 261:18
confounding 240:17
confusing 40:1 166:18
confusion 285:9
conjunction 51:8
connections 18:1
consider 41:10 47:20 51:4 71:8 84:7,23 149:19 150:8 150:17,19 153:7,9 165:25 166:1 167:15 168:16 177:12 191:3 208:19 209:13 213:10 220:8 221:2 236:16 250:20 273:16 274:6 300:12
considerably 280:11
consideration 152:8 180:11 180:17
considerations 68:10 184:25 194:18

considered 23:14 42:16 43:16 44:8 51:17 56:4 121:23 146:3 151:3 153:1 175:1,11 177:23 180:19 180:24 181:18 181:21 191:23 194:10,12 197:2 220:14 220:23 223:13 223:13 244:6 274:3 278:3 283:4,10 295:7 295:21 296:2 299:6

considering 68:22 146:1 148:25 176:9 200:9

consistent 129:19 156:7 156:13 161:3 297:12

construct 164:24 165:1 169:14

construed 220:2

contact 307:9

contains 158:9

contemporan... 293:16

contemporan... 111:11 293:13

content 196:3

context 24:5 46:10 86:22 120:8 166:15 166:25 169:22 170:4 172:10 173:3 189:22 189:23 191:8 191:11 199:1 199:24 214:24 234:19,24 239:17 301:24

continue 18:14 21:11 69:21 203:1 208:8 239:6

continued 11:18 91:22 278:3

continuously 67:9

contribute 20:1

contributed 75:8

contributing 68:5

control 18:3 28:1 67:23,24 68:2 79:9 209:5 213:19 213:20 215:11 251:13 283:18

controlled 212:24

controlling 27:24 215:14

controls 79:11

conversation 102:13 157:8

conversations 11:23 94:16 113:9,10,14 114:9

copays 58:4

copied 174:10

copy 138:15 151:11 285:8

corner 144:3 301:9

correct 6:5,7 9:16,18,22 10:11,21 12:15 12:20,24 13:8 14:9 16:23 17:11 20:4 22:22 26:4 38:10 53:7,25 58:23 68:19 75:17,18 84:23 87:18,22 88:20 92:8 93:4 94:10 98:14 99:23 102:18 105:22 107:23 116:8,11 120:12,23 124:14 129:17 130:13 133:17 138:17 141:13 145:2 149:9 152:25 153:3,4 159:16 162:15 162:25 163:13 163:19 168:23 170:23 171:3 176:3 177:3 180:6 182:9 191:9 205:23 206:17,22,23 207:4 211:21 212:1,2 214:18 217:2 218:3,10 224:21 228:6 229:18 230:2,9 241:3,14 242:8 243:3,11,15 246:6 247:10 247:13 248:7 248:20 251:4 252:24,25 253:11,15,19 255:16,17,22 259:8 263:5 265:3,7,14,15 267:4 274:16 275:17 276:2 276:11,15 280:20 281:1,7 281:16 282:11 284:7,21 286:3 286:12,14 292:2,16

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 324

298:20 301:18
corrections 307:14,15 308:3,4
correctly 6:5 23:23 25:9 77:13 86:5 91:6 151:10 204:9 217:15
corresponds 248:1
cost 58:25 89:8 89:15,18,20
coun 164:6
counsel 4:3 5:8 27:24 35:22 82:8 83:1 113:10,14 114:9 116:16 116:25 118:4,7 125:1 139:15 143:10 152:7 154:24 155:5 155:25 157:9 159:2 161:9 162:7 163:6,12 163:18,23 164:6 170:23 173:18 174:19 175:21 179:21 180:6 183:22 183:24 225:1 226:17 233:19 256:6 258:1 261:7 285:1
288:11 299:1 300:24 305:13 307:18,21 308:7
counsel's 155:8 162:24
couple 16:6 17:24 55:7 61:8 123:13 203:8
course 14:23 68:3,13 91:7 271:9
courses 269:7
court 4:15 5:11 246:10,13 304:6
create 124:23
creates 37:5
criteria 239:11 241:2,11,21 242:5,7 243:6 243:14,25 244:4,25 245:3 245:6,17,25 246:5 247:1 248:24 252:16 254:5,11,20 280:14,15,18
cross 32:14 69:19,20 267:12 270:2
curious 49:2
current 41:2 42:16 50:3 69:19 88:14 125:23 127:5,6 127:6,7 240:22
currently 51:17 88:12 89:23 90:2
cut 18:21 285:7
cycle 209:14 213:5,7
cycles 213:10 213:11
cystic 15:9 64:25
cysts 64:25

d

d 3:1 162:18,18
daily 105:12,16 235:19 285:23 285:25 299:25
damage 67:8 269:13
damaged 17:23 18:15 19:22
data 36:4,23 37:3,11,17,24 39:3,8,12,22,25 40:6,10,14 58:10 65:21 70:1,5 77:7,14 78:4,8 79:13 79:15,19 80:4 100:3 101:21 105:1,25 107:7 111:6,24 113:3 124:6 127:12 127:20 134:10 135:4,9 236:14 236:14,17,20 236:23 237:5 237:13 238:9 238:13 239:2,3 243:24 247:4,6 247:9 248:6 249:3 250:13 253:7,17,21 254:1,24 255:6 255:18,24 265:2,6,10 288:18 289:1,4 290:18 291:2,3 292:8,12 293:4
date 5:3 119:23 120:1,8 128:10 144:10 145:2,6 145:7,13,17,21 145:22 146:13 146:23 148:1 148:12,21 149:2,21 150:19,24 151:6,24 152:4 152:10,14,17 152:22 154:1,2 154:22 155:1,4 156:18 164:12 164:14 167:19 167:25 169:8 171:7 196:6,12 196:14,18,25 227:8 307:16

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 325

308:5 309:24
dating 155:7
david 109:15
day 127:4 305:18
days 127:4
dealing 17:1 159:24 160:4 171:1
deals 159:23 261:2
decade 124:22
decide 55:2,5 66:10 202:8
decided 16:4 55:2 56:9 175:16
decision 44:18 47:6 55:24 58:6,15 59:9 66:4,18 67:15 67:18 68:12 69:11 85:1 93:19,22 94:2 94:3 95:6 98:25 120:15 120:17,20 121:5,7,10 122:10 140:11 140:13 155:21 156:4,12,17 157:4,10,14,23 158:2,7,8,10,12 158:15 159:3 159:15,16,19 159:20 160:9 160:12,16,19 161:6,19 207:22 208:19 209:25 210:2,4 214:9 241:20 276:19
decisions 65:22 65:23 70:18 74:18 92:18 94:1 120:11,22 121:2 156:11 169:6 184:23 198:14 206:14 246:6
declaration 3:11 12:11 17:2 35:20 81:25 109:8 112:9,11,13,14 113:5 115:1,7 115:17,18,24 116:2,5,17 117:5,9,22,25 119:21 120:2 121:6,12,13,15 121:23,25 122:3,15 138:11,16 143:25 144:17 145:9,11 147:1 147:11 148:16 150:2 153:22 154:21 156:15 157:5,9 160:20 167:22 174:13 205:6 261:17 266:2,5 267:18 271:3 300:21
declarations 11:14,22 13:15 13:17 174:5,11
decrease 248:11 262:3
deemed 167:25 194:22 245:20 249:23 252:6,9 252:23 253:2,3 253:11
defer 175:21
deferral 193:19
deferred 3:14 239:15 240:15 241:2 243:10 243:21 246:25 247:25 254:10 254:16 255:14
define 39:22 85:18 137:16 137:17 138:4 140:23,25 193:1,25 195:3 195:8 218:12
defined 131:2 140:22 164:15 193:20 241:12
defines 25:17 217:21
defining 217:20
definition 25:17 29:25 102:19 131:16 131:21 164:8 173:23 193:11 194:24 198:8 219:3 220:11 220:25 224:15 245:24 246:23 253:14 277:2 300:14
definitions 194:5 198:7
definitively 239:1 255:19 255:25
degeneration 59:17 134:18 186:13 199:7 199:10
degree 225:19
deleterious 19:6
delivered 140:10
demonstrate 32:3 61:15 62:11 69:13 77:15,19 78:18 105:7,17 132:24 200:3 201:14 202:16 203:14 208:17 209:3 213:6 250:23

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 326

demonstrated 58:11 62:15 106:25 202:20 203:3
demonstrates 104:20 237:14
department 236:5
depen 72:1
depend 84:12 189:21 280:13
depending 23:10 43:13 46:14 72:1 84:7
depends 24:2 26:11 27:11 28:11 44:23 48:17 97:12 103:16 207:7 213:15,15 226:10 277:1
deponent 304:10
deposed 6:9 8:21 9:4 10:14 205:17
deposition 1:13 4:1,18 5:7 9:9 9:11,15,23,25 10:3,15 48:9 48:12 81:25 83:9,13 112:8 113:8,11,15,22 114:11,12,22 114:25 115:4,9 115:10 121:17 162:7,8,9 201:4 205:9 236:23,25 244:12 299:10 305:3,5,15,16 307:19,22,24 308:8,10
depth 17:20 20:9
describe 23:8 172:24 202:13 224:6 280:18 286:23 292:7
described 66:15 70:22 91:11 219:16 219:17 261:22 276:23 277:15 278:24 293:7 294:3
describes 217:20 259:11 259:13 263:17 273:17 275:16 275:25 283:24 283:24
describing 217:15 272:18
description 3:7 217:7 230:7,8 230:12 277:10 301:17 302:1
desiccated 103:17
design 75:17 80:9 188:7 252:2
designate 159:11
designated 8:24 118:22 155:24 190:18 228:6
designed 75:19 75:21 79:24,25 241:7 249:21 251:10
desired 84:5,22 190:16
desmarais 7:21 8:2
detachment 106:14
detail 205:19 242:2
determination 30:12,14 32:8 54:14,18 55:25 60:8,10 166:23 176:1 180:16 180:21 182:3 188:23 210:11 232:14 244:6 297:7
determinations 169:6 171:2
determinative 31:4
determine 31:17 68:24 76:23 77:2,23 100:10,15 175:9 183:21 200:5 202:5 208:4 210:13 212:12 283:17 293:12 296:1
determined 56:5 59:25 218:22,23 262:8 278:1 279:7 307:18 307:22 308:7
determining 31:22 108:24
develop 19:16 33:22
developed 52:3 55:21 96:5,6 102:12 165:3 171:16 200:1
developing 14:23 158:17 169:19
development 20:1 45:25 263:18 264:25 268:5 287:4
developments 125:22 126:15

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 327

device 70:2
devices 124:24
dia 24:25
diabetes 17:22 17:24 18:14 20:11,13 21:20 22:19 23:5 25:22 70:24 225:15
diabetic 3:15 17:19 18:10 19:16 21:9 22:1,22 23:2,6 23:11,15,16,19 24:1,7,9,10,19 24:22,23,25 25:3,19,19,23 26:10,15,19,22 27:12,17 29:17 29:21 31:9 32:4 33:24 44:3,7 60:22 62:1,20 67:3 70:24 73:24 74:11 83:15 129:23,25 130:1 142:16 142:17 207:21 211:6,8 212:4 213:25 222:9 222:11 223:2,7 223:10,16,24 224:2,5,11,14 224:19,23 225:3,13,20,21 226:6,7,12,13 232:19,19 239:25 263:18 264:25 267:24 268:6,21 269:6 269:8,9 284:9
diagnose 33:23
diagnosed 21:4 226:2
diagnosis 33:7 34:12,25 63:21 65:22
diagnostic 32:18 226:3
diana 110:13
dickinson 4:5
differ 184:20
difference 45:9 57:14 102:6 159:19 178:12 178:22 179:6 179:12,20 196:11 201:25 206:12 219:15
differences 36:4 97:18,24 102:8 103:24 104:22 181:3 181:12,17,22 211:11
different 11:14 11:15 14:25 25:6 41:22 60:25 63:16 65:3 67:19 68:10 72:13,24 75:24 77:22,25 82:10 83:9 84:8 90:15,16 98:8 101:22 104:1 115:7,7 126:2,9 131:10 131:10 135:19 135:20 137:6 140:6 161:6 174:24 185:11 187:25 188:6 198:6 201:20 201:23 208:23 209:19 210:7 217:9 225:23 231:3 236:14 238:13 260:8 267:25 268:18 274:15 275:3,9 275:25 278:8 280:24 283:4 298:23
differential 77:24
differently 99:9 114:10 115:9 115:12
difficult 16:9 16:14 39:1 51:11 105:6 199:20,20,21 221:13
difficulty 39:15 199:5 224:9
diffuse 43:19
digits 7:2
dilated 18:5
direct 139:2 143:25 155:16 166:9 216:18 272:23 285:3
directing 158:12
directly 74:20 260:10
disagree 78:6 279:7 292:23 292:24
disagreed 123:4
disclose 8:10 177:23 237:10
disclosed 277:7 279:6 286:9
discloses 237:17 263:19 268:4
disclosing 237:6
disclosure 257:24 258:15 273:4 288:19 296:22 302:10
disclosures 288:16 301:16 301:21
discontinued 7:24

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 328

discretion 241:23 249:24 252:5,11 253:4 253:10 255:4 259:18
discuss 126:1
discussed 84:5 88:10 92:16 115:23 117:7 117:14 136:16 136:21 143:21 174:20 227:8 259:10 268:11
discussing 10:14 18:11 23:4 34:25 42:5 244:18 254:4
discussion 101:19 146:16 155:13 162:13 197:3 217:15 249:13 264:17 290:14 304:3,9
discussions 116:15 117:9
disease 14:22 17:15 18:10 19:18 21:14 23:9 27:14 28:3,4,7,8,12 28:13 29:14 31:8 32:6 42:9 46:3,24 47:10 47:16 58:13 61:22 67:21 68:14 83:16,22 132:24 189:24 190:13 193:19 193:20 199:6 202:22 206:16 206:21 207:2,8 210:13 212:21 212:23,24 213:16,19,24 213:25 214:11 215:2,5,7,10,11 215:15 216:6 223:4,11,25 225:14,16,24 226:4,11 239:18 251:24 283:19 285:18 287:13,21,22
diseases 15:22 24:12 41:19 51:10 126:7 134:13 164:22 200:20 211:8 251:7 278:5 286:20 287:22
disorder 287:4 300:2
distinction 194:12
distinguished 130:16
diverse 17:22
division 95:7 125:25
dme 21:9,13 22:9 23:24 24:12 25:8,10 25:14 26:4,7 27:9 28:18 30:4,10,17 31:3,5 41:2 43:1,4 47:2,23 60:16 61:7 62:5,12 71:20 72:18 73:15 102:16 129:16 129:20 130:8 133:7 142:10 206:2 207:11 207:18 211:13 221:12,21 222:1,6,16 251:3 269:11 275:17 276:1 277:8
doctor 14:20 123:16,17 221:3 241:22
doctoral 14:20 14:24 15:13,23
doctors 44:13 123:22 124:7 209:18
document 46:17 49:3 122:8,14 123:8 128:23 129:2,4 138:20 147:1 148:5,22 149:25 154:5 154:11 155:24 156:22 159:6 162:3,6 227:16 230:21 256:13 256:19 263:4 273:2 283:5 285:10 291:17 299:3,5,9,11,23 300:2
documentation 85:25
documents 3:8 115:2,8 121:14 121:15,16,20 123:12 149:19 155:7 167:18 172:9 173:9,12 173:22 179:23 179:25 180:3,5 185:4 228:11 228:25 256:5 266:1 267:8 283:8 288:20
doing 22:17 69:21,22 83:4 143:14,17 170:12,14 202:10 203:7,8 209:2 250:8 272:9 280:16
domain 181:13
dosage 136:24 137:13,23,23 142:9,13

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 329

dosages 285:22 287:2
dose 57:17,20 140:12 206:3 211:25 212:7 229:13,21 230:1,3,5 253:5 255:9 257:1 268:6 282:25 286:6
dosed 87:16 107:23 108:8 108:17 263:20 277:22
doses 59:14 77:22,25 86:15 107:15 199:9 199:17 200:12 211:1,5,12,17 229:12,17,20 229:21,25 230:8,9,17,18 232:18 237:12 237:15,19 238:3,6,11,15 238:16,16,16 238:24 255:22 259:14,15,17 260:2,4,5 262:3,7 263:22 263:23,25 264:21 268:9 271:15 272:10 274:22,24 276:5,11 278:14 279:22 281:9 282:10 284:1,20 285:16 289:17 289:19,20,21 290:20,21 291:13,14 292:1,2
dosing 49:14 79:25 80:5,10 85:12,13,17,19 85:22 86:3,6,9 86:12,18 107:25 108:2 111:25 137:3,4 137:6,12,25 140:3,5,7,12,18 140:19 141:1 141:13 142:17 147:14 190:23 192:7 199:8,23 201:12,13 202:4 206:14 208:20 209:22 210:6,23 211:18 217:2,8 217:17 218:1,2 218:9 220:4,9 220:19,20,22 232:24 253:22 258:16 259:1,7 259:11,22,23 260:4,8 261:18 261:20 262:10 267:25 268:18 268:20 269:3 270:18,20,21 270:21 271:5 274:15,19,20 274:20 275:10 275:16,25 276:5,9,14,21 277:6,7,11,13 277:18 278:18 279:1,1,4,6,13 279:15,21 280:1,1,19,24 281:19,25 282:2,8,14,19 283:4,9,13,16 283:18,22,23 283:25 284:1,3 284:16 286:16 286:18,23 288:25 291:12 292:5,8 294:5 297:16 300:1,6 302:15
dosings 241:8
dozen 43:24,25 50:7
dr 3:11 5:7 6:1 23:19,23 24:12 25:8,10,15 26:3,7 27:8 28:19 29:4,9 30:4,9,17 31:2 31:5 35:1 41:3 43:1 71:20 82:25 109:13 109:15,23 110:1,3,8,10,13 110:14,15,19 128:24 129:17 129:20 130:9 138:17 142:10 143:8 195:19 198:2 221:12 222:1,6,22 233:25 257:22 293:15 303:18
drafted 35:13 174:14
drafting 34:10 35:1 160:20
draw 71:10
drawing 194:13
drcr 75:6,9,12 233:25
dried 104:25 210:22
dries 104:2
drug 17:1 29:19 44:19 46:1,3,5,6,6,7 49:15 50:21 51:8 52:10 60:5 61:21 76:24,24 77:2 78:4 79:18,20 80:6 86:11,13 86:15 87:4 90:9,23,24 96:2 100:2

