1 UNITED STATES PATENT AND TRADEMARK OFFICE 2 BEFORE THE PATENT TRIAL AND APPEAL BOARD 3 4 MYLAN PHARMACEUTICALS, INC.,) 5 Petitioner,) 6 vs.) 7 ALLERGAN, INC.,) 8 PATENT OWNER.) 9 10 DEPOSITION OF DANIEL BLOCH, Ph.D. 11 8:45 a.m. 12 13 July 14, 2017 14 701 Fifth Avenue, Suite 5100 15 Seattle, Washington 16 CASE IPR2016-01127, PATENT 8,685,930 17 18 CASE IPR2016-01128, PATENT 8,629,111 19 CASE IPR2016-01129, PATENT 8,642,566 20 CASE IPR2016-01130, PATENT 8,633,162 CASE IPR2016-01131, PATENT 8,648,048 21 22 CASE IPR2016-01132, PATENT 9,248,191 23 24 25 REPORTED BY: Pat Lessard, CCR #2104

DANIEL BLOCH, PH.D. - 07/14/2017

DTI Court Reporting Solutions - Woodland Hills

www.deposition.com

Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

826-0277

DANIEL BLOCH, PH.D. - 07/14/2017 Pages 2..5

1	A P P E A R A N C E S		1 2	DANIEL BLOCH, being duly sworn, testifie upon oath, as follows:
3	FOR THE PETITIONER:		3	E X A M I N A T I O N
4	MR. MICHAEL J. KANE		4	BY MR. KANE:
5	Fish & Richardson		5	Q. Good morning, Dr. Bloch.
6	3200 RBC Plaza		6	A. Good morning.
7	60 South Sixth Street		7	Q. Could you state your full name for the
8	Minneapolis, MN 55402		8	record.
9	612.335.5070		9	A. Daniel, middle initial A, last name Bloch
10	kane@fr.com		10	spelled with an H.
11			11	Q. What's your current business address?
12	FOR THE RESPONDENT:		12	A. My current business address?
13	MR. STEVEN W. PARMELEE		13	Q. Yes.
14	MS. GRACE A. WINSCHEL		14	A. 8987 East Tanque, spelled TANQUE. A
15	Wilson Sonsini Goodrich & Rosati		15	then another word Verde, V E R D E. And then a pou
16	701 Fifth Avenue, Suite 5100		16	sign 309-387. Tucson, Arizona 85749.
17	Seattle, WA 98104-7036		17	I've given you that. That's my mailing
18	206.471.2083		18	address. I have an office at Stanford but I live is
19	sparmelee@wsgr.com		19	Tucson and my letterhead has that address on it, my
20	MS. JACQUELINE ALTMAN		20	Tucson address.
21	Wilson Sonsini Goodrich & Rosati		21	Q. Thank you. Have you been deposed before?
22	12235 El Camino Real, Suite 200		22	A. Yes.
23	San Diego, CA 92130-3002		23	Q. How many times, approximately?
24	858.350.2300		24	A. A dozen.
25	jacqueline.altman@wsgr.com		25	Q. So you've been through the drill before b
		Page 3		
1	EXAMINATION		1	I'll just kind of give you the ground rules again.
2	ATTORNEY	PAGE	2	A. Okay.
3	BY MR. KANE:	4	3	Q. So I'm going to be asking questions. You
4			4	going to be providing the answers. Your counsel ma
5	EXHIBIT INDEX		5	have some objections at some points along the way.
6	No. DESCRIPTION	PAGE	6	Our court reporter here is going to be
7	Exhibit 2078 Center for Drug Evaluation and	95	7	taking down everything that we say, so it's importa
8	Research Medical Review(s).		8	that a couple things. One, it seems like you ma
9	Exhibit 2079 Document titled "Ophthalmology	77	9	be a fast talker and I'm definitely a fast talker,
10	Volume 107, Number 7, July 2000."		10	we both should try to maybe slow down to help her o
11	Exhibit 2080 QuickCalcs Unpaired test	85	11	Another thing is I'll do my best to let y
12	results.		12	finish your answer before I start speaking again an
13	Exhibit 2081 QuickCalcs Unpaired test	86	13	likewise, you should let me finish my questions bef
14	results.		14	you start speaking so that she can get that down.
15			15	Okay?
16	REFERRED EXHIBIT INDEX		16	A. Sure.
17	Exhibit 1040 Declaration.	7	17	Q. If I don't ask a question that you
18	Exhibit 1043 Curriculum Vitae of Daniel A.	8	18	understand or is confusing to you please let me kno
19	Bloch, Ph.D.		19	and I'll try to clarify for you. Okay?
20	Exhibit 2027 Report marked 074.	44	20	A. Okay.
21	Exhibit 1004 Excerpt.	48	21	Q. And if you answer the question I'm going
22	Exhibit 1007 Sall publication.	77	22	assume that you understood the question. All right
23	Exhibit 2008 Portion of the Restasis label.	92	23	A. Yes.
24			24	Q. That's another thing, you have to answer
25			25	verbally "Yes" and "No," not uh-huhs or huh-uhs or
-	DTI Court Reporting	~ 7		ions - Woodland Hills

ALARM

Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

DANIEL BLOCH, PH.D. - 07/14/2017

Pages 6..9

	D	<u> </u>	D-
1	Page nods of the head or shakes of the head. She can't get	° 1	Pa Is that right? No? I'm not really quite
2	that down, so that's a good point to remember.	2	sure. Sorry.
3	Finally, we'll take periodic breaks roughly,	3	Q. The signature is June 30th.
4	usually about an hour or so of questions and then let	4	A. All right. So it had to be early in June.
5	everybody stretch their legs and what have you.	5	Q. Okay. How much time did you spend working
6	If you need a break	6	on the declaration?
7	A. I'll let you know.	7	A. Many hours. I don't really have an estimat
8	Q let me know.	8	with me. Certainly more than 50.
9	A. Okay.	9	Q. And did you draft the declaration yourself
10	Q. Very good. Is there any reason that you	10	or how did that process work?
11	can't give accurate and truthful testimony today?	11	A. Yes, I did.
12	A. No.	12	Q. So you typed the words yourself?
13	Q. You understand that you're under oath and	13	A. No. Counsel counsel prepared the
14	the testimony you are giving is under oath and is	14	formatting of the declaration and they aided me in
15	admissible in court?	15	figures, formatting and things of that nature, but I
16	A. I do understand, yes.	16	wrote the text.
17	Q. You were talking over me there. You've got	17	Q. How did you write the text? Did you type i
18	to slow down and let me finish my question. Okay?	18	in some sort of document and send it to counsel?
19	A. Yes.	19	A. Yeah. Yeah, we went back and forth.
20	Q. What did you do to prepare for your	20	Q. Okay. I'll hand you what's previously been
21	deposition today?	21	marked as Exhibit 1034.
22	A. I read over materials that are pertinent to	22	Do you recognize that document?
23	or included in my declaration and I met with counsel.	23	A. It appears to be a version of my CV. Yes.
24	Q. When did you meet with counsel?	24	Q. I see it's dated November 1, 2016.
25	A. Yesterday for several hours as well as the	25	A. Yes, I see that, too.
	Page	7	Ра
1	day before.	1	Q. Was it accurate as of that date?
2	Q. Did you speak to anyone other than counsel	2	A. Yes.
3	about the deposition?	3	Q. Have there been any changes to your CV in
4	A. No.	4	the meantime?
5	Q. I'm going to hand you, Dr. Bloch, what's	5	A. There are some minor ones, I believe. Ther
6	been marked as Exhibit 1040.	6	has been at least one manuscript that was submitted
7	A. Okay.	7	that has been accepted, so that would be a change.
8	Q. Do you recognize that document?	8	Otherwise, I don't think I changed I
9	A. Yes, this is my declaration, a copy of my	9	would have changed anything. I think that's probably
10	declaration.	10	the only change of substance, maybe.
11	Q. And on page 35, that's your electronic	11	Q. What was the nature of that manuscript?
12	signature?	12	A. Oh, it had to do with an intervention of a
13	A. Yes, it is.	13	pharmaceutical company having to do with artificial
14	Q. And if you look at the front cover you'll	14	protection of too much scarring as a result of back
15	see that there are a total of six IPRs listed.	15	surgery on the spine.
16	Do you see that?	16	Q. When you say "intervention," what do you
17	A. Right.	17	mean?
18	Q. And you provided the same declaration or one	18	A. They have to cut you open and put this tube
19	deposition for all six IPRs?	19	in here where they are surgically trying to help you
20	A. That's my understanding why they're listed	20	with your debilitation.
21	here.	21	Q. Thank you. And looking at the front of you
	Q. When did you begin working on this	22	CV I may have said 1034 before but it's actually
22	declaration?	23	Exhibit 1043, if I misspoke I saw you got a BS fro
22 23			Stanford in statistics and a Dh D. from Johns Manhing
	 A. Sometime early in June no, sometime early in July, I think. 	24	Stanford in statistics and a Ph.D. from Johns Hopkins

