

# Transcript of the Testimony of **M. Jayne Lawrence**

**Date:** September 4, 2015

**Case:** Senju Pharmaceutical Co., LTD., et al. v. Lupin, LTD., and Lupin  
Pharmaceutical, Inc.,



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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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SENJU PHARMACEUTICAL CO.,  
LTD., BAUSCH & LOMB  
INCORPORATED, and BAUSCH  
& LOMB PHARMA HOLDINGS CORP.,

Civil Action Nos.:  
1:14-cv-00667-JBS-KMW  
1:14-cv-04149-JBS-KMW  
1:14-cv-05144-JBS-KMW  
1:15-cv-00335-JBS-KMW

-vs-

LUPIN, LTD., and LUPIN  
PHARMACEUTICALS, INC.,  
Defendants.

INNOPHARMA LICENSING, INC.,  
INNOPHARMA LICENSING, LLC,  
INNOPHARMA, INC., INNOPHARMA,  
LLC, MYLAN PHARMACEUTICALS,  
INC., and MYLAN INC.,  
Defendants.

Civil Action Nos.:  
1:14-cv-06893-JBS-KMW  
1:15-cv-03240-JBS-KMW

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Deposition of:

M. JAYNE LAWRENCE, Ph.D.

September 4, 2015  
New York, New York

Page 2	Page 4
<p>1 VIDEOTAPED DEPOSITION of M. JAYNE LAWRENCE,  2 Ph.D., taken pursuant to Notice, held at the law  3 offices of GOODWIN PROCTER, LLP, 620 Eighth Avenue,  4 26th Floor, New York, New York, 10018-1405, on  5 Friday, September 4, 2015, at 8:00 a.m. before  6 JEANNETTE MCCORMICK, a Certified Shorthand Reporter,  7 and a Notary Public.  8  9  10  11  12  13  14  15  16  17  18  19  20  21  22</p>	<p>1 APPERANCES (CONTINUED):  2  3 ALSTON &amp; BIRD, LLP  4 Attorneys for Defendant Innopharma  5 333 South Hope Street, 16th Floor  6 Los Angeles, California 90071  7 BY: H. JAMES ABE, ESQ.  8 (213) 576-1000 (Telephone)  9 (213) 576-1100 (Fax)  10 james.abe@alston.com  11  12  13  14 Also Present:  15 Thomas Del Vecchio (Videographer)  16  17  18  19  20  21  22</p>
Page 3	Page 5
<p>1 APPEARANCES:  2 FINNEGAN, HENDERSON, FARABOW, GARRETT  3 &amp; DUNNER, LLP  4 Attorneys for Plaintiffs  5 901 New York Avenue, NW  6 Washington, D.C. 20001-4413  7 BY: JUSTIN J. HASFORD, ESQ.  8 BRYAN C. DINER, ESQ.  9 (202) 408-4000 (Telephone)  10 (202) 408-4400 (Fax)  11 justin.hasford@finnegan.com  12 bryan.diner@finnegan.com  13  14 GODWIN PROCTER, LLP  15 Attorneys for Defendant Lupin  16 The New York Times Building  17 620 Eighth Avenue  18 New York, New York 10018-1405  19 BY: DANIEL P. MARGOLIS, ESQ.  20 (212) 813-8800 (Telephone)  21 (212) 355-3333 (Fax)  22 dmargolis@goodwinprocter.com</p>	<p>1 INDEX  2 WITNESS EXAMINATION BY PAGE  3 M. JAYNE LAWRENCE, Ph.D.  4 MR. HASFORD 17  5  6 EXHIBITS  7 LAWRENCE  8 NUMBER DESCRIPTION PAGE  9  10 Exhibit 1 Declaration of M. Jayne  11 Lawrence, Ph.D. and  12 Appendices and Exhibits 18  13  14 Exhibit 2 "Models for Intestinal Drug  15 Absorption", Wood &amp; Lawrence  16 (1991) Journal of Biopharmaceutical  17 Sciences (pgs. 147-172)  18 (Publication No. 5 on CV) 206  19  20  21  22</p>