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 330

102:12 131:1 133:1,22 134:1 134:4,16 171:17 185:9 249:20 250:5 279:22
drugs 16:23 44:1 52:14,15 55:16 57:11,15 77:22 81:2,10 94:17 106:24 107:3 124:24 130:21 131:6,8 131:10 132:19 132:21 133:4 165:3 170:5 171:15
dry 102:24 103:9,12,17 104:16 208:7 208:10,18 209:7,12 210:11,25 211:12 213:4,6 269:16
duly 5:21 305:4
duration 105:21 106:4 107:14 108:13 217:9 282:14
durations 206:25
dye 32:23 33:3 33:8,10
dying 16:8
dynamic 67:3,6
dynamics 67:12 209:4 212:23

e

e 3:1 306:1 307:9,12 308:1 309:3,3,3
earlier 88:10 135:17 152:14 155:13 224:18 227:5,8 233:23 243:23
earliest 144:10 145:5,21 146:13,23 148:1,12 149:2 149:20 150:19 151:6 152:22 164:12 167:25 171:7 196:13
early 61:25 62:10 90:22 170:6 171:18
easily 202:22
economic 88:9
economics 88:11
edema 3:15 17:20 18:11 20:2 21:9,12 22:1 23:15 24:10,20,24 25:1,2,18,19,20 25:21,24 26:16 26:20,23 27:18 28:7 29:18 30:1 31:9 32:4 43:19 44:4,7 60:23 62:1,20 64:21 65:5 67:3 68:6 70:24 73:24,25 74:1,6,12 102:19 103:6 105:10 130:1,3 142:16 207:21 208:6 209:4 211:7,9 212:4 213:17 214:3,4 215:10 222:9 223:16 226:13 232:20 240:1 240:15 263:19 265:1 267:25 268:6,21 269:6 269:9,9 284:9
edge 52:5
edward 1:14 3:3,11 4:2 5:7 5:20 305:3 306:2,20 307:5 309:2
effect 23:4 46:2 83:16,22 86:24 87:1,3,6,10,11 87:21 98:11 100:2 134:11 134:11,14
effective 41:7 42:17 60:1,9 60:18 61:17 106:7,25 135:1 196:5,12,18 261:19,21 297:15
effectively 203:4 269:15
effects 19:5
efficacies 77:24
efficacious 61:16 62:5 78:4 133:2 134:5 135:6 251:24 286:19
efficaciously 268:20
efficacy 61:25 62:12,15 76:25 77:15,20 78:19 79:10 80:15,19 80:23 97:25 107:9 132:25 134:23 199:17 240:17 250:23 262:5 267:23 275:8
efficient 202:14
effort 259:20
efforts 128:9
egress 18:3
ehr 50:2
eight 43:25 208:24 210:14

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 331

213:10,11 229:16,25 230:4,9,14,18 238:16 263:22 268:8 270:20 274:21 280:4 284:5,14,19 286:23
eileen 2:13 5:19
either 90:4 121:16 188:6 205:13 209:14 245:20 246:6 260:18 266:9 267:12 270:2 303:17 305:14
el 237:2
element 187:15
elements 187:8
eligible 242:11
elman 74:25 75:10 118:22 232:3,8,11,15 233:16,17,25 236:8,17 237:2 237:10,17 238:1,1,9,13,23 257:24 258:7,8 259:7,10,13,23 260:9 271:20 271:21,23 272:4 296:21 296:25 297:6
elman's 232:22 258:15,16 259:1
emanuel 2:3 7:9,11,14,17,25 8:20,23 10:9 10:21,25 11:4 13:16 115:16 115:22 174:7
embodiments 229:13,15
employ 43:9 44:13 51:5
employed 200:23
employing 204:18
enable 295:8,22 296:7,16,23
enabled 296:2
encompass 29:24 152:18
encompassed 259:22 300:7
endothelial 19:4,9
engineering 124:22 125:7
enrolled 75:15
enrollment 265:1
entire 73:9 119:2 264:12
entirely 254:1
entirety 253:1
entities 186:18
entitled 39:4,12 40:14 129:11 145:16 162:19 305:5
equal 256:17
equilibrium 67:11
era 55:12
errata 307:14 307:16 308:3,5
especially 269:4
esq 2:3,8,8 307:1
essence 165:4 302:2
essentially 76:1
establish 12:7 103:22
established 102:17 251:19 280:14
et 4:10 149:19 213:12
evaluate 28:2 63:24 296:1
evaluated 76:25 295:17 295:20
evaluating 3:13 150:8,9 163:11 191:21
evaluation 47:21 167:24
eventually 292:19
everybody's 72:12
evidence 61:13 61:25 64:22 65:1 102:4 104:19,19
ex 261:3
exact 41:6 100:1
exactly 79:13 102:11 148:22 247:15 272:22
exam 47:15 60:13 70:20 100:14,14 208:17 218:24 219:2,9
examination 3:4 5:24 31:25 212:1 217:23
examine 27:7 73:9 202:5,9 202:23 208:3,4 283:16
examined 5:21 51:10 62:22 152:11 153:14
examining 31:24 69:24
examp 168:11
example 24:21 26:21 27:16 39:16 51:8

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 332

66:23 73:23 76:24 120:7 133:19 147:3,6 147:13 152:6 152:16 168:11 168:14 176:6 185:17 186:8 186:10,18 197:2 199:7,8 206:2 207:9 213:2,17 218:23 222:10 229:12,15 272:16 274:6 274:10 291:12 296:10
examples 74:15
excellence 124:10
except 4:11
exciting 15:4
exclude 223:5
excuse 17:20 107:22 150:9 151:15 165:20 198:6 258:21 270:15
exercise 281:5
exhibit 3:8,9,11 3:12,16,18,20 3:21 112:18 116:18 128:20 128:21,25 129:11 135:12 138:10,12,25 139:12 141:11 142:9,13 143:25 151:14 151:15,16,17 152:6 153:18 155:12,18,24 156:22 157:5 164:16 180:9 190:19 227:4 227:12,22,23 228:5,15,23 230:21 231:22 233:18,20 234:7 239:6 249:18 258:4,5 260:13 262:25 263:1,12 264:21 272:14 273:25 274:14 275:17,24 276:24 277:15 278:25 280:2 281:20 284:24 284:25 296:15 297:21 298:8 298:10,12 299:6,23 302:12
exhibits 3:6,7 112:10,12 113:6 117:22 118:3
exist 225:17
expand 61:20
expanding 188:12
expands 175:23
expansion 196:1
expect 79:13 104:1 190:11
expectation 104:16 190:5,8 190:22 191:4,8 191:13,23 192:13,21 193:1 194:9 233:7 258:24 261:3,14 262:14
expected 172:19 265:3
expedite 304:7
expensive 89:11
experience 16:15 27:4 45:1 55:13 101:6 165:16 165:22 171:1,1 184:24 212:16
experienced 164:19
experiencing 16:11
experimentat... 188:1
expert 7:17 10:25 12:10,15 13:5,10 36:15 147:5 153:22 166:2
expertise 8:12 8:14 55:13 66:3 101:16 117:10
expires 305:25 306:25
explain 173:19
explained 35:22 162:24 163:17 179:21
explains 173:11 261:22 262:6
explanation 163:2
explicitly 237:10
explore 80:5
explored 79:25
exploring 251:6
expression 17:21
extend 201:6,8 201:10,12,16 201:19 202:4 203:9,10,22 204:2 206:13 206:19,24 207:1,17 208:19,23,25 208:25 209:1,7 210:9,14,24

211:24 212:3 214:9,20 217:16,21 282:13 283:13 283:23 284:16
extended 108:25,25 206:20 210:9 211:18,20 213:3,21 284:1 284:19
extending 209:14 213:10 214:15,16,18 280:1 282:8,14 283:22 284:3 284:13
extends 209:21
extension 107:8 107:9 212:22 213:14
extent 173:14 203:9 279:5
eye 14:21 18:7 18:10 19:1 21:7,22 23:5,9 23:13 28:9 33:11 106:19 133:22 134:12 250:5,8,11,25 251:15,18 263:17,19 268:2 269:14
eyes 239:15 241:1 254:6,9 254:15,17 255:13
eylea 3:8 29:4,8 30:5,6,9 50:16 83:14,21 84:8 84:23 85:5,9 86:24 87:21,25 88:3,7,12 89:20,22,24 93:9 97:6 100:18,20 101:7,18 102:4 103:25 104:15 104:16,23 105:20 129:2,4 133:14 135:12 135:22 136:2,9 142:2,20 192:17 211:13 237:6

f

face 153:18
fact 8:22 9:3 38:8 59:5 115:6 141:11 163:14 266:13
factor 19:5 31:4 102:2 181:8
factored 84:13
factors 47:20 71:8 180:11,12 180:15,20,25 190:2 198:16 210:7
failed 43:20
failure 239:11 254:5
fair 22:7 25:11 37:25 42:24 50:10 63:4 65:23 75:24 83:17 91:14 100:4 103:7 107:15 123:16 146:5 155:5 158:17,21 165:17 189:22 201:22 204:12 209:21 217:17 224:20 232:8 233:14 241:16 247:22,22 253:18 267:11 282:17 289:7
fairly 235:3
familiar 9:1 22:24 38:18 45:15 50:8,20 80:21 81:13 97:21 110:23 111:11 117:17 117:23 118:1 118:13,15,18 118:20,23 119:1 120:7 129:9 137:15 149:14 170:16 170:21 171:8 183:25 197:12 198:2,21 204:22 234:11
familiarity 81:17
families 16:8
famous 195:23
far 48:15 150:21
faster 104:17
fda 30:9,14,16 44:1 55:25 79:1,16,19 81:11 130:8,11 130:15,20 131:3,12,18 132:13 133:20 134:1
fda's 30:11,21
feature 25:3 29:13 66:22 219:8 226:11
features 24:8,8 27:14 28:13 31:7 32:3 45:8 46:23 47:9 65:4 66:15 67:20 189:25 223:4 240:17
federal 4:8 308:1,8,9
feel 6:12 71:1 208:13
felt 59:19 88:8 99:3,14,15

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 334

fibrosis 15:9
fibrous 18:23
fibrovascular 19:14
field 109:19 125:22 165:9 185:10 188:5,6
fifth 241:10,20 255:9
figure 166:1 242:16,19,21 242:22,23,23 242:25 247:4 247:14 248:1 248:23 259:21 280:23 291:16 291:22 292:9 292:19
figures 236:24
figuring 278:7
filed 12:9 35:17 147:12 152:1,2 153:17 154:6 154:10 158:1 168:15 274:11
filing 152:10 164:14 196:6 196:12,18
filled 64:25
film 18:6
final 120:11,15 121:2,4,4,7,10 155:20,23 156:4,12,16 157:4,10,14,23 158:2,7 159:2 159:15,20 160:9
financial 58:5
find 144:17 161:11 221:13 244:10 256:7 256:18 257:23 271:10
finding 187:2 242:22 256:11
findings 127:8
fine 195:18
finish 139:20
finished 273:1
finite 189:8,13
firm 5:18 7:20 8:2
first 5:21 50:23 53:25 56:1,8 61:4,5 70:4 90:9 105:12 111:13 121:1 132:4 136:8 172:2 175:13 182:2 219:5 234:9,19 235:13 250:2 265:3 284:5 289:16,21
firsthand 16:11
five 229:16,21 230:8,14,17,19 232:17 233:1 237:11,11,15 237:18,19 238:3,3,5,10,14 238:14,24,24 255:21,21 264:21 276:5 281:16 284:20
fix 15:7
fixed 137:25 138:4,7 140:2 140:6,18,22 141:1,13
flexibility 133:4
flip 258:11
floor 2:4
fluid 18:3,5 19:24,25 31:9 31:14,18,23 32:4,9,9,17,22 63:3,6,12,14,15 63:17 64:25,25 65:1,4,4 66:16 66:17,19 67:1 67:7,9,10 68:1 102:17,20,24 103:20 269:12
fluorescein 32:20,24 33:8 33:9 43:14
fluorescin 60:14
focal 43:15 55:13 263:25
focus 16:19 27:3 68:17 73:12 121:1 125:19 132:23 174:2 175:12 176:5 207:11
focussed 282:20
foerster 2:9 5:18
follow 28:1 100:13 105:9 126:24,25 155:12 172:19 294:9 295:12
followed 5:10 172:12,15 219:5 222:9 230:9,17 259:15 261:20 261:25 270:20 270:21 282:21 291:13 292:8 297:16
following 144:10 146:4 146:13,17,22 148:1,11 149:20 151:6 152:14 304:4 306:4
follows 5:22 229:24 249:14 307:8
footer 139:5,6 139:11 285:10

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 335

forces 184:14 185:1,17 186:4 186:9 188:8
foregoing 305:3 306:3
forgive 124:25 126:17 242:22
form 4:12 19:17 20:17 21:16 22:13 24:13 26:8 27:10 28:21 29:10 30:19 31:6,19 33:19 35:4,5 36:9 37:18 38:1,11 38:20 39:5,13 40:16 41:4 42:18 43:10 44:15 47:4 49:16,23 52:18 54:12,22 57:6 59:7 60:19 62:6,17 63:22 65:13 66:13 69:1 70:16 71:13,23 72:8 72:20,21 73:7 73:16 76:17 77:11 78:5,15 80:16 84:15 94:12 95:12 96:19 98:2 100:5,21 101:10 104:5 112:1 114:13 116:1,20 123:5 129:21 135:7 136:17 138:2 140:20 146:6 150:10 151:8 154:8 157:16 161:1 168:3 176:13 177:5 177:25 178:16 178:25 179:15 181:9 182:18 183:2,15 185:20 186:25 187:6 188:24 191:15,25 193:3 195:6 200:24 204:13 206:6 207:6,19 210:16 212:14 216:3 217:3,11 217:18 218:4 219:25 220:10 220:21 221:4 222:17,25 226:9 230:10 230:24 231:6 231:13 232:12 235:5 237:20 238:17 241:15 242:9 243:16 244:1 245:11 246:1 248:3 249:1 252:7 253:24 255:23 263:15 265:8 265:24 266:22 267:5,16 270:4 274:17 275:18 276:16,25 279:9 280:6 281:21 282:22 289:2 290:1,12 291:7 292:10 294:7,17 295:16 298:23
formalities 4:9
formally 225:22
format 57:21
formed 156:4
forming 158:4
formulary 88:25 89:2,23 90:1 91:17,21 91:24 92:3,8 92:11,13 93:9 93:13,17,21 94:7,17 136:15
forth 23:17 137:5 164:3 180:8,9 184:5 233:11 259:23 261:12 295:12
forward 15:1 202:23 258:11 258:20
found 156:6,13 157:10 160:25 161:2,25 232:23 242:25
foundation 112:2 191:16 192:1
four 180:12 208:24 219:4 229:16,19 230:13 233:1 240:2 241:8 253:19 255:15 255:15 259:14 259:16,18 275:3,10,16,25 276:4,23 277:7 278:22 282:18
fourth 276:8,13
fovea 72:11
fragment 96:23
frame 69:25 126:12 128:2 165:3 167:8,10 167:11 170:4,5 170:6 202:8 281:6
francisco 2:10
frcp 308:1
free 6:13
freeman 2:13
freeze 271:24
frequencies 302:15
frequency 107:2 209:16 217:23 220:13 268:20 271:11

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 336

frequent 205:3 219:6 261:20 262:1 278:25 279:1,4,6,13,15 280:1 297:16
frequently 108:7,19 202:24 278:18 289:21 290:21 294:15
front 119:9,19 228:24 263:9
full 92:21 93:2 95:21 96:20 264:4
fully 13:2 208:6 213:22
function 19:7 63:13 193:18
further 145:12 175:23 196:1 206:24,25 210:14 262:6 262:12 269:2 302:21 303:16 304:10 305:13
fusion 101:25
future 28:4 74:21 200:4,7 215:22
fwd 156:6,6

g

garnered 77:6
gears 258:3
gel 19:13
gen 37:3
gene 15:3,3,5,8 15:13,14
genentech 96:8 96:12 108:11 108:16 288:15 294:5 299:19
gener 70:1
general 8:13,16 11:10,11 21:22 22:15 23:6,12 24:2 40:1,5 61:17 76:4,12 76:19 77:13 78:2,13 81:16 86:9 87:12 97:22 98:5 105:24 113:10 120:17 143:11 143:12 147:14 171:15 204:6 259:23 264:18
generally 14:13 76:2 77:8 81:7 81:15 226:2
generate 175:9 176:15
generated 70:2
generates 37:4
generating 117:4
generically 130:25
genetics 14:21
gesture 123:19
getting 64:11 78:4,8 79:18 99:12 130:19 224:9
give 28:23 59:14 73:22 86:11 90:20,24 185:16,17 207:8,9 208:8 208:11 209:13 211:25 213:5 242:17 244:17 246:23
given 20:8 60:10 86:13 90:24 103:24 107:3 141:8 207:14 269:4 277:17 285:25 286:3
gives 127:24
gleaned 166:24
go 9:10 16:12 20:7 21:18 40:3 48:5,16 48:21,23,25 49:21 56:14,16 60:4 81:2 82:1 83:18 95:22 118:8 123:8 126:11 130:18 132:12 142:8,8 145:19 155:11 161:16 171:24 175:22 181:24 186:24 195:11 197:11 241:25 243:7 244:9 249:5 253:4 258:4,5,20 266:5 293:11 294:25 295:3 297:9 299:23 299:24 301:2 302:12 303:5,7
goal 103:1,8 215:1,12,13 255:1
goals 102:22 103:9 269:4
goes 32:25 151:1 173:8 215:11 253:8 284:4
going 5:2 11:19 15:1,7 33:24 38:17 39:17 65:11 66:11 67:17 69:21 82:17,21 101:3 127:2 128:10 139:18 142:25 143:4 161:24 174:15 195:12 195:19 197:19 197:23 198:14 202:23 211:24 212:5,7 214:7

215:7 218:25 247:21 253:4 257:5,15,18 303:9,13 304:1
gold 41:2,11,14 41:18
good 5:1 6:1,3 27:25 49:5 51:18 55:12 73:25 82:13,16 126:22,22 127:22 200:8 213:19,19
gotten 255:8
graph 260:1,3
great 139:19 227:1
greater 246:7 256:16 281:9
grounds 184:1
group 240:11 240:15,25 241:2 242:5 243:10,21 246:25 247:25 254:8,10,15,16 254:25 255:14
groups 292:1
grow 18:19 19:2,10,10,13
growth 18:23 19:4 102:2
guess 44:10 49:5 53:9 66:8 76:11 78:23 89:9 100:9 127:6 137:4,10 178:21 216:19 234:16 239:6 243:17 245:16 252:21 278:15
guidance 280:19
guide 68:23 191:22

h

h 309:3
habits 44:11
half 7:8 11:4,7 43:24,25 50:7 263:10,20 265:3 268:7
hallmarks 27:9
hand 18:21 104:23 128:19 139:6,10 144:2 151:14,15 206:12 227:21 233:16 239:8 249:9,18 298:10 301:7 305:18
handful 59:24
handled 307:8
hands 233:9
happen 17:24
happened 9:14
happening 19:1
happens 18:20
happy 120:3
head 80:25 134:21,21 226:20
heading 136:24 136:25 137:14 137:24 142:14 162:19 244:19 249:9 264:7 270:2,3,23
heal 18:24
healing 18:21
health 48:22 50:2,2 52:3 57:24
healthcare 58:3
healthy 71:20 202:21 203:15
hear 11:23
heard 15:19 76:1
hearing 4:13
height 72:10
held 233:9 304:5
help 228:19 242:15
hemorrhage 28:6
hereunto 305:17
hey 80:5 94:6
high 17:23 19:22 21:20 161:25 213:24
hindsight 166:11,15,19 166:21 167:2 168:21 169:10 169:24
history 44:25 45:14 66:24 70:21 74:11
hit 207:1
hold 256:3
hope 223:19
hoped 294:22
hoping 61:19
hour 139:18 195:15 257:5
hours 113:25
huge 106:21
huh 24:4,18 31:12 39:20 50:9 63:11 68:20 69:8 70:7 72:3 139:1 145:10 186:5 189:3 193:10 212:18 213:8 214:1,25 224:10 225:25 246:20 281:14 283:7
human 95:25
humanized 96:2 97:2
hypertension 67:23 213:20