ALARM

Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

DANIEL BLOCH, PH.D. - 07/14/2017 Pages 10..13

Page 10 Page 10 1 A. Thi's correct. Page 10 2 0. Res your sequences history been forced on statistics? Iteratment of dry eye or RDS 4 A. Yes. Well, In terms of the scadenic part of sy carrest. a bits specify a bits if damped at the set of sy carrest. Iteratment of dry eye or RDS 6 I've hem self-employed as a contractor as well. That's a completely different profession. if dry eye and abe haded no to at the time that abe specified at the set of the scadenic part of sy that diagones is permet that may - it wasn't thing perhaps working better than another. 7 Well. That's a completely different profession. if thing of the scale is a contractor in California. 11 huild hemse. if the scale is a spectra to serve the serve these are FDS and bay if drived wasnes thin ER, or these are FDS and bay if drived wasnes thin ER, or these are FDS and they if drived wasnes thin ER, or these are FDS and they if drived wasnes thin ER, or these are FDS and they if drived wasnes thin ER, or these are FDS and they if drived wasnes thin ER, or these are FDS and they if drived wasnes the scale is a bitstrict if drived wasnes the scale is a bitstrict if drived wasness and that thene's a bitstrict if drived wasness and they thene's a bitstrict if drived wasness and they is a bitstriptic origin of the scale is a bitstrict if drived wasness and they well at it a drived wasness and they is a bitstriptic origin of the scale is a bitstrict if drived wasness and they well at it drived wasness and they well at it a drive the FDA is a drived wasne scale is a drive of the FDA i		DANIEL BLOCH,			
2 0. Has your employment history been focused on a strainting? 2 A. Been you may have I down any work, I've a strainting? 3 strainting? 3 adviced people. I had a colleage at Standord with has diver exit ale acide us to - at the time that has been understand, you know, what the evidence is of one well. That's a completely different profession. 3 a dviced people. I had a colleage at Standord with has diver exit ale acide us to - at the time that has diver exit ale acide us to - at the time that has sourcestor? 3 0. Mat kind of activities div you mortake as a contractor? 5 built homes. 10 A. I has a general contractor in California. I built homes. 10 Diverse with a scale that the evidence is the a scale that the scale bas of the that's a contractor? 3 11 built homes. 10 For that was not people. 10 12 0. Prior to -wall. let m step back. You're or thiggstion going on in the battent Office, or control? 10 0. Are you assisted in review of the 20 A. Yee. 13 A. Yee. 20 N. Was the generation form. 21 9 14 0. Are you assisted in review of the 20 A. Yee. 21 9 A. Well. 15 A. Excuse me. 21 0. Rave you assisted in review of the 20	1		10	1	Page 12
3 statistics? 3 advise people. I had a collassue at Stanford who has 4 A. Yes. Well, in terms of the academic part of symptoms. 5 advised people. I had a collassue at Stanford who has 5 The been self-equipyed as a contractor as 5 got that diagnois to permet the interature to help 6 The been self-equipyed as a contractor as 6 her understand, you know, what the evidance is of one 7 N. Wast kind of activities did you undertake as 5 So that was a case that was it wasn't 9 a contractor? 9 through a planmoeutical company, it was just a 10 A. I was a general contractor in California. I 11 Duite homes. 11 11 built homes. 12 realewide is of your you how, what the evidence is of your professional company. It was just a 12 O. Bare you assisted in review of the 10 11 13 A. Yes. I have. 14 0. Star you assisted in 14 A. Yes. I have. 12 0. Star you assisted in 15 A. Yes. I have. 14 0. Star you assisted in 16 A. Yes. I have. 14					
4 A. Yes. Well, in terms of the academic part of 5 my correr. 4 dry rep and the acked as to at the time that the 5 5 my correr. 10 A. Yes. Part completely different profession. 5 7 well. That's a completely different profession. 6 her understand, you know, what the evidence is of core 7 well. That's a completely different profession. 7 thing perhaps working better than another. 8 0. What kind of activities did you undertaks as 9 a contractor? 9 10 A. Tes a general contractor in California. I 10 private kind of thing. 11 10 private kind of thing. 12 0. Really. 13 an otherwise, I think with dry eye, I don't 13 A. Ottom homes, things of that mature. That's 13 involved with. 14 why there's a gap between 1972 and 1984 on that front 13 13 involved with. 15 o. Trior to well, let me step back. You're 14 0. Neap you assisted in review of the 15 o. Neal, you're been magaed to work on the 14 14 0. Neap you assisted in review of the 16 O. Neap you assisted in the back of the system 10 N					
5 my career. 5 got that diagnosis to peruae the literature to help 6 I've been self-employed as a contractor as 5 got that diagnosis to peruae the literature to help 6 I've been self-employed as a contractor as 5 got that diagnosis to peruae the literature to help 7 9 Neak kind of activities did you undertake as 5 got that diagnosis to peruae the literature to help 8 0 Mat kind of activities did you undertake as 5 got that diagnosis to peruae the literature to help 9 a contractor? 1 thing perpaers withing between 1972 and 1984 an that front 1 10 bit observeen the literature to help 13 A. Yee, I've been told that. 1 0 Reave the and pervalue that it is a set pervalue that it is a set pervalue that it is a pervalue that it is a very treat of the pervalue that it is a very treat of thought when the objection or pervalue that it is a very treat of thought when the objection or pervalue that it is a very treat of the pervalue that it is a very treat of the pervalue that it is a very treat of the pervalue that it is a very treat of the pervalue that it is a very treat of the pervalue that is incalled in setting in the back of the pervalue that is incalled in setting is a very verify of the FRA. 1 0 N've, i 0 N've, i 2 0 0 <t< th=""><th></th><th></th><th></th><th></th><th></th></t<>					
6 I've been self-employed as a contractor as 6 her understand, you know, what the evidence is of one 7 well. That's a complexity different profession. 7 thing perhaps working better than another. 8 0. What kind of activities did you understake as 8 5 both to sea case that wasit was't 9 a contractor? 9 both to sea case that wasit was't 10 A. T was a general contractor in California. I 10 private kind of thing. 12 0. Really. 11 But otherwise, I think with dry eye, I don't 13 A. Outon honse, things of that nature. That's 13 involved with. 14 0. Frior to well, let me step back. You're 0. Clay. 1 0. A payt of your professional career as a 17 christisin agoing on in the Fatent Office. 0. Reare you assisted in review of the 1 0. Reare you assisted in review of the 18 a tradition that have done to probably in the startup companies 1 0. Reare you assisted in review of admissions 19 A. Yes. I have. Page 11 2 0. Reare you assisted in review of admissions 20 Park of you two been engaged to work on the 2 3. Nei		-			