Page 6				Page 8			
1	EXHIBITS			1	EXHIBITS		
2	LAWRENCE			2	LAWRENCE		
3	NUMBER	DESCRIPTION	PAGE	3	NUMBER	DESCRIPTION	PAGE
4				4	Exhibit 9	"Recent Advances in	
5	Exhibit 3	"Effect of diclofenac sodium		5		Microemulsions as Drug	
6		and disodium		6		Delivery Vehicles" in	
7		ethylenediaminetetraacetate on		7		"Nanoparticulates as Drug	
8		electrical parameters of the		8		Carriers," (pgs. 125-171)	
9		mucosal membrane and their		9		(Book Chapters No. 14 on CV)	262
10		relation to the permeability		10	Exhibit 10	"Drug Delivery Systems:	
11		enhancing effects in the rat		11		Neutron Scattering Studies" in	
12		jejunum" by Yamashita, et al,		12		"Encyclopedia of Pharmaceutical	
13		in the J. Pharm. Pharmacol.		13		Technology," (pgs. 1049-1070)	
14		1987, volume 39, pages 621 to 626	208	14		(Book Chapters No. 15 on CV)	265
15				15	Exhibit 11	"New Medicines, Better	
16	Exhibit 4	U.S. Patent No. 8,192,755 B2	232	16		Medicines, Better Use of	
17	Exhibit 5	U.S. Patent Application		17		Medicines," (120 pgs.)	
18		Publication No. 2013/0210878 A1	237	18		(Other Outputs No. 12 on CV)	267
19				19			
20				20			
21				21			
22				22			

  

Page 7				Page 9			
1	EXHIBITS			1	EXHIBITS		
2	LAWRENCE			2	LAWRENCE		
3	NUMBER	DESCRIPTION	PAGE	3	NUMBER	DESCRIPTION	PAGE
4	Exhibit 6	"Structural Investigations of		4	Exhibit 12	"Association Characteristics	
5		the Monolayers and Vesicular		5		of Synthetic Non-ionic	
6		Bilayers Formed by a Novel Class		6		Surfactants in Aqueous Solution"	
7		of Nonionic Surfactant" in the		7		in "Physical Chemistry in	
8		"Chemical Aspects of Drug		8		Condensed Phases," (pgs. 1903-1910)	
9		Delivery System," (pgs. 65-76)		9		(Articles in Academic Journals	
10		(Book Chapters No. 6 on CV)	240	10		No. 1 on CV)	279
11				11			
12	Exhibit 7	"Neutron Scattering in		12	Exhibit 13	"Effect of Structural	
13		Pharmaceutical Sciences" in		13		Variations of Non-ionic	
14		"Applications of Neutron		14		Surfactants on Micellar	
15		Scattering to Soft Condensed		15		Properties and Solubilization:	
16		Matter," (pgs. 325-356)		16		Surfactants with Semi-Polar	
17		(Book Chapters No. 7 on CV)	257	17		Hydrophobes" in "Journal of	
18	Exhibit 8	"Molecular Modelling of		18		Pharmacy & Pharmacology,"	
19		Surfactant Vesicles" in		19		(pgs. 585-589) (Articles in	
20		"Synthetic Surfactant		20		Academic Journals No. 2 on CV)	281
21		Vesicles," (pgs. 9-23)		21			
22		(Book Chapters No. 8 on CV)	259	22			

Page 10				Page 12			
1	EXHIBITS			1	EXHIBITS		
2	LAWRENCE			2	LAWRENCE		
3	NUMBER	DESCRIPTION	PAGE	3	NUMBER	DESCRIPTION	PAGE
4	Exhibit 14	"Analysis and Modelling of the Structures of Beta-Cyclodextrin Complexes" in "BBA, Biochimica et Biophysica Acta, (pgs. 27-36) (Articles in Academic Journals No. 8 on CV)	283	4	Exhibit 18	"Microemulsions as Drug Delivery Vehicles" in "Current Opinion in Colloid & Interface Science," (pgs. 826-832) (Articles in Academic Journals No. 18 on CV)	295
5				5			
6				6			
7				7			
8				8			
9				9	Exhibit 19	"Aggregation & Surface Properties of Synthetic Double-Chain Non-ionic Surfactants in Aqueous Solution in "Journal of Pharma & Pharmacology, Volume 49, May 1997 (pgs. 594-600) (Articles in Academic Journals No. 20 on CV)	297
10	Exhibit 15	"Surfactant Systems: Their Use in Drug Delivery" in "Chemical Society Reviews," (pgs. 417-424) (Articles in Academic Journals No. 9 on CV)	285	10			
11				11			
12				12			
13				13			
14				14			
15				15			
16				16			
17				17			
18				18			
19				19			
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21				21			
22				22			
Page 11				Page 13			
1	EXHIBITS			1	EXHIBITS		
2	LAWRENCE			2	LAWRENCE		
3	NUMBER	DESCRIPTION	PAGE	3	NUMBER	DESCRIPTION	PAGE
4	Exhibit 16	"Surfactant Systems: Microemulsions and Vesicles as Vehicles for Drug Delivery" in "European Journal of Drug Metabolism & Pharmacokinetics, 1994, No. 3, (pgs. 257-269) (Articles in Academic Journals No. 12 on CV)	288	4	Exhibit 20	"Physicochemical & Solubilization Properties of N,N-Dimethyl-N-(3-Dodecylcarbonyloxypropyl) amineoxide: A Biodegradable Nonionic Surfactant" in "Journal of Pharmaceutical Sciences," (pgs. 798-806) (Articles in Academic Journals No. 33 on CV)	299
5				5			
6				6			
7				7			
8				8			
9				9			
10				10			
11				11			
12				12			
13	Exhibit 17	"The Formation, Characterization & Stability of Non-Ionic Surfactant Vesicles" in "STP Pharma Sciences." (Pgs. 49-60) (Articles in Academic Journals No. 16 on CV)	292	13	Exhibit 21	"Toxicological Evaluation of Mixtures of Nonionic Surfactants, Alone & in Combination with Oil" in "Journal of Pharmaceutical Sciences," (pgs. 859-868) (Articles in Academic Journals No. 47 on CV)	304
14				14			
15				15			
16				16			
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21				21			
22				22			