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 338

hypothetical 164:15,24 165:1 169:14 169:22

i

i.e. 196:4
idea 33:18 35:8 81:8 174:12 202:3 300:9
ideally 251:16
identified 145:1 154:22 163:22 173:18 189:8 210:20 220:5 242:20 245:8
identify 164:8 194:25 195:3 255:2 256:3 262:24
ignorant 126:18
image 64:19 65:11 66:2 69:19,20,24
images 64:15 64:17 66:24 69:25 105:16
imaging 32:7 43:2 44:24 60:13 63:24 64:2 100:15 105:11 208:18
immediately 230:1,5
impact 17:18 17:21 19:20 20:10 21:7,19 22:18 46:3,7 51:19 63:17 66:20 74:16 97:25 104:1,24 192:8 222:10 239:25 240:13 250:12 251:17
impacted 240:5
impacts 20:11
imply 256:24
important 31:24 66:17,22 69:12 153:15 275:10 287:20 293:6
importantly 58:10
improve 187:19 188:2
improvement 62:20 69:14 87:13,14 193:15,16,18 245:18 253:11 253:14
improvements 187:22
improving 193:7
inaccurate 163:5
incites 251:15
incl 24:9
include 24:8 26:16,20 36:23 37:11 39:11 40:6,10,13 51:16 86:12 122:2 129:25 130:3 157:4 167:20 168:16 175:16 187:18 193:15,16,17 193:18,19 223:5 247:5 265:14 300:10
included 23:14 92:15 122:2 148:23 152:8 163:15,21 168:1,10,12,15 180:21 187:13 194:8,16 251:25 307:14 308:3
includes 24:10 142:1 152:15 180:10,16
including 186:4 267:8
inclusion 251:25
incompetence 33:2
incompetent 18:1,4
incomplete 163:4
incorporate 29:24 58:6 68:11
incorporating 67:14
incorrect 103:14
incredibly 200:11
increments 213:14
independent 156:5,7 158:5 163:9,16 167:24
independently 13:17,22
index 3:6
indic 28:25
indicated 88:8 208:5
indicates 159:4
indicating 108:2
indication 3:8 26:24 28:25 29:4 30:4,17 74:9 86:11 129:2,4,17 130:8 131:12 133:8 223:9
indications 20:14 21:3,5

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 339

129:12 130:13 132:20,22 133:4 135:19 136:23
individual 49:3 49:13 50:1 109:3 110:7 204:20 247:9 247:15 289:17 289:19,20,21 290:20,20
individualized 198:3,9 210:1
individualizing 198:13
individuals 17:13 20:11,12 247:16
industry 61:23
infection 106:13
inflammation 250:12
inflammatory 126:6 251:15 251:16
inform 160:23
informally 225:22
information 37:4 69:9 101:5 127:8,24 147:10 158:9 158:13 166:22 166:23 167:7 167:21 168:1 168:11 211:14 232:16 256:2 260:7 273:9,12 273:16 299:19
informative 20:10 158:11 158:16
informed 11:13 11:16 159:1
ingredient 95:11
initial 7:23 8:12 16:15 62:19,23 77:7 77:14 133:21 134:9 135:13 145:12 152:4 152:10 199:9 199:13 207:16 211:1,5 217:9 229:20 230:17 232:17 241:5 259:14,16 261:23 269:20 270:20 279:20 283:25
initially 7:19 91:20 240:16
initiate 207:22
initiated 91:3
initiation 61:9
injec 243:25
injected 32:24
injecting 290:11
injection 43:22 60:12 67:25 71:2 90:20 105:8,9,12 133:25 202:18 208:8,9,11 209:13,15 217:22 219:6 232:25 241:3,5 241:13 242:6,8 242:11,12 243:25 246:17 247:2 250:3,4 250:4,18,20,22 251:11,14,23 252:1,17,24 254:12 256:17 257:1 268:13 268:14 270:19 271:11
injections 59:21 106:10 106:12 207:25 215:13 217:10 233:2 249:21 249:21 253:19 254:19 255:1 255:10,15 268:23,25 269:18,21 270:19,22 271:6,12 283:17 284:4,5
injects 210:5
injury 18:22
input 57:4
insight 246:23 283:3
instance 17:19 21:2 35:25 80:4 94:6 133:6 148:11 192:17 207:5 238:15 241:21 289:10
instances 83:17 83:23,24 84:1 212:7 224:22
institution 48:18 50:3 120:22 122:10 159:16,19 160:12,15,19 161:6,19
institutional 134:7
institutions 49:3 52:13
instructed 154:25 159:1
instructions 155:8
instructive 192:3
insubstantial 106:17
insufficient 301:17

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 340

insurance 58:3
intellectual 170:9
intellectually 170:3
intensive 202:2
intentional 226:19
inter 1:6 12:10
interact 125:24
interacted 94:5
interaction 212:19
interactions 85:25 200:18
interest 8:12 14:17 15:12,21 37:5 46:2 61:16 105:25 107:1,11,17 108:23 185:8 186:15,19
interested 14:24 55:22 85:21 95:3 218:19 305:15
international 3:18
interpret 29:21 236:23 240:20 273:16 284:15
interpretation 111:23 198:5 236:13,17,20 244:4 248:6,18 250:13
interpreted 194:15 196:5 196:22
interpreting 235:19 239:19
interval 201:17 201:18 202:4 212:22,25 214:20,23 215:20 261:24 262:1
interval's 215:22
intervals 203:11 214:17 260:4 276:22 277:6,7
intervention 45:3 46:7 59:12 101:2 189:25 190:15
interventions 45:13
intit 61:9
intraocular 252:1
intravitreal 41:19 43:22 133:25 217:22 219:6 268:25
intricacies 45:10
introduce 138:9
introduced 50:23
introduction 5:6 170:4
invalid 12:24 13:8
invalidity 173:2
invariably 25:5
invasive 250:8 250:11
invention 150:5 168:22 188:19 188:19 229:10 262:11 295:9 295:11 296:3,9 302:1
inventor 33:14 34:6
investigate 53:16,20
investigation 54:10,19 288:14
investigator 109:4 249:24 252:5,11 253:4 253:10 259:19
investigators 109:5
invitations 198:6
involve 264:21
involved 94:24 95:1 109:13,20 111:3 115:23 234:2,4
involvement 34:10 35:1
involving 204:25
ipr 6:15 8:24 10:10,23 13:4 83:9 117:3 120:11,15,19 120:23 121:7 122:5 155:14 157:3 158:16 159:8,8,12,23 160:15 184:1
ipr2023-00739 1:7
ischemia 68:4
issue 38:19 95:2 136:15 158:6 175:3 188:7
issued 147:13 150:20 154:2 288:9,12 299:16
issues 13:24 21:4 117:1,2,6 117:11 120:18 222:23

j

jack 2:8 5:17
janu 153:8
january 1:16 4:3 5:4 152:1,2

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 341

152:15,23 153:2,17 154:6 164:13 165:16 167:17,25 168:2,9,18 171:8 196:19 196:24 203:24 204:3 221:10 221:18 305:18 307:3,5
jargon 138:7 140:2 193:12 194:23 233:14
job 307:5 309:2
joined 5:16
journal 36:6,21 40:7
journals 36:19 126:19,22,24 128:4
judgment 64:14,18
judicious 214:8
july 48:23,25 145:17,23 146:2,2,4,17 147:10,12,20 148:13 150:24 152:7 153:2,10 167:13,17 168:2,15 196:19,25
junctions 18:2

k

keep 126:8,14 128:5 195:19 209:7
kept 127:1
key 21:14 117:5
kind 42:21 124:24 150:12 186:22
klibenon 110:10
knew 46:18 118:8
know 6:9 16:12 29:20 30:8,11 30:16,20 33:20 36:20 37:6,13 37:15,23 38:9 40:20 41:13,18 47:12 49:18,24 50:1,2,4 51:3,6 51:6,12 52:21 52:22 53:5,13 55:21 56:7 59:1 64:2 67:16 69:3,4 69:15,15 74:10 74:25 75:11 79:4,12 80:13 81:6,9,12 89:3 89:17,19,25 91:25 92:2,12 93:15,22,25 94:3,20 95:20 95:24 96:2,5 96:22 97:2,6 97:23 98:3,15 101:17,20 102:11 105:1 108:5,6,9,11,15 109:9,12,15,17 109:18 110:2,2 110:7,14,15 112:24 114:5 116:15 118:6 118:11 122:9 122:14 124:1 125:4 126:19 127:18 129:5 130:15 131:11 135:21,25 137:17 138:8 139:13,18 154:4 156:18 157:12,13,19 157:22,24 158:24 159:18 160:3,8,10 163:24 164:5,5 173:1 174:4,8 174:9 178:3 179:6 180:23 185:10 193:23 195:13 196:18 199:8 200:10 200:12 203:2 204:5 205:3,5 209:6,8 214:19 215:6,22 222:7 225:8 227:16 229:2 231:10 234:3 241:19 244:16 251:22 254:14,17 257:5,9 259:13 260:13 272:21 272:25 274:9 274:12 282:23 288:2,8,10 293:15,20 294:4 298:2,6 299:4,15 300:14 302:6,7
knowing 287:13
knowledge 81:1 135:18 146:1,4 151:4 152:12 155:3,6 163:10,16 171:15 182:10 182:15,25 183:9,24 184:13,18 185:5,12 190:12 260:7 269:7 287:15
knowledgeable 164:23
known 21:19 102:10 103:2 109:19 187:9 187:15,19,20 187:21 279:12

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 342

l

l 4:14 305:24
label 29:4 30:5 30:7,12,22 44:2 52:9 108:2,5,7,10 129:5,6,9 130:7,19,21,23 131:6,14,16,21 132:2,9,11,13 133:7,9,14,19 134:4 135:12 142:7 251:3
labels 141:12 141:18,19 142:1
laboratory 34:1 35:10 125:12
labs 22:17
lack 69:14
laid 174:24 260:2
laminated 64:24
lamp 32:1
lane 2:8 5:17
language 175:16 181:11 190:9 229:19 256:24 298:5,6 300:25
large 55:9,10 90:13 93:3 126:14 127:11 127:12
larger 63:16,17 77:19 78:17,19
laser 3:14,15 43:15 47:3,22 48:4 55:13 68:6 74:5 239:16,24 240:3,4,9,11,15 240:18 241:2 243:10,21 246:19,25 247:25 254:8,8 254:10 255:14 264:1 269:20
lasted 114:1
laundry 300:13 300:16 301:16 301:21 302:5 302:10,16,18
law 37:13,14,16 37:23 38:9,18 174:23
layers 64:23
lcr 305:24
lead 60:9 224:20
leading 52:5
leak 18:5 19:24 19:25
leakage 18:8 32:22 33:3 47:10,11 203:17 269:11 269:17
leakiness 103:1 103:4
leaking 67:7
leaky 19:21
learned 21:25
learning 165:5 165:8
learnings 21:14
leave 53:22 128:16 130:3
led 14:16 144:11 145:6 145:21 146:14 146:24 148:2 149:21 151:7 188:17
left 129:13 249:9,18
legal 35:21 40:17 120:9 121:14 149:18 157:13,17 162:20,23,25 163:3,4,10,15 163:17,21 164:2 173:6,17 173:20 178:1 178:16,25 179:15 182:19 183:3 185:21 189:15 307:7
legally 302:8
length 95:21
lengthen 108:12
letter 245:7 246:7
level 27:12 28:3 28:11 36:4 42:12 161:25 213:19 214:11 224:2 235:18
levels 25:3 223:12 224:4
liberates 19:4
license 305:25
licensing 125:3 125:5
light 252:14
likely 19:25
limit 40:9 289:24 290:7 290:10
limited 58:2 153:24
line 3:2,7 10:2 10:2 71:10 140:3 161:24 161:24 216:24 229:8,24 257:10 270:21 272:15,24 285:4,14 295:3 302:13 306:6 307:15 308:4 309:4,7,10,13 309:16,19
lines 143:20 217:7,16 218:2 218:9 219:16

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 343

219:18 220:5
220:19 273:23
list 52:16 109:9
118:9 186:25
300:13,16
301:16,21
302:5,10,16,18
listed 30:4
129:16 130:8
153:18 162:18
180:25 231:21
266:2 276:9
listing 147:14
301:24
literature
13:23 21:18
22:4 54:5,24
55:6 101:20
117:8 125:23
126:1,16,20
127:5 128:6,9
136:7 181:14
222:3,13
235:11 288:22
293:24
litigation
171:10
little 9:7 63:8
65:18 68:1
72:12,14 81:7
92:20 104:7
124:1 126:18
201:20,23
202:2,14 217:8
227:5 238:12
living 170:6
llp 2:3,9
load 19:23
loading 232:18
237:11,19
238:3,5,10,15
238:15,16,16
238:24 255:22
263:23,25
264:21 268:9
274:22,23
276:5,10
279:22 284:1
284:20 291:13
292:1
location 31:14
66:16
locked 307:12
308:1
logic 273:4
long 109:21
200:11 214:4
216:8 263:10
282:13 303:1
longer 105:21
106:1,4 107:14
201:17,18
202:17,17
203:11,11,21
206:25,25
208:25 216:15
216:15
look 32:13,15
32:21,21 33:21
43:2 48:6,11
48:18 54:4
56:15,16 64:18
66:2 69:18,19
73:3,6,8 77:22
82:1 83:18
86:21 95:22
96:3,21,25
97:4 100:14
105:16 113:4
120:24 121:2
123:8 125:19
129:10 134:8
134:22,23
135:24 142:9
146:10,25
149:23 153:13
159:5,25 174:8
190:17 205:6
206:2 222:3,12
229:19 240:24
242:1,12 243:7
244:3 245:22
248:7 249:3
254:1 257:2
267:14 271:2
288:5,5 293:9
293:25 301:1
302:24
looked 22:5
30:7 48:7 59:1
62:19 63:2
73:1 80:3,9
108:21 120:11
121:9 134:16
175:7 194:3
243:23 274:8
289:13 298:7
looking 16:3
31:3,16 64:14
64:16,18 65:10
66:14 69:24
72:7,17,18
96:4 97:3
99:13 113:2
138:18 161:18
162:13 166:22
166:22 169:21
169:25 173:16
200:16 221:20
221:24 252:3
256:10 257:25
271:4 291:22
looks 27:7
32:12 77:14
79:10 105:2
127:14 243:13
247:25
lose 18:16
203:17
loses 18:17
losing 19:1
loss 18:12
203:19,21
lost 19:12
lot 21:19,24
81:7 214:2
215:25 216:5
lots 22:3 68:9
lower 58:1
144:2 285:8

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 344

301:7
lu 108:13
lucentis 50:16 56:18,18,23,25 57:4,12 59:4 88:15,23,25 89:20 90:6,23 91:11,16,21,23 92:3,10 96:11 98:13,16,21 99:2,10,22 100:11 101:8 103:25 108:7 108:13,17 134:22 237:3 237:12 238:25 294:6
luck 256:9
lunch 143:3,9

m

m.d. 1:14 3:3 4:2 5:20 305:3 306:2,20 307:5 309:2
machine 197:16
macugen 50:21 50:22 51:4,7,9 51:13,13,23 52:9 53:1,24 54:8 58:22,25
macugen's 90:1
macula 32:10 32:17,23 63:7 63:9,25 65:7 72:24 73:1 74:7,16 87:13 193:17
macular 3:15 17:20 18:11 20:2 21:9 22:1 23:15 24:10,20 24:24 25:1,2 25:18,19,20,21 25:24 26:16,20 26:22 27:18 28:7 29:18,25 31:9,15 32:4 43:19 44:3,7 59:17 60:23 62:1,20,21 63:1,20 64:1,7 64:20 65:5 67:3 68:6,17 68:22 69:5,12 70:5,11,24,25 71:8,12,21,25 72:18 73:24,25 74:1,6,12,19 102:19 103:6 105:10 129:25 130:3 134:18 142:16 186:13 199:7,10 207:21 209:4 211:7,8 212:4 213:17 214:3,4 215:10 222:9 223:16 226:13 232:20 239:25
240:14 263:18 264:25 267:24 268:6,21 269:6 269:8,9 284:9
made 16:18 47:6 52:14 58:15 60:8 74:18 88:2 153:16 156:11 202:19
madison 2:4
main 16:16
maintain 106:11 107:3 201:15,17 202:21 203:5 203:14 283:19
maintaining 27:25 262:5
maintenance 291:14
make 6:24 11:22 20:23 23:20 44:18 53:10 54:14,17 57:2 66:3 67:18 70:18 79:22 98:24 106:20 135:17 137:11 169:5,6 184:23 198:14 202:9 206:11 207:22 208:19 209:25 210:2 225:1 240:21
259:20 277:12 286:11 307:14 308:3
makes 63:18 94:2 178:13
making 59:9 67:15 68:11 69:10,20 84:12 85:1 93:19 95:6 128:17 140:13 166:22 171:2 192:13 214:9 258:24
mammal 289:16,18,25
manage 33:24 51:11 68:13 127:19 199:22 202:22
manageable 201:14
managed 28:15
management 27:23 74:14 126:2,4,6 190:16 202:15
managing 127:23 199:6
manifest 20:12
manifestation 18:9 25:2 31:3 225:16
manifestations 23:8 27:13 28:12,13 32:6