7 well. That's a completely different profession. 7 thing perhaps working better than another. 8 0. Mat kind of activities did you undertake as a contractor? A. I was a general contractor in California. I built homes. O. Really. C. One maily. A. Custon homes, things of that nature. That's d. O. Frior towell, let us step back. You're d. Organ ware this IFR, or these are IFRs and they proceeding going on in the Patent Office, O. Prior towell, let us step back. You're A. Yes, I'we been told that. O. You also understand that there's a District A. Yes, I'we been told that. O. And you'we been engaged to work on the Mat kind was the question you assisted in A. Yes., I'we been told that. O. And you'we been engaged to work on the Mat was the question you assisted in Mat was the question you assisted in Page 11 A. Yes., I have. Page 11 Q. Prior to baing engaged with respect to the dispute researchy with the startup company. A. Well, that's a very trood question. As a biostatistician, I'we interacted with perple at Page 13 A. Well, that's a very trood question. As a G. Prior to baing engaged with respect to the A. Well, they can stake scorething in the bake of the cy. Q. Hy question was here I animissions to the FTM? A. Well,		-			
8 Q. Mat kind of activities did you undertake as 9 So that was a case that was it wasn't through a pharmocutical company, it was just a 9 A. I was a general contractor in Galifornia. I 1 built homes. 11 built homes. 1 Derivate kind of thing. 12 Q. Really. 1 But otherwise, I think with dry eye, I don't 12 Q. Really. 1 But otherwise, I think with dry eye, I don't 13 involved with. 14 0. Okay. 14 Wy there's a gap between 1972 and 1984 on that front 15 A. But of your professional career as a 16 Q. Prior to well, let me step back. You're 16 Q. As part of your professional career as a 17 dvicuuly aware this IRP, or these are IRPs and they 18 approval of drugs by FDR? 18 ornerd? 2 Q. Rave you assisted in review of the 19 A. Yes. 1 A. Wes. 20 A. Yes. New you assisted in review of submissions 21 A. Yes. New you assisted in review of submissions 22 Court litigation going on in Marshall, Tessa? 2 Neway we asstasted in review of submissions					-
9 a contractor? 9 through a plasmaceutical company, it was just a 10 A. I was ageneral contractor in California. I 10 private kind of thing. 11 built homes. 11 But otherwise., I think with dry eye, I don't 12 Q. Really. 11 But otherwise., I think with dry eye, I don't 12 Q. Really. 12 recall that being a subject matter that I've been 13 A. Outom homes, things of that nature. That's 4 Q. Okay. 15 A. Decome me. 13 14 Q. Okay. 16 Q. Prior to well, let me step back. You're 16 A. Yes, I've been told that. 16 19 Orivally graan diff Brg. or these are TRS and they 18 approval of drugs by FDA? 19 A. Yes., I've been told that. 19 A. Yes. 10 A. Yes. 10 Rew you assisted in review of the 11 A. Yes. I have. 20 Rew you assisted? 24 14 O. Prior to being engaded with respect to the 23 Mat was the question was have you assisted? 12					
10 A. I was a general contractor in California. I 10 private kind of thing. 11 built homes. 11 But cherwise, I think with dry eye, I don't 12 0. Beally. 11 But cherwise, I think with dry eye, I don't 13 A. Oaston homes, things of that nature. That's 13 But cherwise, I think with dry eye, I don't 14 why there's a gap between 1972 and 1984 on that front 14 0. Clay. 14 why there's a gap between 1972 and 1984 on that front 15 A. Excuse me. 16 0. Prior to well, let me step back. You're 16 0. As part of your professional career as a 17 obviously same this IFR, or these are IFRs and they 18 approval of drugs by FM2 18 orrect? 10 Yes. 14 0. Gay. 20 Or also understand that there's a District 20 0. How you assisted in review of the 21 0. Ady you've been engaged to work on the 21 M. Was. Kano Bare you assisted? 24 0. Ady you've been engaged to work on the 24 A. Wat was the question you assisted? 2 0. Frior to baing engad with respect to the 2 what was the question wool subinissions <th></th> <th>-</th> <th></th> <th></th> <th></th>		-			
11 built homes. 11 But otherwise, I think with dry eye, I don't 12 0. Really. 12 recall that being a subject matter that I've been 13 A. Custon homes, things of that nature. That's 13 involved with. 14 why there's a gap between 1972 and 1984 on that front 14 0. Okay. 15 page. 0. A. Excuse me. 0. 16 0. Prior to well, let me step back. You'rea 16 0. As part of your professional career as a 17 obviously aware this IFR, or these are IFRs and they 16 0. As part of your professional career as a 18 relate to a proceeding going on in the Patent Office, 19 A. Yes. 18 or recer? 19 A. Yes. 20 Curu I thisgation as well? 20 Bawe you assisted in review of the 21 A. Yes. Page 11 10 We question was have you assisted in 21 A. Yes. I have. Page 11 20 We question was have you assisted in 23 A. Yes. I have. Page 13 10 We question was have you assisted in 23 A. Wes. I have dowith whe head of the page. A					
12 Q. Really. 12 recall that being a subject matter that I've been 13 A. Custom homes, things of that nature. That's 13 involved with. 14 why there's a gap between 1972 and 1984 on that front 14 Q. Okay. 15 page. 15 A. Excuse me. 16 Q. Prior to well, let me step back. You're 16 Q. A gart of your professional career as a 17 obviously seare this IPR, or these are IPRs and they 18 approval of drugs by FR? 19 correct? 19 A. Yees. 19 A. Yees. 20 Yees. 10 Ween you assisted in review of the 20 21 May our been engaged to work on the 21 10 My question was have you assisted in 21 A. Yees. Page 11 0. My question was have you assisted in 22 22 Weinstains to the FDR? 3 A. Yee. 10 My question was have you assisted in 23 O. Prior to being engaged with respect to the 24 A. Wall, what 's a very broad question. As a 5 mode to the FDR? 3 A. Yee. 10 My question was have you assisted in		5			
13 A. Custom homes, things of that nature. That's 13 involved with. 14 why there's a gap between 1972 and 1984 on that front 14 0. Okay. 15 page. 5. A. Excuse me. 15 A. Excuse me. 16 0. Prior to well, let me step back. You're 16 0. As part of your professional career as a 17 ovinously seare this TR, or these are TR's and they 18 approval of drugs by TDA? 19 on rect? 19 A. Yes. 19 20 A. Yes. Twe been told that. 20 0. Have you assisted in review of the 21 0. You also understand that there's a District 22 0. Have you assisted in review of the 21 0. And you've been engaged to work on the 23 0. My question was have you assisted in 22 0. Prior to being engaged with respect to the 3 A. Yes. 31 1 A. Yes, I have. 10 0. My question was have you assisted in 2 Prior to being engaged with respect to the 3 A. Yes. 32 A. Yes. Takt's a very bread question. As a 5 make to the FDA? 33 having to do with devices that they've had for the		0. Really.			
14 why there's a gap between 1972 and 1984 on that from 14 Q. Okay. 15 page. 15 A. Excuse me. 16 Q. Prior towell, let me step back. You're 15 A. Separt of your professional career as a 17 chronsly aware this IFR, or these are IFRs and they 16 Q. As part of your professional career as a 18 relate to a proceeding going on in the Patent Office, 16 Q. Sa part of your professional career as a 19 A. Yes. Q. You also understand that there's a District 20 Q. Bave you assisted in review of the 20 A. Yes. Q. And you've been engaged to work on the 21 MR. PARKELES: Objection: form. 21 Q. And you've been engaged to work on the 22 MR. PARKELES: Objection you assisted? 24 Q. And you've been engaged with respect to the 23 My the consulted for startup companies 9 3 A. Yes. 1 Q. Way use some studies with eye tissues. 6 A. Yes. 3 A. Yes. 1 Q. Way question was directed at, if you 14 netword to opthalmology? 1 Q. Have you assisted in review of submissions 3 A. Yes.					
15 page. 15 A. Excuse me. 16 Q. Prior to well, let me step back. You're 16 Q. As part of your professional career as a 17 doviously aware this IFR, or these are IFRs and they 17 biotattistician, have you been involved with the 18 aproval of drugs by FDA? 18 approval of drugs by FDA? 19 A. Yes. I've been told that. 20 Q. Bare you assisted in review of the 20 A. Yes. 20 Q. Bare you assisted in review of the 21 A. Yes. 20 Q. Bare you assisted in review of the 22 Ourt litigation going on in Marshall, Texas? 22 MR. PARGELEE: Objection: form. 23 A. Yes. 23 Q. Foir to being engaged to work on the 24 A. What was the question you asked me? I lost 24 Q. And you've been engaged to work on the 25 my train of thought when the objection case in. Page 11 1 A. Yes. Interacted with respect to the 3 A. West was the question was have you assisted in review of submissions 3 A wing to do with devices that they've had for the 9 A. Well, that 's a very broad question. As a 1 Meer they con anake scenthing in the		_			
16 Q. Prior to well, let me step back. You're 17 doviously ware this IR, or these ar IREs and they 18 relate to a proceeding going on in the Patent Office, 9 correct? 16 Q. As part of your professional career as a 17 host statistician, have you been involved with the 18 approval of drugs by FDA? 10 A. Yes, I've been told that. 20 A. Yes, I've been told that. 20 Q. Rave you assisted in review of the 21 aubiasions to FDA? 20 A. Yes. 20 A. Wes. 20 Q. Bave you assisted in review of the 21 submissions to FDA? 21 Q. Ard you've been engaged to work on the 23 hitigation as well? 23 Q. (Ey Mr. Kane) Have you assisted? 24 Q. Ard you've been engaged to work on the 23 hitigation as well? 24 A. Wast was the question you asked me? I lost 25 my train of thought when the objection care in. 2 Q. Frior to baing engaged with respect to the 3 dispute regarding Restasis, had you done any work 4 related to ophthalmology? 1 Q. May question was have you assisted in 2 submissions to the FDA? 3 A. Weil, that's a very troad question. As a 6 biostatistician, I've interacted with people at 7 stanford that have done studies with ey t tissue. 8 make to the FDA? 2 Weat twa you mow, stroadly, yes, I have beach 2 where thy can aska scenthing in the back of the eye 11 Most recently with the startup companies 9 having to do with coular. they what me thave a device 13 where thy cansmark scompani, you know. 14 to help coular, mecular degeneration.					
17 dviously aware this IFR, or these are IFRs and they 17 hostatistician, have you been involved with the 18 relate to a proceeding going on in the Patent Office, 19 A. Yes. 20 A. Yes, I've been told that. 19 A. Yes. 21 Q. You also understand that there's a District 20 Q. Rave you assisted in review of the 21 A. Yes. 23 Q. Rave you assisted in review of the 22 WR. PARMEES: Objection: form. 23 23 A. Yes. 23 Q. (By Mr. Kane) Have you assisted? 24 A. May was the question was have you assisted in review of submissions to the FDA? 23 3 A. Yes. 23 Q. May question was have you assisted in review of submissions 3 A. Yes. 3 A. Yes. 3 A. Yes. 3 A. Yes. 4 Q. Brow you assisted in review of submissions 5 5 A. Well, that's a very broad question. As a 6 A. Yes. 6 have consulted for startup companies 9 A. Well, that's a very the deforthe 10 eye. 9 A. Well, that's a very with the startup company. 1					
18 relate to a proceeding going on in the Patent Office, 18 approval of drugs by FDA? 19 A. Yes, I've been told that. 19 A. Yes. 20 A. Yes, I've been told that. 20 Q. Have you assisted in review of the 21 O. You also understand that there's a District 20 Q. Have you assisted in review of the 22 Court litigation going on in Marshall, Texas? 23 Q. Have you assisted? A. Wat 23 A. Yes. 23 Q. Have you assisted? A. Wat was the question you asked me? I lost 24 Q. And you've been engaged to work on the 24 A. Wat was the question you assisted in 25 D. Prior to being engaged with respect to the 7 G. May question was have you assisted in 26 D. Prior to being engaged with respect to the 2 3 A. Yes. 3 dispute regarding Restais, had you done any work 4 Q. Have you assisted in review of submissions 5 5 A. Well, that's a very broad guestion, As a 1 Q. Way question was have you assisted in 2 6 hoistatistician, I've interacted with peeple at 7 Q. Mat way the endered minission was. A Phase I submission was. A Phase I submission w					
19 A. Yes. 19 A. Yes. 20 A. Yes. I've been told that. 20 Q. Have you assisted in review of the 21 Q. You also understand that there's a District 20 Q. Have you assisted in review of the 21 Q. And you've been engaged to work on the 21 submissions to FDA? 23 A. Yes. 23 Q. (By Mr. Kane) Have you assisted? 24 Q. And you've been engaged to work on the 23 Q. (By Mr. Kane) Have you assisted? 25 Itigation as well? Page 11 Q. My question was have you assisted in review of submissions 2 Q. Prior to being engaged with respect to the 3 A. Yes. 3 A. Well, that's a very broad question. As a 5 made to the FDA? 3 Stanford that have done studies with eye tissues. 7 Q. Max was your role in review of submissions 8 I have consultaid for startup company. 6 A. Well, it varied degending upon what the 10 eye. 9 A. Well, it varied degending upon what the 10 submission was. A Phase I submission would be a very 11 11 Most recently with the startup company. 11 11		• • •			_
20 A. Yes, I've been told that. 20 Q. Have you assisted in review of the 21 Q. You also understand that there's a District 22 WR. PARMELS: Objection; form. 21 A. Yes. 22 WR. PARMELS: Objection; form. 22 Q. Have you assisted in review of the 23 A. Yes. 23 Q. (By Mr. Kane) Have you assisted? 24 Q. And you've been engaged to work on the 24 A. What was the question you asked me? I lost 25 litigation as well? Page 11 Q. My question was have you assisted in Page 13 2 Q. Prior to being engaged with respect to the 3 A. Yes. 1 Q. Mave you assisted in review of submissions 5 A. Well, that's a very broad question. As a 5 made to the FDA? 3 6 hower consulted for startup companies 8 ade to the FDA? 4 Q. Mat was your role in review of submissions 9 having to do with devices that they've had for the 9 A. Well, it varied depending upon what the 10 eye. 10 ifferent submission was. A Phase I submission would be a very 11 Most recently with the startup company, 12 12					
22 Court litigation going on in Marshall, Texas? 23 A. Yes. 24 Q. And you've been engaged to work on the 25 litigation as well? 26 Q. And you've been engaged to work on the 27 Q. And you've been engaged to work on the 28 Q. And you've been engaged to work on the 29 Page 11 1 A. Yes. I have. 2 Q. Prior to being engaged with respect to the 3 digute regarding Restasis, had you done any work 4 related to ophthalmology? 5 A. Well, that's a very broad question. As a 6 biostatistician, I've interacted with people at 7 Stanford that have done studies with eye tissues. 8 I have consulted for startup company. 10 Wast recently with the startup company. 11 Most recently with the startup company. 12 where they can snake something in the back of the eye. 13 Where they can snake something in the back of the eye. 14 thelp ocular, mecular degeneration. 15 So, you know, broadly, yes, I have been 16 involved with ocular-type th	20	A. Yes, I've been told that.		20	Q. Have you assisted in review of the