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 345

47:9,15 67:20 223:11,25 224:6,13,15,16 224:19,23 225:4 226:6
manner 49:10 198:11
map 43:3
march 115:19
mark 262:23
marked 116:18 128:20 151:16 227:22 233:20 262:25 263:1 284:25 298:12
market 2:9 50:18,24 52:6 54:9 55:21 57:16 184:14 185:1,17 186:4 186:9 188:8
marrow 15:6 15:11,12,18
massachusetts 48:24
material 152:15 168:17
materials 121:22 149:2 149:19 150:17 150:22 152:5 153:1,7,9,14 155:13 157:3 160:14
math 9:8 10:19 277:17 278:7 280:23 281:2,4
matter 10:15 10:16 11:10,11 17:8 86:2 117:17,21 120:6,20 144:8 145:12 151:5 152:13
matters 115:22
maximal 214:23 215:20
maximize 198:19 200:16
maximum 85:7 214:20 215:4
mean 21:17 39:7 41:20 42:7 45:8,21 46:14 49:8 62:5 74:20 85:13,19 86:7 86:10,21,25 87:11,12 95:18 97:12,21 103:16,17 106:3 107:14 121:20 129:1 130:24 138:8 140:2,25 141:1 146:22 147:25 156:10 172:7 172:14 173:14 184:18 193:13 194:15 197:15 198:25 216:4 218:18,21 229:8 245:13 247:5,8 270:24 291:3 293:2 294:15 298:13 301:20
meaning 16:22 39:9 225:14
meaningful 294:2,3
means 25:23 41:14,19,21,21 41:21,25 45:10 75:15 120:8 130:25 166:19 166:21 169:1 172:11 178:8 181:8 198:13 206:1 218:16 233:12 242:6
meant 99:20 140:4 141:5 185:7
measure 63:20 69:5
measurement 69:18
mechanical 197:16
medi 186:17
median 247:11
medical 14:20 48:24 90:13 186:16 288:22
medicare 58:4
medication 29:1,13 59:20 89:18 91:1 131:4,17 132:18 140:16 186:17 190:14 193:6 198:15 199:10 200:12 210:6 215:6,21 277:17,22
medications 90:17 165:6 169:19 170:8 215:14 216:8 281:23
medicine 14:25 15:4,15 45:11 124:23 164:21 185:15 250:17 250:25
meet 113:14 242:7
meetings 62:9 113:18,19,22 114:1 162:6 171:19 265:11
memphis 57:23
mentioned 8:21 14:4 22:21 66:1 79:23 84:3 107:22 132:4 188:8 278:6 284:22

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 346

met 113:16 241:2,11,21 242:5 243:24 246:25 248:24 254:10,19
method 42:9 45:6 187:21 262:11
methods 33:7 33:22 187:9,19 229:9 297:14
metric 64:11 244:5
metrics 64:9 244:10,14
michael 74:25 75:10 110:8
micrometers 68:18
micron 248:11
microns 69:6 69:16,17 70:12 71:1 72:11,12 243:3,23 245:1 245:10,18 246:9,16 247:17 248:10 248:15
middle 57:25 58:1 239:9
mild 24:21,25 27:17 213:17 213:19 226:3,5 226:7,11 251:16
milligram 268:7
milligrams 263:20,21,21 263:23 268:1,7 268:8,10,19 274:22 275:11 276:9 282:20 282:24
millions 106:15
mind 9:21 115:8 246:23 303:3
mine 49:6
minimize 268:23 270:18 271:10
minimizing 268:22 271:15
minimum 85:3
minute 244:17
mis 98:18
mischaracteri... 38:2,12,21 177:5 267:6
mispronounc... 21:12
missing 147:24 260:22
misspoke 108:20 284:7
misstep 6:5
mistaken 33:6 242:20
misunderstood 98:18 177:11 224:18
mitigate 107:2 215:2
mitigation 58:13
moderate 24:22 226:3
modification 188:16 272:12 273:6 282:2,8
modifications 192:7,13,15
modify 184:7 185:18 186:2 188:18 270:17 271:5,8 272:10
modifying 198:18
mofo.com 2:11 307:2
molecular 22:2
molecule 95:10 95:15 96:15,20 97:7,10 101:22 101:23 103:3
molecules 97:25 98:5,7
moment 123:12 242:18,20
moments 155:11 162:12
monitor 226:25
month 9:5,8 10:16 105:11 106:19 208:10 209:8 241:10 241:20,24 277:19,20,23 278:13,13,16 278:19 281:10 281:12,15,15
monthly 57:18 106:10 107:23 107:25 199:7 199:16,18,19 199:21,23 204:11 207:24 208:8,9 210:23 211:1,5,12,17 229:21 230:8 230:17 232:18 241:8 261:18 263:21,22,23 263:25 268:8,9 268:12 274:19 274:23 276:10 277:17 278:3 279:2,23 281:11,12,24 282:2,9 283:17 284:4,20 286:16,24 291:13,25 300:1
months 115:16 209:8 274:21 278:21,22,22

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 347

281:5,13 282:21 292:2
morbidity 213:24
morning 5:1 6:1,3
morrison 2:9 5:18
motivated 186:9 258:14
motivation 184:6 260:23 269:2 283:13 283:16,23
move 14:17 78:12 82:9 213:14
moved 14:8 16:19
multi 84:13
multiple 47:19 47:20 51:8 86:15 113:18 176:2 182:7 183:12,16,21 267:8 268:17 277:10
mylan 159:12 159:23

n

n 3:1
name 6:5 50:12 80:24 109:3 110:2
named 110:7 305:6,16
nashville 4:6
nata 198:22 199:5
national 34:1 35:10 125:11
natural 74:11
naturally 17:11
nature 45:11 47:8 101:25 213:16
naveed 109:4
naïve 45:16,17
neces 62:14
necess 87:7
necessarily 25:15 39:22 69:10 74:9 85:2 185:14 194:18 204:14 237:18 238:8 278:25 279:11
necessary 37:24 211:12 307:14 308:3
need 9:22 11:14 37:17 40:5 42:21 43:6 60:17 65:9 66:9 68:10 69:17 100:3,9 186:19 199:13 204:10 216:15 242:24 251:19 256:3 271:19 272:4
needed 199:5 200:7 201:11 205:25 263:24 268:10 274:23 276:10 277:25 280:10,20 281:8
needle 250:24 251:14
needles 106:19
needs 36:5 42:20 79:19
neovascular 59:17 60:24 61:9,21 134:6 134:12,18,24 186:13 211:7 278:5
network 233:25
never 59:1 80:3 92:12,14 94:4 103:12 287:10
new 2:5,5 15:4 18:19,24 19:2 21:14 37:4 39:18,23 46:1 46:15,21 47:2 47:23 55:19 74:19 76:24 124:23 127:7,8 169:19 202:21 203:17
newer 165:9
nice 124:1
nine 210:15 281:5,13
no.6381270 307:5 309:2
nodding 226:20
nomenclature 137:7
non 24:21 246:17
noninvasive 32:12
nonproliferat... 23:17 24:22,23 24:25 26:21 27:17 29:17
normal 18:20 72:9 103:23 271:9
notary 4:15 305:8 306:23
notating 307:15 308:4
note 145:12
noted 175:23
notice 4:9
notwithstandi... 59:5
now's 82:13
nuanced 63:9 92:20
number 67:19 72:5 126:8,21 131:9,10 189:8

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 348

189:12,13,17
189:18 193:21
200:17 203:6
210:7 211:11
225:23 228:20
229:11 242:17
243:14 244:17
247:16,25
260:4,5 268:22
270:18 271:12
271:15 272:10
277:19 281:9
287:20 289:16
289:18 307:15
308:4
numbers 55:10
70:9 72:7
73:19 139:5
216:20 239:7
301:25 302:5
numerous 24:8
36:16

o

oak 34:1 35:9
125:11
oaths 305:9
object 22:10
38:20 40:16
123:5 267:16
291:7 292:10
objection 13:19
20:17 21:16
22:13 24:13
26:8 27:10
28:21 29:10
30:19 31:6,19
33:19 34:13
35:4 36:9
37:18 38:1,11
39:5,13 41:4
42:18 43:10
44:15 45:18
47:4 49:16,23
52:18 53:14
54:12,21 57:6
59:7 60:19
62:6,17 63:22
65:13 66:13
69:1 70:16
71:13,23 72:8
72:20,21 73:7
73:16 76:17
77:11 78:5,15
80:16 84:15
94:12 95:12
98:2 100:5,21
101:10 104:5
112:1 114:13
116:1,20
129:21 135:7
136:17 138:2
140:20 146:6
150:10 151:8
154:8 157:16
161:1 168:3
176:13 177:4
177:25 178:15
178:24 179:14
181:9 182:18
183:2,15
185:20 187:6
189:14 191:15
191:25 193:3
195:6 200:24
204:13 206:6
207:6,19
210:16 212:14
216:3 217:3,11
217:18 218:4
218:11 219:25
220:10,21
221:4 222:17
222:25 226:9
230:10,24
231:6,13
232:12 235:5
237:20 238:17
241:3,15 242:9
243:16 244:1
245:11 246:1
248:3 249:1
252:7 253:24
255:23 263:15
265:8,24
266:22 267:5
270:4 274:17
275:18 276:16
276:25 279:9
280:6 281:21
282:22 289:2
290:1,12 294:7
294:17 295:16
objections 4:11
179:7
obligated 203:1
observe 25:10
28:18,19 87:9
87:20 222:16
observed 26:3
82:20 83:21
86:24 87:1,3
87:24 98:12
105:4 143:3
197:22 211:10
257:17 303:12
observing
25:10,14
206:15
obtain 187:16
obtaining
132:13
obvious 149:11
175:1,11
176:22 178:13
189:2,4 190:4
190:20 232:3
232:23 260:18
265:18 266:8
270:25 271:13
271:17 272:1
obviously 49:9
115:7 124:15
154:2 186:14
187:25 240:10
obviousness
35:25 149:1,9
149:18,24
150:17 162:14
162:17 163:11

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 349

168:23 173:25 174:21,23 175:1,8,24,25 176:1 177:13 177:20 178:23 179:13,20 180:1,5,10,16 180:21 182:3 182:15,24 183:10 187:2,5 188:22 191:2 194:1 196:2,23 197:4 232:7,14 261:10 263:13 264:16 265:22 267:4 270:11 270:13 282:18 297:8

occasional 59:13

occur 13:17,18 25:5 61:12 276:15

occurred 9:9 48:13 83:10 147:20 280:3

occurring 47:11,12

occurs 18:8

ocp 243:22 245:9,17 248:14

oct 60:13 64:11 64:21 65:21 70:5 71:21,25 105:16 243:2 246:8

october 9:6 48:13 83:10 113:22 114:12 114:22 115:11 122:25 205:16

ocular 126:6

offer 149:8 177:13 232:1 242:4 283:3

offered 12:18

offering 154:17 220:17 266:18

offhand 7:12 8:11 9:24 84:2 110:25 111:12 118:14 135:21 135:25 136:10 159:21 160:7 298:6

office 1:1 35:18 36:7 205:4,20 307:11

offices 4:5

oh 133:15 226:23 228:1 259:3 303:7

okay 6:14,22 7:3,4,10,22 8:1 8:14,19 9:7,13 9:20 10:1,8,18 11:3,12,19 12:4,5,22 14:3 14:7,16 16:18 17:6,9,16,18 20:3,7 21:8,10 22:7,21 23:18 23:22 24:11 25:7,25 27:2,7 27:22 29:3,6 30:8,15,24 31:5 33:12 34:4,9 35:12 35:16,20 36:3 37:2,8,15 38:16,25 39:11 40:3,9,11,12,13 40:24 41:10,15 41:17 42:2,6 42:14,24 43:3 43:5,7 44:10 46:9 47:1,25 48:3,7,11 49:1 49:7,12,20 50:6,20 51:3 51:22 52:11 53:9,19,24 54:7 55:1,4,24 56:3,8,12,17 57:1 58:20 59:3 60:7,15 60:20 61:3,11 62:3,14 63:6 64:5,10 65:10 65:25 66:8,10 68:21 70:3,13 71:6 72:6,16 73:3,12,21 74:22,25 75:13 76:7,10,15 77:8 78:2,11 78:22 79:5,17 79:22 80:8,13 80:21 81:1,6,9 81:16,20 82:7 83:5,20,25 84:10 85:11 86:7,17,23 87:8,19,23 88:2,11,14,17 89:5,9,13,16,19 89:22,25 91:5 91:15 92:1,4 92:10,14,23 93:1,12,20 94:4,20,25 95:17,20,24 96:4,17,22 97:1,5,9,17,23 98:11,17,24 100:3,17 101:4 102:7,15 103:7 103:11,15,24 104:21 105:4 105:19 106:2 107:13,19,21 108:1,6,15,22 109:2,10,12 110:4,15,18,22 111:3,14 112:7 112:12,17 113:1,12,17,21 114:5 115:3,15 115:21 116:13

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 350

117:16,20	158:19 159:22	200:21 201:3	248:22 249:5
118:2,11,16	160:1 161:11	201:19 203:23	249:17 250:2,9
119:2,8,18,21	161:18,23	204:8 205:15	250:14,19
120:5,10,14,21	162:5 163:2	205:20,25	251:1,8 252:3
121:1,14 122:4	164:7 165:7,11	206:18 207:12	252:13 253:8
122:9,15,20,24	165:19,25	208:2 209:20	253:17 255:12
123:2,10 124:8	166:25 167:9	210:8 211:10	255:18 256:22
124:25 125:6	167:15,23	211:16,22	257:2,14 258:3
125:13,17	168:14 169:9	212:6 213:1,13	258:20 259:20
126:11,17	169:13 170:13	214:13 216:13	260:3,6 261:1
128:1 129:7,10	170:20 171:24	216:17 217:6	262:21 264:3,9
130:6,17 131:5	172:13,22	219:13 220:4	264:14,19,23
131:13,20,25	173:1,6 174:1	220:16 221:2,9	265:13,21
132:6,16 133:6	174:4,9 175:6	222:14,20	266:4,17
135:11,22	175:12,18,22	223:18 224:4	267:11 270:8
136:1,12,23	176:5,7,8,18	224:17,22	270:23 272:14
137:10,19,20	177:10,21	225:6,18 226:5	272:23 273:3
137:22 138:6,9	178:5,10 179:5	226:15,15	274:2,6,9,13
138:19,22	179:19 180:2,8	227:19 228:14	275:1,6,19,20
139:9 140:1,17	180:20,24	228:19 229:2	276:4,8 277:12
141:10,17	181:16,21	229:18,23	277:21 278:11
142:23 143:12	182:14 183:7	230:20 231:10	278:15,20
143:15,17,18	183:20,25	231:17 232:10	279:5 280:17
143:20 144:22	185:1,16	233:4,9 234:3	280:22 282:12
144:24 145:4	187:12,17	234:13,16,23	282:17 283:2
145:19,25	188:3,14 189:1	235:12,18,22	284:6,13,22
147:16,19	189:7,11,21	235:25 236:4,7	285:13,15
148:6,10,15,24	190:1,17	237:1,9,16	286:2,8,11,15
150:25 152:3	191:11 192:11	238:12 239:5	286:22 287:1
152:19 153:5	192:24 193:25	239:22 241:6	287:14,24
153:12,16	194:7,11,20	241:19 242:3	288:2,8 289:15
154:4,13,19,23	195:2,11,17	242:15 243:9	290:7,17
155:2,9 156:2	196:17 197:5	243:19 244:9	291:11,16
156:14,20,24	197:17 198:8	245:8,23 246:4	292:18,24
157:12 158:14	198:21 199:4	246:22 247:14	293:20 295:14

295:20,25 296:21 297:3,9 298:2,7,10,25 299:4,8,12 300:5,15,19,23 301:1 302:4,9 302:20
once 9:22 55:25 61:24,24 62:4 88:2 133:1 136:2 202:15 202:16,19 203:3,3 210:25 219:4
oncologist 15:11
oncology 15:18
one's 139:5,6
ones 117:25 118:7,8 164:6 180:18
onset 46:15,21 47:2,23
ophthalmolo... 14:5 32:2 35:7
ophthalmology 8:18 14:8,12 14:17 15:22,24 16:20 125:22 126:23 127:3 128:11 135:2
opine 173:24 175:4
opined 236:20 236:22 284:17
opinion 12:23 13:7 109:23 110:5,19 111:18 117:5 152:12 154:17 156:5,7 158:5 174:3 175:9 176:15 177:16 177:19 179:24 179:25 182:14 187:5 192:11 196:16 219:19 219:22 220:16 232:1,21 239:13 242:4 260:11,17 261:11 265:16 266:17 270:6 270:13 293:22 293:25 297:8 302:17
opinions 12:15 12:18 13:6,11 86:2 144:7 149:7 150:16 156:13 158:12 158:17 160:24 161:3,8 163:23 166:16 167:1 169:10 177:14 181:1 194:2,8 196:23 220:17 259:21 263:13 264:11,16 270:12 282:18 297:4
opportunity 49:21 94:21 209:25
opposed 140:14 141:8
optical 32:11 63:23
optimization 262:15
optimize 215:15 268:19 269:2 271:14
option 47:14 59:5
options 44:6
order 37:10 46:6 65:10 105:14 106:10 107:3 132:24 135:18 177:23 198:19
ordinary 25:20 61:18 149:15 150:3 164:18 166:5,6,8 169:4,18 170:10 182:11 182:16,25 183:9 184:13 184:19,22 185:12 187:24 188:9,17 190:11 192:5 192:19 193:5 194:4 197:8 200:15 207:15 225:14 254:22 262:9,13 268:15 269:1 270:17 271:7 272:12 273:6 283:11 295:22 296:8
original 107:7 199:15 278:14 307:10,21
otc 32:19 43:3 245:6 248:9
otto 124:10
outcome 62:22 74:17 215:20 219:1 305:16
outcomes 74:21 188:2 219:7
output 64:6
outside 46:10
overall 167:21 287:18
overarching 13:6 23:7,13
overexpressed 17:14,17
overexpression 17:19
overlap 13:23
overlapping 257:7 284:10
overview 125:15 249:14

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 352

own 24:14 26:1 27:4 28:22 29:16,25 44:11 45:1,5 46:9 50:3 58:16 59:21 63:19 64:14 120:6 126:10 130:1 158:11,12,17 182:16 198:4 200:21 207:20 208:21,22 209:1,11,17 212:16,19,21
owner 1:8,15 2:7 4:3 5:16
owner's 122:18 123:3,4

p

p.m. 143:6 197:21,25 257:16,20 303:11,15 304:2,12
page 3:2,7 75:11 119:8 129:10 138:23 139:3,4,11 144:1,18 145:11 155:17 156:2 162:15 162:19,22 164:7,16 166:10 171:25 173:8,8 180:9 181:25 189:1 227:6,12 231:18 239:5,7 239:9 240:25 242:17 243:1 244:16,18,21 245:24 249:5 249:18 258:12 258:12,21,21 259:3,4 260:12 263:10 264:4 266:5 285:3,5 285:5,11 289:9 291:19,20,21 295:3 299:25 301:3,4,11 302:13 306:6 307:15 308:4 309:4,7,10,13 309:16,19
pages 129:8 305:10 306:3 307:14,17,17 308:3,6,6
pagination 144:2,18
palmer 134:15
panel 127:12
paper 237:13 244:12
papers 75:3
par 174:10 264:10
paradigms 124:24
paragraph 139:3,12 140:3 140:8 141:6,10 141:19,21 142:4,8 144:1 144:6 145:5,20 146:3,11 147:4 147:17,25 148:13,17 151:1 152:18 152:21 155:17 159:7,14 162:15,22 164:7,16 166:9 167:1 169:3 171:25 173:15 173:21 174:5 175:13,22 176:7 178:6 180:8,25 181:24 184:4 186:1,24 195:11,25 196:13,14 197:7 219:4 227:11 228:10 228:16 229:4 229:23 230:23 231:5,12,22 258:12,22 259:4 260:13 264:4,24 266:6 274:14 275:7 287:15,16 297:9 298:4,20 299:5,24 300:5 301:3,13,21 302:11,13
paragraph's 302:14
paragraphs 173:14,19 230:7
parallel 13:18 13:25
parsed 72:24
part 12:21 13:21 15:23 18:7 47:20 53:22 63:20 64:1 65:6 66:5 66:6 67:15 75:9 90:13 93:18 102:13 106:25 109:7 112:10 120:19 122:22 125:9 126:13 128:6,9 129:9 130:14 135:4 156:11 161:7 162:6 172:2 175:13 186:15 191:2 197:3 205:21 233:25 234:1 235:25 264:13 270:14,15 274:3 276:1 282:3