23 A. Yes. 23 Q. (By Mr. Kane) Have you assisted? 24 Q. And you've been engaged to work on the 24 A. What was the question you asked me? I lost 25 litigation as well? Page 11 Page 13 1 A. Yes, I have. Page 11 2 Q. Prior to being engaged with respect to the sumissions to the FDA? 3 dispute regarding Restasis, had you done any work 4 4 related to ophthalmology? A. Yes. 5 A. Well, that's a very broad question. As a 5 6 biostatistician, I've interacted with people at 6 7 Q. Mat was your role in review of submissions 8 I have consulted for startup company, 6 1 Most recently with the startup company, actually in Tucson, Arizona, where they have a device 14 where they can sake something in the back of the eye 13 Q. I guess my question was directed at, if you 15 So, you know, broadly, yes, I have been 16 Must make to the FDA? 16 involved with ocular-type things. And with 16 A. Bes TA & SI A & 17 So, And by the compound, you know. 16	21	Q. You also understand that there's a District		21	submissions to FDA?
24 Q. And you've been engaged to work on the 24 A. What was the question you asked me? I lost 25 litigation as well? Page 11 1 A. Yes, I have. Page 11 2 Q. Prior to being engaged with respect to the and you've been engaged vith respect to the 3 A. Yes. A. Yes. 4 related to ophthalmology? A. Well, that's a very broad question. As a 5 A. Well, that's a very broad question. As a 6 6 biostatistician, I've interacted with people at 6 7 Stanford that have done studies with eye tissues. 8 8 I have consulted for startup company, 6 10 eye. Most recently with the startup company, 1 12 worker they can sake something in the back of the eye 1 Q. I guess my question was directed at, if you 14 to help ocular, macular degeneration. 16 Nees. 17 15 So, you know, broadly, yes, I have been 16 A. Well, what is it called. Restasis? 20 16 involved with ocular-type things. And with 16 A. Bes TA S I S. 20 20 A. Well,	22	Court litigation going on in Marshall, Texas?		22	MR. PARMELEE: Objection; form.
25 litigation as well? 25 my train of thought when the objection came in. 1 A. Yes, I have. Page 11 2 0. Prior to being engaged with respect to the 1 Q. My question was have you assisted in 3 dispute regarding Restasis, had you done any work 3 A. Yes. 4 related to ophthalmology? 4 Q. Have you assisted in review of submissions 5 A. Well, that's a very broad question. As a 6 biostatistician, I've interacted with people at 7 Stanford that have done studies with eye tissues. 7 Q. What was your role in review of submissions 8 I have consulted for startup companies 9 A. Yes. But not as an employee of the FDA. 9 having to do with devices that they've had for the 9 A. Well, it varied depending upon what the 10 eye. 10 submission was. A Phase I Submission would be a very 11 where they can snake something in the back of the eye 13 Q. I guess my question was directed at, if you 14 to help coular, macular degeneration. 14 weren't an employee of the FDA, why were you reviewing 15 So, you know, broadly, yes, I have been 16 A. Because o	23	A. Yes.		23	Q. (By Mr. Kane) Have you assisted?
Page 11 A. Yes, I have. Page 11 1 A. Yes, I have. 1 Q. My question was have you assisted in 2 Q. Prior to being engaged with respect to the dispute regarding Restasis, had you done any work 1 Submissions to the FDA? 3 dispute regarding Restasis, had you done any work 3 A. Yes. 4 related to ophthalmology? 5 A. Well, that's a very broad question. As a 5 A. Well, that's a very broad question. As a 5 made to the FDA? 6 biostatistician, I've interacted with people at 7 Q. What was your role in review of submissions 8 I have consulted for startup companies 9 A. Well, it varied depending upon what the 10 eye. 10 submission was. A Phase I submission would be a very 11 Most recently with the startup company, 11 different submission was. A Phase III preliminary 12 actually in Tucson, Arizona, where they have a device 13 Q. I guess my question was directed at, if you 14 where they can snake something in the back of the eye 13 Q. I guess my question was directed at, if you 15 So, you know, broadly, yes, I have been 16 A. Because of m	24	Q. And you've been engaged to work on the		24	A. What was the question you asked me? I lost
1A. Yes, I have.1Q. My question was have you assisted in2Q. Prior to being engaged with respect to the3dispute regarding Restasis, had you done any work3A. Yes.3dispute regarding Restasis, had you done any work3A. Yes.4Q. Have you assisted in review of submissions5A. Well, that's a very broad question. As a5made to the FDA?4Q. Have you assisted in review of submissions5A. Well, that's a very broad question. As a6A. Yes. But not as an employee of the FDA.77Stanford that have done studies with eye tissues.7Q. What was your role in review of submissions8I have consulted for startup companies8made to the FDA?9having to do with devices that they've had for the9A. Well, it varied depending upon what the10eye.10submission was. A Phase I submission would be a very11Most recently with the startup company,11different submission than a Phase III preliminary12actually in Tucson, Arizona, where they have a device13Q. I guess my question was directed at, if you15So, you know, broadly, yes, I have been16A. Because of my expertise in biostatistics the17specifically with this compound, you know.17company asks me to do this sometimes.18Q. Yes.A. Well, what is it called. Restasis?20A. No.19FDA to review any submissions?20A. No.20A. RESTASIS.21Q. You've ne	25	litigation as well?		25	my train of thought when the objection came in.
1A. Yes, I have.1Q. My question was have you assisted in2Q. Prior to being engaged with respect to the3dispute regarding Restasis, had you done any work3A. Yes.3dispute regarding Restasis, had you done any work3A. Yes.4Q. Have you assisted in review of submissions5A. Well, that's a very broad question. As a5made to the FDA?4Q. Have you assisted in review of submissions5A. Well, that's a very broad question. As a6A. Yes. But not as an employee of the FDA.77Stanford that have done studies with eye tissues.7Q. What was your role in review of submissions8I have consulted for startup companies8made to the FDA?9having to do with devices that they've had for the9A. Well, it varied depending upon what the10eye.10submission was. A Phase I submission would be a very11Most recently with the startup company,11different submission than a Phase III preliminary12actually in Tucson, Arizona, where they have a device13Q. I guess my question was directed at, if you15So, you know, broadly, yes, I have been16A. Because of my expertise in biostatistics the17specifically with this compound, you know.17company asks me to do this sometimes.18Q. Yes.A. Well, what is it called. Restasis?20A. No.19FDA to review any submissions?20A. No.20A. RESTASIS.21Q. You've ne		Paga	11		Dago 12
3 dispute regarding Restasis, had you done any work 3 A. Yes. 4 related to ophthalmology? 3 A. Yes. 5 A. Well, that's a very broad question. As a 6 biostatistician, I've interacted with people at 7 7 Stanford that have done studies with eye tissues. 6 A. Yes. But not as an employee of the FDA. 8 I have consulted for startup companies 9 having to do with devices that they've had for the 9 A. Well, it varied depending upon what the 10 eye. 10 submission was. A Phase I submission would be a very 11 Most recently with the startup company, 10 different submission than a Phase III preliminary 12 actually in Tucson, Arizona, where they have a device 13 Q. I guess my question was directed at, if you 13 So, you know, broadly, yes, I have been 15 submissions made to the FDA? 14 weren't an employee of the FDA, why were you reviewing 13 Q. I guess my question was directed at, if you 14 to help ocular, macular degeneration. 14 weren't an employee of the FDA? 15 So, you know, broadly, yes, I have been 15 submissions made to the FDA? <t< th=""><th>1</th><th>-</th><th></th><th>1</th><th></th></t<>	1	-		1	