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 353

partes 1:6 12:10
participant 75:14
participate 111:4
participated 233:24
particular 7:6 11:9 23:6 42:9 55:17 80:22 84:11 86:11 91:13 118:15 126:23 131:3 132:24 140:15 140:23 156:22 169:8 171:21 185:6,8,9 194:1 203:4 210:5 213:25 230:13 234:10 240:24 278:10 289:25 290:8 292:14 301:25
parties 158:1 305:14
partner 99:6
partners 95:8
parts 161:22
past 21:25 48:1 215:3
patent 1:1,1,4,8 1:15 2:7 3:9,20 3:21 4:3 5:16 6:16,20,25 7:1 7:17,20 8:24 8:25 10:5,10 10:11 11:9 13:7,12 33:7 33:10,15,18 34:2,4,11,24 35:13,14,17,18 36:7,7 37:9,10 37:14,16,17,25 38:13 39:3,4 39:12,12,17,24 40:14,15,19 112:21 113:3 116:5 117:2,18 118:17 119:3 119:11,17 120:1,8,18 121:8 122:18 123:3,4 125:3 125:5,11 128:6 128:9,14,17 144:8,9,11 145:7,22 146:14,24 147:3,8,13 148:2 149:22 150:20,20 151:5,7,11,25 152:5 153:19 154:2 155:10 156:25 158:20 158:20,25 159:23,24 160:5 163:11 164:3 167:12 168:12,15 171:9 172:3,11 172:15,20 173:3,5 174:22 174:23 175:10 175:14 178:6 180:22 190:18 196:3,6,7 197:3 216:18 216:21 219:17 219:23 220:20 227:18,20 228:6 231:1,8 231:15 260:18 265:18 272:15 273:9,12,17,20 273:24 274:3 287:25 288:7,9 288:12,15 296:9,17,24 297:21 298:3 298:18 299:12 299:15,20 301:24 302:3
patents 6:23 13:25 34:5,7,8 38:9 40:1 119:12 120:6 153:25 158:10 158:21
path 15:20 16:4 16:14
patient 24:16 24:19,24,25 25:6,10,15,23 25:23 26:3,20 26:23,25 27:6 27:16,20,24 28:2,5,9,14,14 28:24 29:16,19 31:2,5,25 42:13 43:1 44:20,23 45:2 45:7,11,16 46:4,8,14,15,16 47:1,7,14,23 48:4 60:10,15 60:17 65:11 66:7,11,19 67:25 68:12 69:11 70:3,23 71:19 73:10 78:19 84:7,13 84:14,21 85:8 85:11,25 90:18 91:3,13 99:16 99:21 100:2,10 100:13 101:1,2 102:16 104:11 104:14 105:8,9 105:11,13 106:22 124:5 127:7,7,17,18 127:19 132:19 133:5 140:16 184:24 189:23 189:24 190:16 192:20,23 193:7,22 194:19,20,22

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 354

198:11,12,18
198:20 199:20
200:2,3,6,17,19
201:14 202:9
202:20 203:1
204:17,21
205:22 206:1
207:15,22
208:4,5,9
209:4,10 210:1
210:2 211:23
212:10,20
213:3,15
214:10 215:16
215:20 225:20
229:11,14,17
229:25 230:4
233:8 237:11
238:10 240:18
241:21 253:23
255:7,8 256:25
265:1 268:13
271:6 272:13
273:7 278:1,10
280:11,11
283:15
patient's 32:1
45:13 58:9
59:11,22 60:11
67:22 70:21
91:10 104:3
140:13,14
141:9 192:8
198:15 210:22
212:20 213:4
219:1,2,9
276:18
patients 15:8
16:23 17:24
18:12 19:15,18
26:7,18 28:17
29:9 30:25
41:8 43:18
44:6 46:11
51:15 54:20
55:10 56:10
57:17,17 58:2
58:25 59:4,13
59:18,23,24
60:22,23 62:2
70:18 73:18,24
73:25 74:18
75:7,15 77:3
83:15 84:4,6
86:23 87:3,8
87:19,23 88:4
88:5,7 90:8,12
90:17,21 91:6
91:9,20 92:17
98:12,12,19
99:3 100:17,19
101:7,8,17
102:5 105:7,17
106:7,9,15,18
107:12 126:2,3
126:5 127:23
133:25 164:21
192:4 194:16
199:6,12,18,19
200:10 201:1
201:17 202:3
202:16 203:16
204:10 211:11
213:16,18,21
213:23 214:2
214:21 215:2,9
215:25 216:5,7
216:9,14
221:12,21,25
222:6,8,16,21
223:10,15,23
226:2 232:25
237:15,18
238:2,5,14,23
239:3 240:8,14
240:21 241:12
242:4 243:2
246:24 248:14
248:16 252:15
253:2,3 254:18
254:24 255:2,5
255:21 256:14
256:14,15,15
260:2 271:11
272:11 294:5
294:12,21,23
pattern 212:21
patterns 90:15
90:16 127:15
210:4
pct 227:13
228:9,15
230:22 231:4
231:11 288:1,2
pdf 307:12
308:1
pearl 124:2
pediatric 14:12
14:14,18,21
15:2,11,18
pediatrics 14:8
14:12,13 15:6
15:16,17
peer 36:6,19,20
36:24 40:6
235:11 293:24
294:1
penalty 307:16
308:5
people 107:10
198:5 243:14
243:20,24
252:14
percent 95:4
241:1 242:4,7
243:15,20,24
244:21 246:24
247:1 248:1,23
252:22 254:7,9
255:20,20
percentage
81:2 243:1
perfect 133:19
perform 297:3
performed
61:23 279:18
performs 42:15
perfusion
43:20

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 355

period 49:9 75:8 84:6 144:10,14 146:12,17,22 147:25 148:7 148:11,17 149:20 150:7 151:5 152:14 153:2 169:22 200:11,22 207:17 216:9 216:15 254:13 277:20 278:9 282:9,14 307:18 308:7
peripheral 68:4
perjury 307:17 308:6
permit 240:16 248:5 277:10
permitted 132:17 277:14 280:25 281:19 302:2
person 24:21 26:12 149:15 150:2 164:18 166:5,6,7 169:4,17 170:10 184:13 184:18,22 185:12 187:24 190:10 192:5 192:19 193:4 194:4 197:8 219:20 254:22 262:13 268:14 268:25 270:16 271:7 272:11 273:5 283:11 296:7
personal 170:11,14,25
personalized 198:6
personally 44:13 53:8 234:4
persons 61:18 200:14
perspective 16:13 22:2 107:6 117:12 149:11 166:4,7 167:16 179:23 187:23 193:14 194:3,4 220:18 235:1,2 254:21
petition 12:9,9 122:5
petitioner 1:4 2:2 5:13 10:9 10:21
ph.d 4:2
ph.d. 1:14 3:3 5:20 14:20 305:3 306:2,20 307:5 309:2
pharmaceutic... 1:6 307:4 309:1
pharmacies 52:7
pharmacy 52:8 52:21 56:25 88:18,20,22 94:2,5,16
phase 76:2,2,2 76:8,9,13,16,22 77:1,4,7,10,14 77:16,17,21 78:3,12,14,16 78:25 79:7,7,8 79:8,14,14,15 80:4,6,9,11,14 80:18,22 81:3 81:3,10 264:24 268:4 276:1
phases 75:24
phil 134:15
phonetic 110:11 134:15
photograph 33:4 168:20
phrase 29:21 29:23 45:16 87:10 120:7 141:5 189:6 219:3
physi 272:1
physician 14:20 16:7,21 26:12 29:23 90:19,19 99:6 99:25 100:25 106:22 198:10 199:22 209:23 209:24 210:2,5 262:8 271:6,13 271:17 272:2 278:1 279:7 280:12,12 283:15
physician's 276:19
physicians 16:12 26:14 29:20 43:13,18 51:4 62:1 98:21 130:20 132:11,14 133:3 200:1,14 208:22,23,24 208:25 251:6 280:16
picture 70:19
pier 108:21 109:1,3,13 110:23 111:4,7 111:9,15,18,24 112:4,19,23 291:11 292:20 293:5,10,14,18 293:23 294:4
pill 250:16
pilot 134:6
place 305:6
placebo 250:6 250:15

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 356

plain 25:20 225:14
plan 15:10 212:9
planned 276:2
plays 18:13
pleasant 106:21
please 5:8 6:5 6:12 7:2 50:13 149:5 168:5 178:18 190:25 218:6 238:19 246:11 266:24 290:24 296:12
plus 3:13,14 239:15 241:1 243:10 246:18 254:7,9
point 28:3 35:23 56:3 77:4,9 78:9 84:22 86:13 92:11 93:7 113:15 121:12 122:25 150:4 169:11 170:17 172:25 186:25 187:14 200:7 207:1 208:13 208:16 209:9 213:9 249:23 250:21 251:1 252:10 255:13 256:23 262:23 265:5 281:9
pointing 145:1
points 16:20 77:6
policies 49:4
poor 43:20
poorer 58:1,1
population 78:20
portion 72:17 139:6 237:9 244:17 262:17 273:24
portions 35:14 263:12 264:14
posa 149:12,14 164:9,15 166:1 167:16 185:17 191:3 192:12 193:1 194:8 196:5 220:18 232:23 238:1,4 238:22 258:13 258:23 261:13 273:15,20 283:3 284:15 287:15,16
posa's 190:21 261:3
posas 165:4
position 169:4 169:17 179:2
possible 106:20 203:18 278:8
postmarketing 76:6,7
potential 55:20 77:19 100:14 105:17 107:9 194:5 209:22 217:16 239:20 259:11,22 268:24 277:7 287:21
potentially 60:13 77:5 107:11,16 134:11 169:24 185:3 186:20 198:17 233:1 279:14
practice 15:1 24:11,15 26:6 27:3 28:23 29:12,16 41:13 45:5 46:9,22 47:21 51:22 52:2 53:22 54:15 55:8,9 57:22 58:7,16 60:4 61:12 63:19 69:3 73:4 83:21 84:3 85:23 88:14,24 90:13 90:15,25 94:22 95:5 98:16 105:5 107:1,12 125:20 127:6 127:14,25 128:15,18 130:1 131:6,25 132:8 133:3 135:2 164:20 169:20 170:8 171:14 185:15 200:21 202:2 202:15 204:7 207:15,21 208:21,22 209:1,11,17 210:3,4,21,24 211:5 213:3,25 216:1,5 222:15 225:19 226:1 235:19 271:10 286:1 295:8 296:3,8,16,20 296:23 300:16 300:17
practicing 169:18 170:1 193:5
practitioner 8:17 164:20
practitioners 69:4,5 140:10
pre 218:24
preceding 230:1,5
preclinical 96:6 101:21 107:7
predetermined 140:15,18

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 357

141:16 218:2 218:10,13,16 218:21,22,25 219:8 220:9,12 220:14,20,24 221:3
predicate 200:4 231:15
predicated 15:6 47:8 58:8 59:10 67:19 270:15 276:18
predict 79:14 99:12,20,21 100:1,19,25
predictable 187:9,16 188:9 189:8,13
predicted 294:22
preference 17:7 139:7
preliminary 122:17 123:3 288:4
preparation 11:20 13:21 48:8,12 113:15 115:4,10 121:17,18 122:22 155:15 244:12
prepare 112:7 113:8 114:10 114:21,24 115:9 121:23 162:7
preparing 11:21 13:15 271:3
prescribe 29:8 29:19 66:11 70:15 85:4 88:15 98:21 130:21 131:6 132:1,11 222:15,20 224:1,20 226:8
prescribed 48:4 49:15 51:23 60:16 90:6,8 91:8,21 91:23 136:9
prescriber 92:24
prescribing 16:21 29:12 44:11 65:23 66:3 91:16 98:19 132:8 133:24
prescription 92:18 130:24
presence 25:22 29:25 31:1,23 32:9,16,21,22 66:16 74:1,6 129:25 223:7
present 2:12 20:15 27:15 64:21 106:15 262:11 287:13
presentation 29:14 31:8
presented 36:5 46:14 62:9 90:25 120:19 127:9,13,21 171:19 236:24 236:24 239:2 247:4 255:25 265:11 291:3,4
presenting 248:19
presents 44:24 65:5 70:23 127:18
preserved 49:2 49:9
prespecified 141:7
press 3:17 105:24 111:14 118:12,15 170:16 171:9 171:12,22 177:12,17 178:8 232:2,6 232:22 258:7 258:14,25 260:18,24 261:5,11,15 262:20,23 263:4,16 264:12,15 265:17,22,25 266:9,13,15,20 267:3,8,20,21 268:3,16 270:11,16,25 271:3,19 272:3 272:8,20 273:12 274:13 275:16,25 276:23 277:8 280:2,7,17 281:1 282:12 282:19 283:2 283:21 284:18 296:7,15,18 297:7
pressure 28:1
presumably 199:14
presume 134:7
previous 44:25 46:17 55:12 66:24 69:18 119:12 236:22 236:25
previously 8:22 46:5,12,16 105:19 115:23 118:20 129:23 136:16 170:15 205:17 254:3 262:25 285:21 290:14 299:6
primarily 45:23 77:16

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 358

83:14 201:5
primary 77:3,4 78:9 92:24 268:11
principal 269:14
principles 162:24,25,25 163:3
printed 196:4
prior 7:13,16 32:19 83:9 115:21 117:8 117:16,20 120:5 150:4,8 150:9 154:25 162:9 165:16 167:16 168:9 168:22 169:8 176:2,3,6,10,11 176:21,23 177:2 178:11 178:12 181:4 181:12,17 182:4,8 183:7 183:8,13,14,17 183:21 184:5,8 185:18 186:3 187:8 188:16 188:18 190:20 191:21 192:2 196:23 201:4 205:9 269:7 273:5 295:21 297:13
priority 119:23 120:1,8 144:10 145:2,6,13,17 145:21 146:13 146:23 148:1 148:12 149:2 149:21 150:9 150:19,24 151:6,24 152:4 152:14,22 155:1,4 167:25 171:7 196:14 227:8
prn 198:22 200:23 201:20 202:7,25 203:15,17,21 203:23,23 204:9,18 205:1 205:4,25 206:12,14 209:21 217:2 270:21 276:10 277:10,14,23 277:24 278:8 278:24 280:2 280:20 282:3 282:21
pro 198:22 199:4
probably 7:7 21:24 43:25 56:15 114:4 204:5 288:4 300:25
problematic 106:7 200:18
problems 268:12
procedure 4:8 106:21 250:8 307:19,20
procedures 250:11
proceed 81:3 81:10
proceeding 7:6 8:20,23 9:4 10:5 83:10 116:19 118:23 120:16 122:11 128:20 138:16 154:1 155:7 159:8 160:9,12 160:15 161:7,8 161:10 174:14 184:2 191:12 219:24 227:22 234:14,18,20 300:20
proceedings 6:10 10:20,24 11:15,18 12:8 12:14,17,19,23 13:5 120:12,23 122:16 155:14 157:3 158:16 167:8,10 304:4 304:11
process 11:21 12:6 13:14 16:9 18:21 30:21 34:10 35:2 47:21 63:21 67:4,6 74:14 79:4,18 94:23 95:1 115:24 116:14 116:16,24,25 119:6 124:4 128:6 130:15 130:19 132:12 156:15 160:20 161:7 170:7 188:1 190:13
produced 97:3
produces 17:11
product 96:8 96:12
professional 109:22 110:5 110:19
profile 102:5,9
program 15:25
progress 69:21
progression 20:1 28:2 193:20
proliferation 18:23 19:9
proliferative 19:16 23:16 28:7,8 222:11 226:4

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 359

promise 55:20
promised 197:6
prompt 3:13,15 188:5 240:9 246:18 254:7 254:15
pronounce 6:4
pronto 204:23 205:8
proper 163:10
prophylactica... 287:8
proposed 261:4 270:19
pros 128:14
prosecution 128:14
prospective 79:9 251:12,20
protein 17:11 101:25
protocol 241:12,17,22 242:1,13,17 249:10 272:19 282:4
provide 37:17 83:15,21 120:3 144:7 151:11 153:15 162:13 176:6 179:25 180:12 184:6 206:3 207:16 258:2 260:3 293:10
provided 10:4 13:5,10 118:3 118:7 150:22 152:16 155:25 160:11 164:6 170:23 173:18 177:19 183:22 183:23 186:3 191:6 260:2 290:18 294:11 297:24 298:25 300:24 307:19 308:8
provides 150:3 182:2 196:1 232:15 236:6 245:24 253:13
providing 117:10 141:15 179:23 193:6 200:20
provisional 152:1,24 153:17,21,23 153:25 154:6 154:10 155:4 164:14 274:10
public 4:15 181:13 305:8 306:23
publication 36:6 40:11 170:22 196:4 236:21 298:3 298:19
publications 36:16 293:16
publicly 265:11
publish 126:22
published 36:24 37:7 40:6 82:4 134:25 150:18 293:24
pumping 67:9
purchase 56:25 57:3,5 88:19 88:21,23
purpose 76:12 76:16,22 77:10 78:13 87:4 131:2 132:18 193:7 209:2
purposes 4:7 234:14,14 265:23
pursuing 262:14 268:17
push 210:14
put 19:15 106:19 116:17 155:9 156:20 169:17 170:3 189:12,16 231:17 233:10 263:5 295:2
putting 35:12 115:24 156:15 169:3 272:8

q

quantifying 248:17
quantitative 70:1
quantitatively 69:13
quarterly 111:25 291:13 292:4 294:6,16
question 12:1 13:1 20:19 21:23 22:15 29:7 34:20 36:11 37:20 38:4 39:16 40:22 42:22 44:10 51:7 57:8 61:1 65:18 71:16 84:17 86:5 100:7 101:12 105:3,15 106:3 111:21 114:18 116:10 123:7 125:1 126:17 137:9 140:1 141:4,23 145:4 146:8,20 148:7 149:5 150:12 150:25 151:10 157:13 158:23 160:18 162:4 163:8,25 166:17 168:5

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 360

171:5 176:24 177:7,21 178:3 178:18,21 179:3,6,9,17 185:23 188:11 190:25 191:19 192:24 194:14 194:15 197:5 199:12 206:8 210:18 218:6 221:3,14,16,16 223:6,21 225:1 237:22 238:19 252:19 261:8 266:24 270:1 273:10,18 275:2 278:15 281:5,18 287:17 290:24 291:9 295:24 296:11 297:2
question's 238:12
questioning 6:24 139:22 143:21
questions 4:12 6:11 11:20 77:13 97:1 123:13 164:18 164:25 166:4 195:21 226:21
quick 214:7,14 256:12
quickly 213:22
quinn 2:3 7:8 7:11,14,16,25 8:20,23 10:9 10:20,25 11:4 13:16 115:16 115:22 174:6
quinnemanue... 2:6
quite 17:22 146:19 191:18 209:22
quote 83:15,17 102:23 130:21 158:21 280:19 297:14,18
quotes 189:2,5 233:10

r

r 2:8 306:1,1 307:1 309:3,3
r&s 308:1,9
ran 107:21
randomized 3:12
range 44:5 72:7 114:4
rani 60:3 99:5
ranibizumab 3:13 50:15,16 57:12,15 58:14 58:17 60:3 90:23 91:3 97:20 99:6 106:8 107:21 107:22 108:2 141:20 192:18 192:21 199:16 237:3 239:15 239:20 240:3 240:13 241:1 243:10,22 254:7,9 279:19
rate 104:2,24
rather 19:12 110:23 169:24 190:4 249:9 251:2 266:16 279:1
rationale 200:9 203:7,9 283:13 284:15
rationales 187:1,4 188:22 203:8
raw 101:21
reached 7:10
reaction 251:15
reactivate 212:4
reactivated 206:3 207:3 212:11
reactivation 206:15,22 210:12
read 9:10,11 45:24 108:4 111:1,9,13 119:2,7,9,10,18 125:23 126:16 126:20 144:22 156:16,19 157:11,25 171:21 234:10 234:17 235:13 235:16 248:7 262:18 264:12 267:18 271:18 272:3,25 306:3
readily 262:8
reading 4:17 110:22 111:6 126:10 147:11 147:16 158:6 188:20 264:3 264:24 268:15 269:25 307:23 308:9
reads 273:20
real 125:8 240:19
reality 165:11 169:15
realized 15:19 197:6 247:20
really 250:7
realm 51:20
reason 10:3,7 16:17 88:4 99:8 121:13 132:21 184:7 184:12 185:18 186:2,8 309:6 309:9,12,15,18

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 361

309:21
reasonable
24:1 99:18
190:5,8,21
191:4,7,13,23
192:12,21,25
194:9 233:7
258:24 261:3
261:13 262:14
reasons 16:6
55:8 58:18
84:4 88:9,11
136:16,20
recall 7:10 8:11
11:12 33:17
34:9 35:13,15
35:16,19,23
54:2 56:12
58:24 61:5
75:7 82:6
83:11 84:2
85:6,10 88:1,5
91:2 93:12,16
102:7 110:22
110:25 111:6
111:10,12,14
111:16 113:1
113:25 115:15
118:14 121:9
121:16 122:4
122:17,20
135:22 136:5,8
136:10 148:15
156:14 160:17
160:19 162:11
165:2 170:18
175:15,17
195:9 196:21
196:24 214:19
221:23 234:21
235:12 244:14
256:13,21
294:9 299:2,9
recei 256:15
receive 29:1
124:4 241:3,4
241:13 242:6,8
242:10,11
247:2 252:24
254:11,18,25
received 30:13
124:16 163:3
237:11,15,18
238:3,5,10,14
238:24 239:15
243:25 252:16
253:19 255:9
255:14,21
256:14,16
257:1
receiving
104:12 205:22
243:21
recent 48:3
73:23
recently 95:23
receptors
101:24
recess 82:20
143:3 197:22
257:17 303:12
recharacterize
42:22
recognize
128:23 129:1
recognizes
18:22
recommend
43:15,21 71:4
recommending
28:1
reconstruct
151:20
record 5:2,9
82:18,22
138:10 139:4,9
143:1,5 197:20
197:24 226:18
226:24 228:5
228:15 242:21
257:16,19
262:18,24
270:1 298:15
303:6,8,10,14
304:2,3,5,9
records 48:6,8
48:12,16,20,22
48:24 49:13,22
50:1
recover 203:18
recrudescences
215:5
redirect 302:25
reduce 103:1
199:11 200:17
200:19 201:13
203:6 215:16
271:5
reduced 103:21
202:18 209:15
reduces 103:3
203:12
reducing
217:22 270:22
refer 6:19,22
23:11,18 35:21
40:25 46:11
60:1 85:22,24
86:19 137:12
145:5 147:25
167:9 173:21
185:2 196:12
196:14 216:23
225:21 227:12
231:5 255:13
259:7 283:22
reference
112:15,19
118:17,19,21
119:22 146:12
150:3 153:16
176:2,6,10,11
176:21,23
177:2,22,24
178:11,13
182:4 183:8,14
188:18 196:4
229:19 232:8
233:17 234:5
234:10 235:15

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 362

236:9,18
237:10 249:6
256:19 257:24
258:9 262:17
279:6 284:23
287:17,19
289:13 290:18
291:2,4,5
292:7 295:1
296:22 300:22
referenced 38:8
113:2 121:15
218:1,9 228:16
264:20 281:20
282:19 298:4
298:19 307:6
references
118:13 119:12
171:2 176:3
182:8,17 183:9
183:13,17,21
288:21 289:4
referencing
229:4,5
referred 17:2
50:6 96:24
98:20 99:5
104:22 112:14
125:10 137:13
141:21 148:12
148:17 154:5
164:13 214:14
227:5 228:9
233:17 285:20
referring 6:25
120:25 121:5
141:18,19,25
145:22 147:5
148:4,6,18,19
151:2 152:23
159:15,16
173:13 196:19
214:15 217:2
231:12 245:2
285:6
refers 121:6
146:14 147:2
155:20 159:7
166:10 167:3
181:25 189:2,7
190:3 197:7
228:20 229:3
229:24 244:24
266:6
reflected 33:18
reflection
45:10
reformulation
57:20
regard 14:1
51:15 302:8
regarding 10:5
10:10 40:21
44:18 47:7
59:9 102:13
111:24 120:18
144:8 149:24
151:4 156:5
158:1,11,13
164:25 179:9
179:24 180:1
196:16 197:3
270:6 288:22
297:8
regardless
206:21 211:25
regeneron 1:6
2:13 3:17 5:16
5:19 6:11
118:12 130:18
157:22 170:16
171:9,12,22
177:13 232:1,6
258:7 263:5
265:7,22
267:21,22
268:17 270:10
271:4 272:8
275:7 296:6,14
296:18 307:4
309:1
regeneron's
122:17 123:3
regimen 44:19
80:10 85:12,14
85:17,19,22
86:3,6,10,18
108:3 137:6
141:8 190:23
201:13,13,18
209:10 210:6
212:3,25
215:16 220:19
230:13 232:24
233:5,6,6
258:16 259:1,8
259:23 270:18
270:20 271:5,8
271:14 274:20
276:9,14
277:10,18
280:20 281:19
281:25 282:2,8
283:14,22,23
283:25 284:1,3
284:16,19
286:16,19
288:25 291:12
regimens 79:25
80:5 147:14
192:7 199:8
203:16 259:12
268:1,18 269:3
274:16,19
275:3,10,16
276:1,5 277:11
277:13 282:19
283:4,10,16
regression
193:19
regular 140:4
202:7 203:2
204:11
relate 125:14
167:8,11
270:14 291:5
related 8:12
33:10 63:3
74:20 112:21

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 363

116:5 117:2,8
117:11 120:20
126:4,5 134:18
152:6,16
155:21 158:10
158:21 159:2
172:21 173:25
177:20 185:15
186:11 199:10
232:14 271:12
292:13 301:25
relates 112:19
160:3 167:19
267:19 290:14
relating 6:10
8:2,8,24 121:7
relationship
25:8 31:13
112:22,25
relative 58:24
79:10 89:18,20
203:21 239:10
246:5 254:4
relatively
213:24 269:19
release 3:17
118:12,15
170:17 171:9
171:12,22
177:13,17
178:8 232:2,6
232:22 258:7
258:14,25
260:18,24
261:6,12,15
262:20,23
263:5,17
264:13,15
265:17,22
266:1,9,13,16
266:20 267:4,9
267:20,21
268:3,16
270:11,16
271:1,4,19
272:4,9,20
273:13 274:14
275:16,25
276:23 277:8
280:3,7,18
281:1 282:12
282:20 283:3
283:21 284:19
296:7,15,18
297:7
released 307:21
releases 111:15
relevance
157:9 286:17
relevant 128:15
128:18 154:1
158:9 161:10
161:12,17,20
161:22 162:1
162:20 163:4
163:23 164:2,8
164:18 166:4
167:11 172:21
173:6,17
183:17 232:16
239:14,19,23
264:13,15,18
293:5,25
reliability
287:17
relied 264:10
rely 149:2
152:16 170:22
183:12,22
relying 162:23
232:6,11
263:13 265:21
266:13,15
267:3,7 270:10
remainder
145:15,16
remember 82:3
136:1 205:9
234:9
remind 92:6
222:14
remove 102:24
removed 89:2
89:10,15 91:23
removing
93:21
render 176:22
265:18
rendered
160:24 266:8
270:25
rendering 86:1
150:16 161:7
166:15 169:10
181:1 194:1
196:23 259:21
297:4
renders 232:3
repeat 34:20
38:4 71:15
149:4 261:8
296:11
repeated
268:24
rephrase 12:4
36:11 37:20
146:8 150:12
168:4 171:4
178:18 185:23
206:8 210:18
218:6 221:15
237:21 238:19
266:23 271:24
273:18 290:23
repopulate
19:11
report 14:4
36:16 40:25
86:17 120:10
121:18 141:6
141:11 145:20
146:11 147:5
147:17 151:1
155:11 162:14
163:22 164:4
166:10 170:22
171:25 173:7
173:19,21
175:16,20
192:14 195:2,9

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 364

195:25 196:13 196:15 227:4 228:17 231:19 233:18 242:3 258:5 261:10 266:18 269:25 274:14 275:6 294:24 297:10 298:4,20 301:2 301:3,22 302:12
reported 111:7 112:5 135:4 234:4 235:11 272:19 305:7
reporter 4:16 5:11 246:10,13 304:6 305:8
reporter's 305:1
reports 113:3
representation 7:13 8:8
requested 308:1,9,10
require 28:9 46:24 202:10 215:6 249:22 251:13
required 27:19 39:3,8 79:15 106:9 250:22 269:21 272:11 278:2 294:23
requirement 301:18 302:7
requirements 40:20 210:3
requires 200:6 202:5 278:25
reread 234:12 234:13,17,18
rereading 234:21
research 22:9 22:17 95:4 235:21 236:6
reserved 4:12
residency 14:15,18
respect 8:15 11:8,9 13:24 34:6,12,24,25 37:16,24 38:9 38:10 40:1 117:1,4 120:22 158:5 160:18 167:21 170:13 174:22 178:8 190:22 193:21 203:25 204:6 207:16,17 232:16 235:16 260:25 261:4 266:19 295:18 296:5,21
respected 109:24 110:20
respond 98:13 99:9,22 100:20 101:7,8,17 192:20 200:10 203:4 213:18 214:7 235:7,9
responded 100:10 192:4 200:3 208:6
responding 202:6 203:3
response 18:18 45:3 59:12,19 59:22 60:12 65:7 101:1 103:23 122:18 123:4 140:13 140:14 141:9 189:24 198:15 199:14 200:5 201:15,16 214:11,13 226:20 239:25 251:15,17 276:18 277:25 283:20 286:4 294:21
responses 45:1 45:12 46:19 250:10
responsible 75:16 93:22,25
restate 13:1
result 67:11
results 43:14 61:20 64:11 82:5 84:13 111:15,18 187:10,16,22 237:6,17 240:5 265:14 293:13 293:23 294:1
retained 7:5,20 7:25 8:22 10:9 10:20,24 11:3 13:16 115:16 174:6
retention 8:20 49:4 117:17,21 120:5
retina 8:18 14:23 15:25 17:23 18:4,6,6 18:8,16,18 19:1,6,13,15,21 19:25 21:21 22:19 23:5,12 31:10,14,18 32:1,5,13,14,16 33:1,3,13 63:4 63:7 64:22,23 65:1,2 67:8,8 68:5 72:4,10 72:17 73:4,9 90:14,19 92:21 93:2 95:7 102:18,20,24 103:9,12,21,22 104:2,16

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 365

109:24 110:21
125:25 126:14
126:23 127:3,9
127:13,15
165:4 171:14
193:15 202:21
203:14 208:7
208:18 209:7
209:18 210:22
210:25 211:12
213:4,6 247:17
251:18 269:14
269:16
retina's 19:6
104:25
retinal 15:22
17:25 18:15
19:11 21:21
65:10,21 66:2
72:13 105:24
126:6 164:21
225:14 251:18
retinoblastoma
14:22
retinopathy
19:17 22:22,22
23:2,7,11,16,17
23:19 24:2,7,9
24:20,22,23
25:1,4,24
26:10,16,19,22
27:12,18 29:17
29:22 33:24
129:24 130:2
142:17 222:11
223:2,8,10,24
224:3,5,12,14
224:19,24
225:3,13,20,21
226:6,8,12
232:19
retreatment
202:11 244:19
246:5 249:20
249:23 252:4
252:10 253:10
retreatments
239:10 249:22
254:4
return 307:17
308:6
reveal 12:2
34:15 114:14
116:22 174:16
review 1:6 9:17
9:22 12:10
49:22 81:19
117:7 119:6,11
120:3,18 128:3
128:5 134:7
148:8 154:15
156:24 157:2
158:24 160:6
160:14 161:5
161:21 162:5
167:18 179:22
179:25 180:3,4
205:15 235:11
244:11,13
256:12 270:9
289:12 294:1
307:8,10,13
308:2
reviewed 35:17
36:6,19,20,24
40:6 81:24
82:4 95:23
112:9 113:5
115:1,2 120:22
122:5,10,21
128:9 151:25
155:14 156:3
156:12 160:21
162:3 170:24
205:5,12,19
242:2 245:21
293:24
reviewing 10:2
121:16 122:17
148:20 244:14
reviews 126:1
138:20 147:1
149:25 172:9
173:9,12,22
185:4 228:11
228:25 256:5
273:2 288:20
ridge 34:1 35:9
125:11
right 10:16,19
21:5 25:12
30:16 33:8
36:17 38:19
40:7 52:25
53:2 58:22
67:5 70:19
82:15 86:1
96:9,12 103:12
103:20 115:4
123:20,20
133:8,23 139:6
139:10,11
140:19 141:21
142:2,5,18,21
144:2 146:18
147:21 150:6
153:19 156:8
158:15 163:6
163:12 165:23
170:17 171:10
177:14 182:5,8
186:6 187:14
202:13 203:25
205:1 206:5,16
207:3 208:15
215:13,21
217:10,25
218:24 225:5
225:10,10,11
230:6,16,18
231:22 237:3
239:8 240:6
241:8 244:16
245:1,20,25
247:7 248:2
250:19 252:6
257:5 258:9,15
259:12,16,17
260:19 272:20
273:7,11,13,21

275:4,11 276:6 276:21,24 277:8 278:9 280:5,10,12 281:5,10 282:6 282:10 284:20 285:8,19,20 286:9 287:11 289:22 291:14 292:20,22 295:9 296:4 297:2,24 298:23 299:13 301:7 304:8
risk 106:11,12 106:13,13,15 106:16 200:19 203:20 270:22
risks 106:14 199:22
road 74:17 202:24
robust 78:17 288:21
role 18:13
rosenfeld 134:15
roughly 9:4 248:1
routine 188:1 213:2 226:1 262:10
routinely 128:8 271:9
rule 68:23 71:9
rules 4:8 149:18 308:8
run 61:14
running 286:21

s

s 309:3
safe 77:3,17 133:2 134:17 134:25 135:5
safety 78:19 98:1,4 134:22
saith 304:10
samsung 1:3 5:13 6:10 7:20 8:5,23 10:10 10:21 12:9,19 12:24 13:6,8 13:15 174:7 307:4 309:1
samsung's 122:5
san 2:10
satisfied 243:14 252:15
satisfy 301:17
saw 122:13
saying 25:18 147:9 156:3 169:22 178:12 224:11,12 245:16 277:9
says 36:16 64:7 108:7,10 120:10,21 124:9 135:12 144:6,9 156:3 168:20 172:3 175:24 184:11 196:2 197:8 230:3 239:10 240:25 245:3 248:8 249:3,19 252:4 254:6 258:13 265:1 275:7 285:16 285:22 286:2 287:2 295:6
scan 64:12
schedule 49:14 86:10,12,19,20 90:21 111:25 137:13 140:5,7 140:12,15,18 140:19 141:2 141:15 142:10 142:17,20 200:5,5 202:17 202:18,18,25 203:5,5,17,22 206:5,19,20 207:24 208:20 218:3,10 220:9 220:20,23 261:23 262:7 262:11 274:20 277:2,5 279:21 281:12 285:17 292:9 294:6 307:10
schedules 137:3,5,25 140:3 141:13 209:22 253:22 259:12,22 260:8 276:14 276:22 278:8 280:25 300:7
scheduling 283:18
schema 291:19 292:18
science 48:23 52:4 57:24
scientific 146:1 146:3 151:3 152:12
scientists 35:9
scope 52:19 182:19 183:3 221:5
score 245:7,19 246:7
search 50:4
searching 139:16
seat 254:22
second 55:11 181:3 184:4 254:5 256:4 289:19,20 290:2
secondary 229:11,13,16 229:20

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 367

section 32:14 129:11 145:1 145:14 173:7 190:4 227:4,7 232:5 249:14 260:21 261:2,9
sectional 69:19 69:20
see 6:25 9:19 9:24 16:2 17:2 18:7 23:12 30:25 32:16 45:23 60:17 61:25 64:21,22 64:24 65:1,9 66:10 70:8,9 77:17 78:11 79:19 87:5 88:6 91:6 100:3,10,12 105:13 108:24 123:15 125:17 129:13 133:12 135:14 137:1 142:11 144:12 144:25 154:20 159:9 164:10 166:12 172:5 173:10,16,23 180:13 181:5 182:12 184:9 184:15 185:4 196:8 203:1 204:10 206:2 206:21 207:2 208:9 209:11 216:20 220:6 222:9 223:23 227:14 228:12 228:18,21 229:1 231:23 244:10 246:2 249:11,15,25 259:2 266:10 272:22 287:5 289:7 291:18 291:21 292:19 295:4 297:18 301:14 302:24
seeing 24:16 27:8 67:17 84:21 148:9 256:13,21 299:2,9
seek 270:17 271:8,10
seeking 271:14
seemed 282:1
seems 20:9
seen 33:4 104:19 106:6 122:8,19 170:18 171:11 199:17 203:15 228:13 299:22
sense 23:20 63:18 120:9 128:16 184:14 184:19,22,25 201:12 225:1 251:10
sentence 172:2 175:14 182:2 184:4 239:9 254:6 286:23 286:25 287:2 295:6
sentences 264:10 271:18 272:2
separate 10:19 12:14 24:12 30:4 129:16 130:8,12
separately 30:9 30:17
september 3:16 232:1 258:25 261:5,11,15 263:7 266:8 267:3 270:10 270:25 271:18 272:3,19
sequentially 142:21
series 59:20 269:17
served 7:17 115:25
service 95:7
set 34:5 137:5 164:3 259:23 261:12 295:12 305:17
sets 180:8,9 184:5
setting 140:24 251:21 256:23
seven 113:20 113:21 210:14 229:16 230:14 238:16 280:4
several 186:25
severe 19:17 214:3 226:4
severities 25:4
severity 28:4 216:6 223:12 225:24
shaking 226:20
sham 79:10 240:10 246:17 246:18 249:21 250:3,4,20,22 251:10,25
shams 109:4,11 112:15,18,20 113:2 118:16 170:21 171:9 260:19,24,25 261:5,12,14,18 261:22 262:17 262:19 265:20 266:9,16,21 267:9 271:19 271:20 272:4 279:17 284:22 286:9 287:11 287:15,17