4related to ophthalmology?5A. Well, that's a very broad question. As a6biostatistician, I've interacted with people at7Stanford that have done studies with eye tissues.8I have consulted for startup companies9having to do with devices that they've had for the10eye.11Most recently with the startup company,12actually in Tucson, Arizona, where they have a device13where they can snake something in the back of the eye14to help ocular, macular degeneration.15So, you know, broadly, yes, I have been16involved with ocular-type things. And with17specifically with this is ti called. Restasis?20A. Well, what is it called. Restasis?21Q. Yes.22A. RESTASIS.23Q. Yes. That's the brand name. Cyclosporin is24the active ingredient.	2	Q. Prior to being engaged with respect to the		2	submissions to the FDA?
5A. Well, that's a very broad question. As a5made to the FDA?6biostatistician, I've interacted with people at6A. Yes. But not as an employee of the FDA.7Stanford that have done studies with eye tissues.7Q. What was your role in review of submissions8I have consulted for startup companies8made to the FDA?9having to do with devices that they've had for the9A. Well, it varied depending upon what the10eye.10submission was. A Phase I submission would be a very11Most recently with the startup company,11different submission than a Phase III preliminary12actually in Tucson, Arizona, where they have a device13Q. I guess my question was directed at, if you14to help ocular, macular degeneration.14weren't an employee of the FDA?15So, you know, broadly, yes, I have been15submissions made to the FDA?16involved with coular-type things. And with16A. Because of my expertise in biostatistics the17specifically with this compound, you know.18Q. Have you ever been involved or engaged by19FDA to review any submissions?20A. No.21Q. Yes.21Q. You've never been on an FDA advisory panel?22A. RESTASIS.22A. I have been, yes.23Q. Yes. That's the brand name. Cyclosporin is24A. Again, that's a very varied topic.	3	dispute regarding Restasis, had you done any work		3	A. Yes.
 6 biostatistician, I've interacted with people at 7 Stanford that have done studies with eye tissues. 8 I have consulted for startup companies 9 having to do with devices that they've had for the 10 eye. 11 Most recently with the startup company, 12 actually in Tucson, Arizona, where they have a device 13 where they can snake something in the back of the eye 14 to help ocular, macular degeneration. 15 So, you know, broadly, yes, I have been 16 involved with ocular-type things. And with 17 specifically with this compound, you know. 18 Q. And by the compound, you know. 19 cyclosporin? 20 A. Well, what is it called. Restasis? 20 A. RESTASIS. 21 Q. Yes. 22 A. RESTASIS. 23 Q. Yes. That's the brand name. Cyclosporin is 24 the active ingredient. 	4	related to ophthalmology?		4	Q. Have you assisted in review of submissions
7Stanford that have done studies with eye tissues.7Q. What was your role in review of submissions8I have consulted for startup companies9having to do with devices that they've had for the10eye.9A. Well, it varied depending upon what the11Most recently with the startup company,10submission was. A Phase I submission would be a very12actually in Tucson, Arizona, where they have a device13Q. I guess my question was directed at, if you13where they can snake something in the back of the eye13Q. I guess my question was directed at, if you14to help ocular, macular degeneration.14weren't an employee of the FDA?15So, you know, broadly, yes, I have been16A. Because of my expertise in biostatistics the17specifically with this compound, you know.16A. Because of my expertise in biostatistics the19cyclosporin?19FDA to review any submissions?20A. Well, what is it called. Restasis?20A. No.21Q. Yes.That's the brand name. Cyclosporin is2223Q. Yes. That's the brand name. Cyclosporin is23Q. What does that consist of?24A. Again, that's a very varied topic.	5	A. Well, that's a very broad question. As a		5	made to the FDA?
8 I have consulted for startup companies 8 made to the FDA? 9 having to do with devices that they've had for the 9 A. Well, it varied depending upon what the 10 eye. 10 submission was. A Phase I submission would be a very 11 Most recently with the startup company, 11 different submission than a Phase III preliminary 12 actually in Tucson, Arizona, where they have a device 13 Q. I guess my question was directed at, if you 14 to help ocular, macular degeneration. 14 weren't an employee of the FDA, why were you reviewing 15 So, you know, broadly, yes, I have been 15 submissions made to the FDA? 16 involved with ocular-type things. And with 16 A. Because of my expertise in biostatistics the 17 specifically with this compound, you know. 18 Q. Have you ever been involved or engaged by 19 rcyclosporin? 19 FDA to review any submissions? 20 A. R E S T A S I S. 21 Q. You've never been on an FDA advisory panel? 22 A. R E S T A S I S. 23 Q. What does that consist of? 24 the active ingredient. 24 A. Again, that's a very	6	biostatistician, I've interacted with people at		б	A. Yes. But not as an employee of the FDA.
9having to do with devices that they've had for the9A. Well, it varied depending upon what the10eye.10submission was. A Phase I submission would be a very11Most recently with the startup company,11different submission was. A Phase I submission would be a very12actually in Tucson, Arizona, where they have a device13Q. I guess my question was directed at, if you13where they can snake something in the back of the eye13Q. I guess my question was directed at, if you14to help ocular, macular degeneration.14weren't an employee of the FDA, why were you reviewing15So, you know, broadly, yes, I have been16A. Because of my expertise in biostatistics the16involved with ocular-type things. And with16A. Because of my expertise in biostatistics the17specifically with this compound, you know.18Q. Have you ever been involved or engaged by19FDA to review any submissions?20A. No.21Q. Yes.21Q. You've never been on an FDA advisory panel?22A. R E S T A S I S.22A. I have been, yes.23Q. Yes. That's the brand name. Cyclosporin is24A. Again, that's a very varied topic.	7	Stanford that have done studies with eye tissues.		7	Q. What was your role in review of submissions
10eye.10submission was. A Phase I submission would be a very11Most recently with the startup company,11different submission than a Phase III preliminary12actually in Tucson, Arizona, where they have a device12trial that was done to get approval.13where they can snake something in the back of the eye13Q. I guess my question was directed at, if you14to help ocular, macular degeneration.14weren't an employee of the FDA, why were you reviewing15So, you know, broadly, yes, I have been15submissions made to the FDA?16involved with ocular-type things. And with16A. Because of my expertise in biostatistics the17specifically with this compound, you're talking about18Q. Have you ever been involved or engaged by19cyclosporin?19FDA to review any submissions?20A. Well, what is it called. Restasis?20A. No.21Q. Yes.21Q. You've never been on an FDA advisory panel?22A. R E S T A S I S.22A. I have been, yes.23Q. Yes. That's the brand name. Cyclosporin is24A. Again, that's a very varied topic.	8	I have consulted for startup companies		8	made to the FDA?
11Most recently with the startup company, actually in Tucson, Arizona, where they have a device11different submission than a Phase III preliminary12actually in Tucson, Arizona, where they have a device13Q. I guess my question was directed at, if you14to help ocular, macular degeneration.14weren't an employee of the FDA, why were you reviewing15So, you know, broadly, yes, I have been15submissions made to the FDA?16involved with ocular-type things. And with16A. Because of my expertise in biostatistics the17specifically with this compound, you know.17company asks me to do this sometimes.18Q. And by the compound, you're talking about18Q. Have you ever been involved or engaged by19cyclosporin?19FDA to review any submissions?20A. Well, what is it called. Restasis?20A. No.21Q. Yes.21Q. You've never been on an FDA advisory panel?22A. R E S T A S I S.22A. I have been, yes.23Q. Yes. That's the brand name. Cyclosporin is23Q. What does that consist of?24the active ingredient.24A. Again, that's a very varied topic.	9	having to do with devices that they've had for the		9	A. Well, it varied depending upon what the
12actually in Tucson, Arizona, where they have a device12trial that was done to get approval.13where they can snake something in the back of the eye13Q. I guess my question was directed at, if you14to help ocular, macular degeneration.14weren't an employee of the FDA, why were you reviewing15So, you know, broadly, yes, I have been16involved with ocular-type things. And with16A. Because of my expertise in biostatistics the17specifically with this compound, you know.18Q. Have you ever been involved or engaged by19cyclosporin?19FDA to review any submissions?20A. Well, what is it called. Restasis?20A. No.21Q. Yes.21Q. You've never been on an FDA advisory panel?22A. R E S T A S I S.22A. I have been, yes.23Q. Yes. That's the brand name. Cyclosporin is24A. Again, that's a very varied topic.	10	eye.		10	submission was. A Phase I submission would be a very
13where they can snake something in the back of the eye13Q. I guess my question was directed at, if you14to help ocular, macular degeneration.14weren't an employee of the FDA, why were you reviewing15So, you know, broadly, yes, I have been15submissions made to the FDA?16involved with ocular-type things. And with16A. Because of my expertise in biostatistics the17specifically with this compound, you know.16A. Because of the FDA?18Q. And by the compound, you're talking about18Q. Have you ever been involved or engaged by19cyclosporin?19FDA to review any submissions?20A. Well, what is it called. Restasis?20A. No.21Q. Yes.21Q. You're never been on an FDA advisory panel?22A. R E S T A S I S.22A. I have been, yes.23Q. Yes. That's the brand name. Cyclosporin is23Q. What does that consist of?24the active ingredient.24A. Again, that's a very varied topic.				11	
14to help ocular, macular degeneration.14weren't an employee of the FDA, why were you reviewing15So, you know, broadly, yes, I have been15submissions made to the FDA?16involved with ocular-type things. And with16A. Because of my expertise in biostatistics the17specifically with this compound, you know.16A. Because of my expertise in biostatistics the18Q. And by the compound, you're talking about18Q. Have you ever been involved or engaged by19cyclosporin?19FDA to review any submissions?20A. Well, what is it called. Restasis?20A. No.21Q. Yes.21Q. You've never been on an FDA advisory panel?22A. R E S T A S I S.22A. I have been, yes.23Q. Yes. That's the brand name. Cyclosporin is23Q. What does that consist of?24A. Again, that's a very varied topic.					
15So, you know, broadly, yes, I have been15submissions made to the FDA?16involved with ocular-type things. And with16A. Because of my expertise in biostatistics the17specifically with this compound, you know.16A. Because of my expertise in biostatistics the18Q. And by the compound, you're talking about18Q. Have you ever been involved or engaged by19cyclosporin?19FDA to review any submissions?20A. Well, what is it called. Restasis?20A. No.21Q. Yes.21Q. You've never been on an FDA advisory panel?22A. R E S T A S I S.22A. I have been, yes.23Q. Yes. That's the brand name. Cyclosporin is23Q. What does that consist of?24A. Again, that's a very varied topic.					
16involved with ocular-type things. And with16A. Because of my expertise in biostatistics the17specifically with this compound, you know.16A. Because of my expertise in biostatistics the18Q. And by the compound, you're talking about16A. Because of my expertise in biostatistics the19cyclosporin?18Q. Have you ever been involved or engaged by20A. Well, what is it called. Restasis?20A. No.21Q. Yes.20A. No.22A. R E S T A S I S.21Q. You've never been on an FDA advisory panel?23Q. Yes. That's the brand name. Cyclosporin is23Q. What does that consist of?24A. Again, that's a very varied topic.					
17specifically with this compound, you know.17company asks me to do this sometimes.18Q. And by the compound, you're talking about18Q. Have you ever been involved or engaged by19cyclosporin?19FDA to review any submissions?20A. Well, what is it called. Restasis?20A. No.21Q. Yes.21Q. You've never been on an FDA advisory panel?22A. R E S T A S I S.22A. I have been, yes.23Q. Yes. That's the brand name. Cyclosporin is23Q. What does that consist of?24the active ingredient.24A. Again, that's a very varied topic.					
18Q. And by the compound, you're talking about18Q. Have you ever been involved or engaged by19cyclosporin?19FDA to review any submissions?20A. Well, what is it called. Restasis?20A. No.21Q. Yes.21Q. You've never been on an FDA advisory panel?22A. R E S T A S I S.22A. I have been, yes.23Q. Yes. That's the brand name. Cyclosporin is23Q. What does that consist of?24the active ingredient.24A. Again, that's a very varied topic.					
19cyclosporin?19FDA to review any submissions?20A. Well, what is it called. Restasis?20A. No.21Q. Yes.21Q. You've never been on an FDA advisory panel?22A. R E S T A S I S.22A. I have been, yes.23Q. Yes. That's the brand name. Cyclosporin is23Q. What does that consist of?24the active ingredient.24A. Again, that's a very varied topic.					
20A. Well, what is it called. Restasis?20A. No.21Q. Yes.21Q. You've never been on an FDA advisory panel?22A. R E S T A S I S.22A. I have been, yes.23Q. Yes. That's the brand name. Cyclosporin is23Q. What does that consist of?24the active ingredient.24A. Again, that's a very varied topic.					
21Q.Yes.21Q.You've never been on an FDA advisory panel?22A.R E S T A S I S.22A.I have been, yes.23Q.Yes. That's the brand name. Cyclosporin is23Q.What does that consist of?24the active ingredient.24A.Again, that's a very varied topic.					-
22A. RESTASIS.22A. I have been, yes.23Q. Yes. That's the brand name. Cyclosporin is23Q. What does that consist of?24the active ingredient.24A. Again, that's a very varied topic.					
23Q. Yes. That's the brand name. Cyclosporin is23Q. What does that consist of?24the active ingredient.24A. Again, that's a very varied topic.					
24 the active ingredient. 24 A. Again, that's a very varied topic.					
					-
25 FOI Example, one meeting was a group of		-			
	23	20 make You done any work letared co		2J	TOT EVANIPTE, OTE MEETING WAS & GLOUP OT