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 368

288:16,19
289:1,5,9,13
290:18 291:2,3
292:7,13 295:1
295:15,18
296:1,5 298:6
298:7,22 299:6
302:12
share 90:17
shed 252:14
short 21:9
23:19 269:19
shorten 7:1
84:17
shorter 20:23
208:25 216:9
shorthand
305:8
show 30:6,25
49:13 71:21
109:8 112:4,4
117:24 122:7
122:12 161:15
161:16 238:13
255:19,25
showed 55:20
106:9 111:19
134:4,19
showing 61:25
62:4 80:14
107:7 135:5
shown 73:23
80:18,23 133:1
134:25 286:19
shows 238:9
243:20 248:23
291:25
sic 17:20 26:18
34:11 45:23
116:9 198:7
206:4 284:6
298:11
sickle 15:8
sign 307:16
308:5
signature
138:22 156:21
305:24 307:21
307:23,23
308:9
signed 148:16
significant 58:5
107:1
signing 4:17
similar 46:6
97:1 102:1
160:18 184:21
187:19 202:7
250:6 298:5
similarly 80:8
163:20 167:6
170:20 240:7
261:1
simple 189:6
simply 301:24
simultaneous
257:7 284:10
single 51:11
176:1,6,9
178:11 182:4
183:7,13
229:13
sir 244:20
site 75:6
sitting 9:13,20
10:1 30:15
36:3 42:25
47:22 101:15
111:17 114:11
165:19,22
222:4 300:9
situation 92:15
six 113:20,21
209:2,12,14,15
210:10,24
211:18,20,24
211:25 213:4,5
213:7 229:16
230:14 238:15
280:4 281:15
skill 61:18
149:15 150:3
164:19 166:5,6
166:8 169:4,18
170:11 182:11
182:16,25
183:9 184:13
184:19,22
185:12 187:24
188:10,17
190:11 192:6
192:20 193:5
194:4 197:8
200:15 254:22
262:9,13
268:15 269:1
270:17 271:7
272:12 273:6
283:11 295:22
296:8
skilled 295:8
296:3,16,23
skillset 164:14
slit 32:1 43:2
slow 246:10
small 18:15
106:14
smaller 63:15
society 127:13
solely 182:24
271:17 272:2
solutions 189:9
189:13 307:7
someone's
250:25
somewhat 98:8
sorry 12:25
38:3,22 39:1
71:15 101:11
121:19 133:15
133:18 141:22
142:8,12 146:7
149:4 166:17
173:13 178:17
190:24 206:7
224:25 228:1
244:20 246:12
246:13 247:19
256:6,11

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 369

258:18 259:3 261:7 271:23 275:12,13 284:7 285:7,11 290:23 296:25 299:24 301:4 302:13
sort 49:15 61:19 201:11
sound 105:22 126:18
sounds 46:20 82:16 87:20 177:1 201:20
sources 184:12 186:3 272:6
speak 16:21 52:16 73:14 119:19 210:22
speakers 257:8 284:11
speaking 76:3 77:8 81:7
speaks 287:19
spec 42:11
specialist 8:18 16:1 92:21 109:25 110:21 193:15
specialists 90:14 93:2 126:14 127:14 127:15 165:4
specific 17:1 23:10 24:6,15 28:13,25 29:13 44:11 79:4 83:25 88:5 101:2,2 111:20 131:12 132:1 132:20,21 143:20 148:5,7 189:18 195:8 207:9 219:11 244:3,14 248:16 253:22 253:23 256:7 262:7 292:12 296:19,22 302:5
specifically 11:24 41:24 95:3 111:1 125:14 131:2 131:18 185:15 192:16 195:4 214:10 258:9 268:3 277:14
specification 147:15 295:7 296:2
specifics 113:13 114:9 195:1
specified 137:24 142:18 276:5 282:24
specifies 142:7
specify 141:12 282:13 283:9
specifying 287:11
spectrum 51:16
speculate 89:6 89:8
speculation 89:12,14
spread 107:15
squares 243:11
stages 225:21
stan 279:21
standard 5:6 41:2,11,12,14 41:16,18 42:3 42:6,8,16 43:8 43:11,16,23 44:8,12,16 45:4,9,13 51:5 51:13,18,20 79:11 162:20 163:4,10,17 173:20 240:22 250:20 278:4
standards 35:21 117:3 163:15,21 164:3 173:7,17
standing 176:22
stands 149:15 288:3
stanford 110:17
start 18:1,16 21:8 49:25 65:11 66:11 84:3,20 85:11 119:14,16 166:20 208:3 241:8 247:18
started 14:7 15:16 56:13 115:17 119:8 162:15
starts 18:16 155:17 173:7
state 5:8 132:24 203:15 266:7 301:15 305:9 307:9,12
statement 78:7 142:4 175:19 185:2 252:4 295:15 297:24
statements 123:2
states 1:1 17:15 61:22 290:22
statistical 247:8
statistician 235:24
statisticians 236:2,8,11
statistics 235:19,20,23 235:24
status 63:25 65:6 87:13,16 192:9 193:8,17

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 370

240:14 251:17
stay 125:21
128:10 294:25
stenographic
304:5
step 98:6
stephanie 2:13
steroid 43:22
steroids 55:16
stewart 110:8
stick 250:24
stimulates
18:22 19:8
stipulation
307:20
stop 216:1
269:16,24
stopped 294:5
stops 286:24
strategies
126:3
strategy 198:23
201:6,9,10
204:3 217:2,8
217:17 218:1,9
219:16,17
220:5
street 2:9 4:6
strike 185:6
stronger 269:2
structure 63:10
64:24 95:23
96:21 97:19,24
98:4,7 101:22
102:6,8 103:25
104:22
studied 238:23
studies 22:3
32:7 33:4
36:24 43:2
44:24 45:24
51:10 62:4,8
62:11,19,23
75:6,12 77:21
81:23 96:7
100:15 101:21
106:8 108:16
109:20 127:7
134:3,6 171:19
199:15 208:18
221:11 222:5
265:6 279:18
279:20
study 32:23
37:5 43:14
46:8 73:23
75:15,16,16
77:14,19 78:9
78:18 79:7
81:21 105:15
108:21 109:1,3
109:13 110:23
111:1,7,9,15,19
111:24 112:4
112:19,23
118:24 134:24
135:4,5 204:23
204:25 205:4,6
205:9,18
232:15 235:3
235:10 239:14
240:20 241:7
243:6 245:25
249:19,20,22
251:9 252:5,9
253:9,11,18
254:14 260:9
291:11 292:14
292:20 293:5,8
293:10,14,18
293:23 294:1,5
294:10
studying
221:11,25
237:2 267:23
275:8
subfield 72:23
73:5,13 243:2
243:22 244:25
245:6,9,17
246:8 247:17
248:9
subheading
142:11 162:18
173:10 249:8
258:13,18,22
260:12 261:2
266:19 267:13
subheadings
259:7
subject 11:10
11:11 71:20
144:8 151:4
152:13
submit 39:17
submitted 79:1
115:19 122:16
138:16 288:7
subscribe
126:19
subsection
162:18 231:21
231:25
subsections
260:23
subsequent
51:2 167:7
168:12 262:1,3
subsequently
89:2 166:24
subspecialty
127:3,4
substance 12:3
34:15 114:15
116:22 174:17
substantial
58:4
substitution
187:15
success 190:5,8
190:22 191:4,8
191:13,24
192:13,22
193:1,2,12,12
193:20,25
194:6,9,20,21
194:23,25
195:3,8 208:15
233:7,10,12

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 371

239:10 241:2
241:11,21
242:5,7 243:5
243:24 244:7
244:10,15,24
245:3,5,17,20
245:25 246:5
246:25 248:24
249:23 252:6,9
252:16,23
253:2,3 254:5
254:10,19
255:3,3 258:24
261:4,14
262:14 269:5
280:18 293:21
successful
80:14 190:15
194:22 210:12
successfully
208:14 210:21
sufficient
265:17 295:7
295:21 296:2,7
296:15
sugar 68:2
sugars 17:23
19:23 21:20
27:25 213:20
suggest 101:5
105:25 192:14
272:11 273:5
suggesting
105:18 195:13
suggestion
184:6 188:16
suggests 239:3
255:6
suite 4:6
sullivan 2:3
summers 2:3
5:12,12 13:19
20:17 21:16
22:10,13 24:13
26:8 27:10
28:21 29:10
30:19 31:6,19
33:19 34:13,17
35:4 36:9
37:18 38:1,11
38:20 39:5,13
40:16 41:4
42:18 43:10
44:15 45:18
47:4 49:16,23
52:18 53:14
54:12,21 57:6
59:7 60:19
62:6,17 63:22
65:13 66:13
69:1 70:16
71:13,23 72:8
72:20 73:7,16
76:17 77:11
78:5,15 80:16
82:8,13 84:15
94:12 95:12
98:2 100:5,21
101:10 104:5
112:1 114:13
116:1,20 123:5
129:21 135:7
136:17 138:2
138:13 139:15
139:21 140:20
146:6 150:10
151:8,18 154:8
157:16 161:1
168:3 174:15
176:13 177:4
177:25 178:15
178:24 179:7
179:14 181:9
182:18 183:2
183:15 185:20
187:6 189:14
191:15,25
193:3 195:6,12
195:18,22
200:24 204:13
206:6 207:6,19
210:16 212:14
216:3 217:3,11
217:18 218:4
218:11 219:25
220:10,21
221:4 222:17
222:25 226:9
226:23 227:24
228:3 230:10
230:24 231:6
231:13 232:12
233:19 235:5
237:20 238:17
241:15 242:9
243:16 244:1
245:11 246:1
248:3 249:1
252:7 253:24
255:23 257:4,9
257:14 263:2
263:15 265:8
265:24 266:22
267:5,16 270:4
271:21 274:17
275:18,21
276:16,25
279:9 280:6
281:21 282:22
285:1 289:2
290:1,12 291:7
292:10 294:7
294:17 295:16
298:13 302:23
303:3,7,16,22
supplied
300:24
supply 18:17
18:17 19:2,12
support 187:1
187:5 236:6
270:11 272:7
302:3
supported
12:10
sure 13:3 16:10
20:7,16,18,22
20:24 23:21
34:16,23 36:13

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 372

37:22 38:7 41:5 44:22 46:20 48:19 53:10 57:2 61:3 65:17 71:18 76:21 79:23 80:17 84:19 85:15 87:2 89:7 90:11 96:20 100:6 101:14 103:19 104:10 111:22 114:18 114:20 116:3 119:13 120:25 121:6,19,21 122:13 135:17 137:8,8,10,11 141:24 146:20 148:4,4 149:6 150:15 151:13 151:23 157:18 157:21 163:7 164:1 166:20 168:7 169:15 171:6 176:25 178:20 182:23 185:25 191:1 191:18,21 202:10 206:11 209:9 210:20 211:2 214:5 215:23 221:17 235:7 237:24 238:21 240:21

245:13 252:20 261:9 267:1,15 273:19 277:4 286:12 288:24 290:5,25 293:1 296:13 303:2

surgery 28:10

surgical 126:4

survey 127:16

swear 4:16

swearing 5:10

swelling 269:12

switch 16:19 84:12 88:3 258:3

switched 87:4 87:25 88:4,9 100:18 104:15 201:5

switching 84:8 84:23 85:4,8 87:5

swollen 18:9

sworn 5:21 305:4

syfovre 50:17

t

t 306:1 309:3,3

take 15:7,20 16:5 60:15 70:20 82:12,14 98:6 118:2 139:23 142:24 155:23 156:21 188:21 197:18

221:9,14,15 254:23 257:10 257:12 267:14 301:1 302:24 302:25

taken 1:15 4:2 95:6 216:14 305:6

talk 30:24 83:1 83:3,5 93:20 96:11 97:5 143:10,13 225:8 254:16 277:5 279:25 284:2,23

talked 8:19 40:4 74:22 83:8 118:16 236:7 252:22 275:22 279:16 279:16 299:25

talking 20:4 60:21 62:10 74:8 76:24 94:8 107:10 133:15 140:9 140:11 144:15 167:13 186:23 192:16 198:17 199:25 224:3 224:16,18 225:10 258:6,8 258:17,22 260:16,23 261:10 281:6

284:8,14 288:24 290:5 302:14

talks 289:15 290:18

taper 214:7,14 214:14

taught 279:6

teach 33:23 171:3

teaches 267:22 297:13

teaching 188:16 232:22

teachings 184:7 185:18 186:2

team 93:3 126:14 235:25 236:2,12

technical 146:1 146:4 151:4 152:12

technique 187:19,21

technology 32:20 35:8 64:3,6 124:11 125:2

tell 84:1 117:25 148:10,14 150:6 161:19 161:21,25 171:22 178:7 178:10 223:3 247:15 253:22

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 373

tells 271:4
ten 34:8 90:13 114:3 209:18 209:19 210:15 213:11,12 215:3
tendered 128:21 138:12 151:17 227:23
tendering 228:2
tends 103:2
tennessee 4:7 48:22 52:3,5,8 52:13 53:1,12 56:25 57:3,5 57:23,24 75:5 90:5 92:7,22 93:8,10,14,17 93:23 94:6,9 98:23 99:2 124:12,17 126:13 128:3 233:23 305:9
term 23:7,13,24 24:3 26:10,13 26:15,19 39:25 41:6 42:1,4,20 46:10,13,21,25 86:5,18 129:24 130:13,25 137:11,15,20 193:13 197:12 198:3 203:21 223:3 233:14 300:16 302:11
terminology 85:21 184:1
terms 13:14,23 16:15 23:14,15 31:8 41:18 45:2 46:23 58:13 62:21 64:14 66:25 68:11 69:12 71:10,11,21 74:2 86:19 98:11 108:7 143:11,12 189:13 190:16 192:3 194:21 200:19 202:15 213:24 240:12 250:11 251:18 276:21 277:6 278:7 279:17
tertiary 229:11 229:24 230:3
test 32:12 43:3
tested 46:1 260:8 288:25 292:20
testified 5:22 40:5 83:14 105:20 129:23 135:16 136:19 169:13 170:15 170:21 233:22 267:2
testify 305:4
testimony 9:15 10:4 23:22 25:9 38:2,12 38:17,21 83:6 83:19 97:9,15 143:10 155:15 177:5 219:14 230:21 233:13 237:17,25 266:12 267:6 282:7 299:9 304:1 305:7,10 306:3
tests 31:17,21 32:19
text 119:11 256:7
thank 6:1 40:24 102:21 138:13 151:18 227:1 233:19 263:2 285:1 302:22 303:18,23
thanks 228:3 263:2 298:15
that'd 123:18
theirselves 198:7
theoretical 102:4,9 107:5
theoretically 203:20
thera 199:13
therapeutic 87:6,10,10,20 87:21 88:6 99:13 100:1,1 102:5,9,14 106:1 107:8 199:14 261:24 262:2,4,5,9
therapeutically 261:19,21 297:15
therapeutics 198:17
therapies 51:9
therapy 15:3,5 15:14 198:3,9 198:13 199:11 199:25 200:9 224:1,7,20 226:8
thereof 69:14
thesis 14:21
thick 73:14
thickening 64:21,22 74:7
thicker 63:7
thickness 62:21 63:2,20 64:1,7 65:22 68:17,22 69:6,12,16 70:5,12,25 71:9,12,22,25 72:18,23 73:13 74:15,20 243:3 243:22 244:25

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 374

245:9 246:8
247:17 248:9
248:11,14
thicknesses
72:13
thing 18:25
39:23 49:15
63:2 67:4,16
79:6 124:7,24
186:23 247:12
things 17:24
58:8 62:19,24
70:21 93:21
117:13 132:11
237:2 250:12
think 10:4 11:5
13:20 14:3
16:6,14 20:8
20:25 22:14
23:25 24:1
25:12,25 29:7
34:8 35:6
37:22 41:12
42:3,19,21
47:6 50:7,18
51:15 54:5,10
55:7 56:6
61:18 65:19,19
66:1 78:7
82:11 99:9,11
99:19 103:5,13
104:18 105:6
105:19 106:2
107:22 110:20
128:2 135:16
140:21 142:23
152:19 161:16
162:14 165:12
169:9,12
170:15 172:17
177:6 178:9
179:9 183:5
184:17,21
185:5,7 189:17
190:9 191:6
198:5,10
202:13 206:10
209:18,24
210:20 214:22
214:23 217:19
219:13 220:1
220:22 223:20
223:22 226:15
226:18,23
231:17 233:13
233:22 238:9
244:3 247:3
248:5,18,22
250:16 253:6
256:2 257:2,12
259:10 267:2
267:18 270:13
271:2 272:6,7
275:1 277:16
287:16,19
291:17 293:3,4
293:22 295:1
296:6,14 297:1
thinking 54:7
170:1 204:9
211:16 214:24
third 55:15
58:22 197:5
thomas 110:1
thought 47:13
59:4 98:17,18
99:17 130:11
161:20 170:7
224:18 293:13
thoughts 74:13
151:20 235:13
three 7:1 10:19
11:14,15 12:14
13:4,15 97:25
115:22 183:4
195:16 199:9
207:25 211:4
229:15 230:13
263:22,24
264:9 267:25
268:9 271:18
272:2 273:23
274:15,21,23
275:9 276:10
278:14,17,22
282:9,21 284:5
284:19,20
291:12,25
threshold
68:23
thumb 68:23
71:9
tight 18:2
time 6:23,23
10:19 11:2
15:5,10 18:15
21:1 28:3
35:24 36:1
38:4 48:4 49:2
49:9 52:2
53:21 54:8
55:9,17 56:17
57:9 58:21
59:16,23 60:21
61:4,6,15,19
69:25 70:4
75:5,9 82:4,14
84:6,11,22,25
85:3,8 86:13
86:19 91:17
92:5,11,21
93:2,7 95:4
99:1 105:13
109:21 111:2
111:13 126:12
128:2 137:5
144:14 146:17
148:7,14,17
149:20 150:7
165:2,9,10
167:8,10,11
169:11,18,20
169:22 170:1,4
170:5,6,12,15
170:17 171:12
171:17,22
200:4,7,11,15
200:22 202:8
205:13,16
208:12 209:9