DTI Court Reporting Solutions - Woodland Hills

ALARM

www.deposition.com

Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

DANIEL BLOCH, PH.D. - 07/14/2017 Pages 14..17

1	Page 14 somewhere around 30 of us met with higher-ups in the		Page
1		1	A. Yes, probably. That's right.
2	statistical personnel of the FDA, biologics, devices	2	Q. Okay. So you understand that FDA has
3	and drugs, where the discussion had to do with missing	3	statisticians who review clinical data in connection
4	data in submissions.	4	with a drug approval process?
5	And the FDA wanted advice in terms of how	5	A. Yes, more than an understanding. Yes, I
6	they should handle that broadly but also more	6	know that's true. Yes.
7	specifically how much missing data it would be okay to	7	Q. And have you interacted with those
8	have and that was a very lively discussion.	8	statisticians?
9	So that's just a specific example of the	9	A. Yes.
10	kind of functions that the FDA uses advisory boards	10	Q. In what capacities?
11	for if it's biostatistical in nature.	11	A. Well, again, that's fairly varied. I've
12	Q. How long have you been involved with FDA	12	been on conference calls with companies discussing
13	statistical advisory boards?	13	what the FDA statisticians had concerns with respect
14	A. I'm not currently on the advisory board.	14	to the with the investigational plan that had been
15	You'd have to go to my CV. I think I might have the	15	submitted to the FDA. So there was a discussion about
16	dates there. I don't actually know.	16	the content that way, long distance.
17	Q. Okay. Why don't we do that.	17	I have given lectures at the FDA to
18	A. I don't know if it's here. Is it here? I'm	18	statisticians and interacted with them directly in
19	just looking for it.	19	that way. Those lectures have been mostly having to
20	Well, 1995 to 2006, it's number eleven.	20	do with introducing to them some of the newer things
21	Q. Right. Okay.	21	that were going on in statistics that I had expertise
22	A. It was in that time frame.	22	with in terms of how they could apply it to their
23	Q. Okay. And that's a special government	23	needs.
24	employee, they pay you to be on the advisory board or	24	So it's a variety of ways I've interacted
25	advisory panel?	25	with statisticians at the FDA.
	Page 15	;	Page
1	A. I said including FDA statistical advisory	1	Q. Okay. And do they use those statistical
2	panel. And I was a special government employee also	2	panels, statistical advisory panels, for instance, to
3	working with the Veterans Administration hospital in	3	
	WOINING WICH THE VECETARS AMILITISCIACION HOSPICAL IN	1	stay abreast of current statistical methods?
4	Palo Alto.	4	MR. PARMELEE: Objection; form.
4 5			-
	Palo Alto.	4	MR. PARMELEE: Objection; form.
5	Palo Alto. The way the Veterans Administration performs	4	MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it
5 6	Palo Alto. The way the Veterans Administration performs many very high level clinical trials.	4 5 6	MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are
5 6 7	Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water.	4 5 6 7	MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will
5 6 7 8 9	Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials	4 5 6 7 8	MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because
5 6 7 8 9 10	Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA	4 5 7 8 9	MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could
5 6 7 8 9 10	Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans.	4 5 6 7 8 9 10	MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used.
5 6 7 8 9 10 11	Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans. And these protocols are actually headed by	4 5 6 7 8 9 10 11	MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used. Q. (By Mr. Kane) When you've given lectures to
5 6 7 8 9 10 11 12 13	Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans. And these protocols are actually headed by statisticians, unlike many other grants which are	4 5 6 7 8 9 10 11 12	MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used. Q. (By Mr. Kane) When you've given lectures to the FDA regarding statistics, what format or context
5 6 7 8 9 10 11 12 13 14	Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans. And these protocols are actually headed by statisticians, unlike many other grants which are headed by PIs which are specialists in the particular	4 5 6 7 8 9 10 11 12 13	MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used. Q. (By Mr. Kane) When you've given lectures to the FDA regarding statistics, what format or context did that come up in?
5 6 7 8 9 10 11 12 13 14 15	Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans. And these protocols are actually headed by statisticians, unlike many other grants which are headed by PIs which are specialists in the particular field. And I was the adviser to the VA on the	4 5 6 7 8 9 10 11 12 13 14	 MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used. Q. (By Mr. Kane) When you've given lectures to the FDA regarding statistics, what format or context did that come up in? A. I can recall one lecture which had to do
5 6 7 8 9 10 11 12 13 14 15 16	Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans. And these protocols are actually headed by statisticians, unlike many other grants which are headed by PIs which are specialists in the particular field.	4 5 6 7 8 9 10 11 12 13 14 15	 MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used. Q. (By Mr. Kane) When you've given lectures to the FDA regarding statistics, what format or context did that come up in? A. I can recall one lecture which had to do with presenting to them it's a mouthful it's
5 6 7 8 9 10 11 12 13 14 15 16 17	Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans. And these protocols are actually headed by statisticians, unlike many other grants which are headed by PIs which are specialists in the particular field. And I was the adviser to the VA on the planning and execution of those trials. And there are	4 5 6 7 8 9 10 11 12 13 14 15 16	 MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used. Q. (By Mr. Kane) When you've given lectures to the FDA regarding statistics, what format or context did that come up in? A. I can recall one lecture which had to do with presenting to them it's a mouthful it's called non-parametric regression, non-parametric
5 6 7 8 9 10 11 12 13 14 15 16 17 18	Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans. And these protocols are actually headed by statisticians, unlike many other grants which are headed by PIs which are specialists in the particular field. And I was the adviser to the VA on the planning and execution of those trials. And there are VA centers throughout the country, five or six, that are involved in these clinical trials that are funded	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used. Q. (By Mr. Kane) When you've given lectures to the FDA regarding statistics, what format or context did that come up in? A. I can recall one lecture which had to do with presenting to them it's a mouthful it's called non-parametric regression, non-parametric regression methods, which they wanted to use I'm sorry.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans. And these protocols are actually headed by statisticians, unlike many other grants which are headed by PIs which are specialists in the particular field. And I was the adviser to the VA on the planning and execution of those trials. And there are VA centers throughout the country, five or six, that are involved in these clinical trials that are funded through the government.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used. Q. (By Mr. Kane) When you've given lectures to the FDA regarding statistics, what format or context did that come up in? A. I can recall one lecture which had to do with presenting to them it's a mouthful it's called non-parametric regression, non-parametric regression methods, which they wanted to use I'm sorry.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans. And these protocols are actually headed by statisticians, unlike many other grants which are headed by PIs which are specialists in the particular field. And I was the adviser to the VA on the planning and execution of those trials. And there are VA centers throughout the country, five or six, that are involved in these clinical trials that are funded through the government. 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used. Q. (By Mr. Kane) When you've given lectures to the FDA regarding statistics, what format or context did that come up in? A. I can recall one lecture which had to do with presenting to them it's a mouthful it's called non-parametric regression, non-parametric regression methods, which they wanted to use I'm sorry. I haven't had this frog in my throat all week and now I have to have it.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	<pre>Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans. And these protocols are actually headed by statisticians, unlike many other grants which are headed by PIs which are specialists in the particular field. And I was the adviser to the VA on the planning and execution of those trials. And there are VA centers throughout the country, five or six, that are involved in these clinical trials that are funded through the government. So I was a special government employee for that. I don't believe I got paid but they had to</pre>	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used. Q. (By Mr. Kane) When you've given lectures to the FDA regarding statistics, what format or context did that come up in? A. I can recall one lecture which had to do with presenting to them it's a mouthful it's called non-parametric regression, non-parametric regression methods, which they wanted to use I'm sorry. I haven't had this frog in my throat all week and now I have to have it. Q. That's the way it goes.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans. And these protocols are actually headed by statisticians, unlike many other grants which are headed by PIs which are specialists in the particular field. And I was the adviser to the VA on the planning and execution of those trials. And there are VA centers throughout the country, five or six, that are involved in these clinical trials that are funded through the government. So I was a special government employee for that. I don't believe I got paid but they had to designate me somehow to be involved. 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used. Q. (By Mr. Kane) When you've given lectures to the FDA regarding statistics, what format or context did that come up in? A. I can recall one lecture which had to do with presenting to them it's a mouthful it's called non-parametric regression, non-parametric regression methods, which they wanted to use I'm sorry. I haven't had this frog in my throat all week and now I have to have it. Q. That's the way it goes. A. And they were hoping to be able to use that
5 6 7 8	<pre>Palo Alto. The way the Veterans Administration performs many very high level clinical trials. Excuse me, I'm going to get some water. In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans. And these protocols are actually headed by statisticians, unlike many other grants which are headed by PIs which are specialists in the particular field. And I was the adviser to the VA on the planning and execution of those trials. And there are VA centers throughout the country, five or six, that are involved in these clinical trials that are funded through the government. So I was a special government employee for that. I don't believe I got paid but they had to</pre>	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 MR. PARMELEE: Objection; form. A. I think well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used. Q. (By Mr. Kane) When you've given lectures to the FDA regarding statistics, what format or context did that come up in? A. I can recall one lecture which had to do with presenting to them it's a mouthful it's called non-parametric regression, non-parametric regression methods, which they wanted to use I'm sorry. I haven't had this frog in my throat all week and now I have to have it. Q. That's the way it goes.

www.deposition.com

DTI Court Reporting Solutions - Woodland Hills www.deposit: Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

DOCKET A L A R M



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.