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 375

214:4 216:8,10 216:15 234:19 239:18 240:4 240:23 250:21 251:1,22 257:3 262:4,7 265:5 278:9 279:12 281:6,9 282:9 283:10 285:17 302:22 303:18 305:6 307:10 307:18,24 308:7
times 135:20 302:15
timing 220:13
tips 143:18
tissue 18:23 19:12 32:15 64:23
today 9:13,20 10:2 32:11 36:3 41:13 42:25 47:23 51:4 74:9 101:15 111:17 113:8,23 114:11 121:17 122:23,25 125:19,20 155:13 165:23 166:1 179:6 222:4 227:5,9 237:17,25 244:12 300:10
today's 6:23 48:9 112:8 115:4,9 122:16 155:15 304:1
together 35:12 115:24 116:17 156:15 247:9 266:1 293:11 297:7
told 163:12
tolerable 106:20
tomography 32:11 63:24
took 116:15
top 80:25 135:12 216:20 229:6,7
topic 82:10
total 114:1 254:6 263:9
totally 195:18
touched 106:2
track 256:20
traction 19:15
trademark 1:1
trained 55:12
trans 9:10
transcribed 305:11
transcript 9:11 9:23,25 10:3 306:3,4 307:6 307:8,10,13,13 307:21 308:2,2
transfer 15:3 15:13 124:11 125:2
transferring 125:8
translating 124:22
translational 124:20
transplantation 15:7,12,19
trap 263:17,19 268:2
treat 26:6,17 26:25 29:13 31:1 43:6 44:3 47:3,7 55:10 71:11,11 73:18 74:3,3,5,18 131:10,17 134:12 198:11 200:2 201:6,8 201:10,19 202:3 203:8,22 204:2 206:12 206:18 207:1 207:13,23 210:9 211:24 212:3,5 214:8 217:16,21 241:23 255:4 267:24 269:15 275:9 287:21 287:22
treated 26:24 46:4,5,16 57:18 105:7,10 106:16 130:12 189:24 198:19 199:13,18 240:3,8,18,22 255:5
treating 16:22 22:9 42:9 60:22,23 102:16,23,25 199:19 206:21 207:8 233:8 268:21 269:6
treatment 27:19 41:2,19 42:17 43:15 44:6 45:6,16 45:17,22 46:12 46:24 47:13 49:14 55:14,18 60:18 61:9 65:7 66:18 68:6,7,24 70:18 74:10 90:7 103:5,21 134:5,14,17 186:12,13 198:23 200:6 203:12 205:21 215:16,17 218:25 222:10 223:9,14 232:18 239:21

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 376

239:24 240:4,4 240:9,11 241:5 242:1 246:19 249:10 251:3 251:24 254:8 261:23 264:1 264:25 268:5 269:8,20 271:14 278:2,2 278:5 282:3 285:18 286:20 291:18 292:18 294:23
treatments 43:12 45:25 46:17 103:22 103:23 186:21 199:2 200:4 207:16 256:16 294:11,15,15
treats 209:21
trend 66:25
trial 1:1 3:13 45:24 61:14 75:20,22 76:2 76:5,8,13,16,22 77:1,4,10 78:14,17,25 80:4,6,9,11 99:5,16 111:4 134:20,21,22 247:6 251:20 252:2 253:13 259:14 276:1 280:15,16
trials 72:23 75:24 76:6 79:8,24 80:1 80:14,18,22 81:3,4,10,14 107:24 108:12 132:23,23 221:20,24 250:23 251:12 264:18,20 267:23 272:10 275:8 286:21
triamcinolone 3:14 240:8
true 254:1 306:3
truthful 10:6 142:5
try 18:18 20:8 24:15 38:25 106:20 146:21 187:25 189:2,4 190:4 201:16 202:4 214:8 226:24 269:16
trying 19:2 33:22 39:1 66:9 76:11 107:2 108:12 132:6 146:11 151:2,20 152:9 152:17 206:10 206:11 215:15 219:11 223:19 252:21 256:7
256:18
tumor 14:22
turn 135:11 143:24 156:2 216:17 227:3 231:18 239:5 242:16 245:23 260:11 272:14 289:8 291:16 291:20,21 294:24
turning 37:9 274:13
two 11:7 14:24 15:17 19:5 57:10 58:8,21 74:2,17 130:16 139:4 195:20 209:8 213:10 213:11,14 229:15,15 230:7,13 263:20,21,23 268:1,7,8,10,18 269:4 274:19 274:22 275:10 276:9 278:16 278:21 282:20 282:24 286:12
type 17:1 33:8 40:14 64:6 95:10,15 96:15 97:6,10,13 124:7 186:17 200:9 247:11
types 40:10 94:1 117:13 124:23 127:23 236:14
typewriting 305:12
typical 90:19 105:8
typically 36:25 79:1,8 132:3 211:6,8 213:5 213:14

u

u.s. 3:9,20,21 6:16 8:24 10:10 121:8 135:13 228:6 297:21 298:3 298:18 299:12
uh 24:4,18 31:12 39:20 50:9 63:11 68:20 69:8 70:7 72:3 139:1 145:10 186:5 189:3 193:10 212:18 213:8 214:1,25 224:10 225:25 246:20 281:14 283:7
ultimately 78:25 81:10 134:20 215:17

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 377

umbrella 23:23 23:24 129:24 130:13 223:2
unclear 6:12 7:2 148:3
under 4:7 23:24 67:22,23 71:6 76:11 134:7 136:23 137:13,24 142:13,16,20 162:18 209:5 232:24 244:18 260:12 261:17 263:18 266:19 280:1,20
undergo 132:22
underlying 59:11
underneath 65:2
understand 6:12 10:17 12:8 13:1 20:19 21:6 23:23 25:8 26:1 35:22 38:16 39:7 46:6 47:19 54:17 57:9,22 66:9 67:2 71:7 76:12 77:12 86:4,5 91:5 100:7 107:6 111:21 114:18 116:3,25 121:20 125:1 132:7 137:9,15 137:16 145:24 146:12,20 147:11,19 150:2 151:2,10 152:6,20 154:3 158:22 163:7 168:21 169:6 172:3 173:5 175:14 176:24 178:6 184:17 187:1 192:6 194:24 196:3 204:8 206:11 214:12 218:17 219:13 223:22 226:16 235:23 235:24 245:13 252:22 255:12 281:4 295:11 301:16
understanding 6:17 17:10 20:9,13,14 21:2 22:9,18 25:21 37:9 39:2,15 41:24 46:2 51:19 52:12 67:13,14 68:19 74:19 75:23 76:14,16 77:9 78:3,13 78:23 81:22 85:16 86:3 91:20 95:9 96:14 102:15 112:18 117:11 119:25 120:14 127:22 129:20 130:17 132:7 132:10 148:25 149:17 153:6 153:24,24 161:9 166:7,14 166:19 167:2,5 168:25 169:2,5 170:10,12,14 172:14,23 174:21 175:2,8 175:19,24,25 176:10,20 177:2,8,22 178:22 179:10 180:10 181:7 181:11 182:3 184:5 190:7,13 190:14 191:7 191:18 192:3 196:2,10 200:22 201:3 209:3 212:20 212:23 217:1 218:15,20 219:12 221:19 228:8,14 239:18 240:12 241:6 243:20 246:4 252:18 261:18 270:9 273:17 287:20 287:25 291:9 295:23 297:13 301:23 302:10
understood 28:16 35:24 37:22 45:15 47:18 57:2 65:20 71:6 102:21 134:9 148:16 194:14 217:14 247:7 268:16 282:7 283:12
underway 221:24
unique 132:9
united 1:1
units 68:18
university 48:22 52:3,4,8 52:12 53:1,11 56:24 57:3,5 57:23 75:5,14 90:5 92:7,21 93:8,9,13,17,23 94:5,9 98:22 99:2 124:11,16 126:13 128:3 233:23
unquote 102:23 130:21 158:21 280:19

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 378

unsure 34:21
urquhart 2:3
usage 129:12 136:24
use 3:8 26:15 26:18 29:15 32:10 39:25 41:7 42:1,4 46:13,21,25 50:24,25 51:10 51:14 53:3,5,8 53:16,23 54:14 54:18 55:3,5 56:2,9,22 57:11 58:16 59:9 61:21 62:2 63:19,23 64:10,13 65:21 65:21,24,25 66:3,5 68:23 72:23 77:2,17 80:10 85:12,21 90:16 94:18 106:5 128:17 129:2,4 131:9 131:13,16 132:17 133:2,4 133:8,19,21 134:2,23 135:2 136:11,14 137:6 139:7,10 164:23 165:5 166:21 170:5 186:11 187:18 187:20 188:5 188:12 209:23 232:17,23 235:20 251:3,6 251:14 288:23 300:17
used 23:8 32:21 41:6 42:10 44:3 45:23 51:7,14 52:10 53:11 55:18 57:15 64:9 77:21 83:14 86:22 90:7 92:12,15 98:15 112:23 131:1 131:24 134:17 140:2 141:5 168:21 169:10 183:4,7 196:24 197:1 203:24 204:3 222:8 245:25 251:10 253:22 273:4 280:15 281:23 297:6 300:15 300:19 302:11
useful 69:10,17 215:14 256:2 293:7
uses 169:19
using 24:3,6 25:20 26:9,12 26:13 33:8 52:5 54:11 55:23 56:4,13 57:10 60:3 64:17 70:1 86:18 88:7 137:11 140:16 144:2 167:6 186:20 192:17 199:7 210:22 211:13 219:12 239:6 265:19 265:25 268:1
utilized 199:16

v

vague 13:19
valid 12:20 13:12
validated 186:12
validity 164:3 173:25
vanderbilt 48:21 52:14 74:23 88:19 89:1,23 90:1,5 90:14 91:4,16 91:22 94:1,16 236:1,6,12
variables 47:20
variation 201:11
variations 187:25 188:5,9
varies 71:25 72:14 216:6
variety 276:14
various 20:14 23:8 25:3,4 35:21 45:25 64:8 71:8 90:16 103:21 103:23 147:14 175:7 180:11 221:19 223:12 259:11 302:15
vary 194:21 211:2 280:11
vascular 19:4,9 33:2
vasculature 21:21
vegf 17:3,4,5,10 17:21 18:13 19:5,5,19,23 20:10 21:2,7 28:19,23 29:8 31:1 41:1,1 43:21 44:1,2 50:7,23 51:11 53:25 54:9 56:8,19 57:10 58:7,21 61:6 61:21 65:11 66:11 68:8,24 70:15 71:3,11 74:4 88:8 92:16 99:14,17 101:24,24 102:23,25 103:2,3 104:3 106:5 112:21

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 379

112:23 131:13 131:21,23 132:1 134:10 136:19 141:12 141:18 142:1 186:11,11 188:12 192:4 192:22 199:2 199:23,25 203:25 204:18 205:22 206:4 207:23 210:23 212:8 216:1,7 216:14 221:11 221:20,25 222:5,7,15,21 223:9,14 224:1 224:7,20 226:8 229:12 232:24 251:23 261:19 261:21,25 263:17,19 268:2 269:5,10 269:17 278:4 279:4 286:6 287:7,23 288:23 289:17 289:19 290:8 290:11,19 297:16,17
vein 32:25
verdict 143:16
veritext 307:7,9 307:11
versus 118:7 178:13
vessels 17:25 18:4,14,15,19 18:24 19:3,21 19:22,24 32:25 67:7 103:2,4 269:13
video 5:6,6
videographer 2:13 5:1 82:17 82:21 142:25 143:4 197:19 197:23 257:15 257:18 303:9 303:13,20,25
videotape 1:13 4:1
view 24:12 42:14 44:12 62:16 73:14 140:7 149:12 187:5 188:21 189:11 190:20 190:21 258:23 260:19 261:12 266:9 271:13 271:16,25 296:19
viewed 150:5
vision 18:12 66:21 87:14,16 193:16 203:17 203:19,21
visit 28:2 69:6 206:5 241:20 249:19,22 252:5,9 253:9 253:11
visits 203:6 204:11,19 205:4,21
vista 81:14
visual 62:24 66:18 73:25 74:2,21 193:18 219:7 245:7,19 245:19 246:6
vitreous 19:13 28:6
vivid 81:13
volume 32:15
vs 1:5 307:4 309:1

w

wait 84:11 85:1 85:8
waived 4:11,19 5:5 307:23,23
waiving 307:20
walk 207:14
want 11:22,23 23:11 24:6 26:1 27:3 34:14 39:23,23 53:9 69:15 79:22 113:12 114:8 116:14 123:11 128:19 135:17 137:10 140:23 161:23 176:5 202:9 209:6 216:18 218:17 257:10 260:22 266:4 275:21 284:23 285:3 299:24
wanted 15:20 49:21 53:11 57:2 118:6 123:12 154:19 155:12 175:4 194:24 240:20
wants 198:11
warrant 77:18
warranted 68:25
watch 139:17 195:15
way 20:11 24:1 29:12 56:6 65:8 115:12,13 127:18 128:16 128:17 140:9 140:22 146:21 161:14 163:5 164:18 185:6 187:20 194:1 195:8 198:18 202:12,13 208:23 239:2 241:7 247:23 250:15 269:15 305:15

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 380

ways 126:9 193:21 225:23 271:10
we've 102:17 106:6 139:18 203:15 211:20 233:11
week 213:5,7 213:14 241:23 243:9,21 247:1 247:2,24 248:24 249:19 252:24 253:5,9 270:20 278:17 284:5,19
weekly 125:24 286:3,6 299:25
weeks 208:24 208:24 209:2 209:12,14,15 210:10,15,24 211:18,20,24 211:25 213:4 213:10,11,11 213:12,12 215:3,4,7 219:5,5 230:1 230:4,9,18 233:1 252:17 254:11 263:22 268:9 274:21 278:17,17 280:4,4,4 281:15,16 284:14 286:13 286:24
welcome 143:8 257:22
went 15:25 116:14,17 119:6
what'd 83:3
wheeley 124:10
whereof 305:17
widget 39:18
willing 67:24 88:23
withdraw 104:13 123:11 153:8 182:1 275:13
witness 3:3 4:16,18 5:11 5:14,23 13:20 20:18 21:17 22:14 24:14 26:9 27:11 28:22 29:11 30:20 31:7,20 33:20 34:14,19 35:6 36:10 37:19 38:3,13 38:22 39:6,14 40:18 41:5 42:19 43:11 44:16 45:19 47:5 49:17,24 52:20 53:15 54:13,23 57:7 59:8 60:20 62:7,18 63:23 65:14 66:14 69:2 70:17 71:14,24 72:9 72:22 73:8,17 76:18 77:12 78:6,16 80:17 84:16 94:13 95:13 98:3 100:6,22 101:11 104:6 112:3 114:14 114:17 116:2 116:21,24 123:6 129:22 135:8 136:18 138:3,20 139:24 140:21 146:7 147:1 149:25 150:11 151:9,15,19 154:9 155:19 157:18 161:2 168:4 172:9 173:9,12,22 174:16,19 176:14 177:6 178:2,17 179:1 179:8,16 181:10 182:20 183:4,16 185:4 185:22 187:7 189:16 191:17 192:2 193:4 195:7 200:25 204:14 206:7 207:7,20 210:17 212:15 216:4 217:4,12 217:19 218:5 218:12 220:1 220:11,22 221:6 222:18 223:1 226:10 228:11,25 230:11,25 231:7,14,20 232:13 235:6 237:21 238:18 241:16 242:10 243:17 244:2 245:12 246:2 248:4 249:2,7 252:8 253:25 255:24 256:5,6 263:16 265:9 265:25 266:23 267:7,17 270:5 273:2 274:18 276:17 277:1 279:10 280:7 281:22 282:23 288:20 289:3 289:11 290:2 290:13 291:8 292:11 294:8 294:18 295:17 297:11 305:2,7 305:17 307:13 307:16 308:2,5

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 381

309:24
wo 3:18
wonderful 16:12
wondering 186:7
woo 2:13 5:19
word 25:21 166:19 208:15 219:12
wording 300:23
words 195:23
work 7:16,19 7:23 8:1,3 11:21 13:14,17 13:22 14:1,24 15:14,22,23 33:22 51:1 101:16 115:17 115:21 124:21 125:14,16 126:23 148:20 188:5 233:24 234:2,4 292:22 293:2,6
worked 7:14 34:11 293:3
working 14:11 15:17 16:7
works 21:2,15 52:23
world 37:10 125:8 127:16 210:9 240:19
worse 42:15,20 87:24 215:8
wound 18:24
wright 4:5
write 188:4,15
written 120:11 120:15 121:2,5 121:7,10 131:18 155:20 155:23 156:4 156:12,16 157:4,10,14,23 158:2,7 159:3 159:15,20 160:9 189:10 190:10 286:1 301:17
wrong 242:21
wrote 175:13 219:20

x

x 3:1 308:9

y

y 243:1 248:8,8
yancopoulos 227:13 228:9 228:15 230:22 231:4,11
yeah 17:4 20:18 36:8,10 39:6,6 40:18 41:5 42:19 48:2 50:22 53:3 64:9 65:14 69:2 70:10 71:14 73:17 76:9 82:13 92:2,19 104:6 108:4 112:3 114:17 138:24 139:21 139:21,21 146:10,19 173:16 176:14 179:1 182:20 190:24 191:17 194:23 195:22 195:22 196:9 209:24 229:9 233:15,15 234:1 247:19 253:25 275:19 284:8,13 285:22 288:1 301:6,8,10,12 302:23 303:7
year 7:8 9:6 11:4,6 115:19 127:4,5,11,16 254:13 255:15 277:20 278:9 281:6
years 11:7 14:5 15:17 20:5 21:25 61:8 74:3,17 101:6 101:16 165:15 165:21,22
yep 201:21 243:17
yield 187:9,21 288:7
york 2:5,5

z

zach 2:3 5:12
zachsummers 2:6
zoom 2:13 5:19 113:16 162:6

Samsung et al. v. Regeneron IPR2023-00884
Regeneron Pharmaceuticals, Inc. Exhibit 2062 Page 382

Tennessee Rules of Civil Procedure

Depositions Upon Oral Examination

Rule 30

Rule 30.05: Submission to Witness; Changes; Signing.

When the testimony is fully transcribed the deposition shall be submitted to the witness for examination and shall be read to or by the witness, unless such examination and reading are waived by the witness and by the parties. Any changes in form or substance which the witness desires to make shall be entered upon the deposition by the officer with a statement of the reasons given by the witness for making them. The deposition shall then be signed by the witness, unless the parties by stipulation waive the signing or the witness is ill or cannot be found or refuses to sign. If the deposition is not signed by the witness within 30 days of its submission, the officer shall sign it and state on the record the fact of the waiver or of the illness or absence of the witness or the fact of the refusal to sign together with the reason, if any, given therefor; and the deposition

may then be used as fully as though signed unless on a motion to suppress under Rule 32.04(4) the court holds that the reasons given for the refusal to sign require rejection of the deposition in whole or in part.

DISCLAIMER: THE FOREGOING CIVIL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE STATE RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS

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Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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