Page 14			Page 16		
1	EXHIBITS		1	The court reporter today is Jeannette	08:11:53
2	LAWRENCE		2	McCormick with the firm of Ace-Federal	08:11:57
3	NUMBER DESCRIPTION PAGE		3	Reporters. My name is Thomas Del Vecchio. I	08:12:00
4	Exhibit 22 "Formulation of Electrically		4	am the legal video specialist representing	08:12:04
5	Conducting Microemulsion-Based		5	Ace-Federal Reporters, 1625 I Street,	08:12:06
6	Organogels" in "International		6	Northwest, Washington, D.C., 20006.	08:12:12
7	Journal of Pharmaceutics"		7	Will counsel identify themselves and who	08:12:17
8	(pgs. 65-83 (Articles in Academic		8	they represent.	08:12:19
9	Journals No. 49 on CV) 305		9	MR. HASFORD: Justin Hasford of Finnegan	08:12:20
10	Exhibit 23 "Molecular Dynamics Simulations		10	on behalf of plaintiffs Senju and Bausch &	08:12:21
11	of the Interfacial & Structural		11	Lomb.	08:12:21
12	Properties of		12	MR. DINER: Bryan Diner of Finnegan,	08:12:25
13	Dimethyldodecylamine-N-Oxide		13	also on behalf of plaintiffs Senju and Bausch	08:12:27
14	Micelles" in "Langmuir, The ACS		14	& Lomb.	08:12:31
15	Journal of Surfaces & Colloids"		15	MR. MARGOLIS: Dan Margolis from Goodwin	08:12:31
16	(pgs. 546-553 (Articles in Academic		16	Procter for the Lupin defendants.	08:12:33
17	Journals No. 87 on CV) 308		17	MR. ABE: James Abe of Alston & Bird for	08:12:36
18	Exhibit 24 "Microemulsion-Based Media as		18	the Innopharma defendants.	08:12:38
19	Novel Drug Delivery Systems" in		19	THE VIDEOGRAPHER: Thank you. Now, will	08:12:42
20	"Advanced Drug Delivery Reviews"		20	the court reporter please swear in or affirm	08:12:43
21	(pgs. 175-193 (Articles in		21	the witness.	08:12:45
22	Academic Journals No. 102 on CV) 312		22	M. JAYNE LAWRENCE, Ph.D.,	
Page 15			Page 17		
1	PROCEEDINGS		1	having been first duly sworn	
2	THE VIDEOGRAPHER: Good morning. We are	08:10:15	2	testified as follows:	
3	now going on the record. Please note that	08:10:16	3	EXAMINATION	
4	microphones are sensitive and may pick up	08:10:20	4	BY MR. HASFORD:	08:12:57
5	whispering and private conversations. Please	08:10:22	5	Q. Good morning, Dr. Lawrence.	08:12:57
6	turn off all telephones or place them away	08:10:25	6	A. Good morning.	08:13:01
7	from the microphones as they can interfere	08:10:29	7	Q. Would you please state your name and address.	08:13:02
8	with the video deposition audio.	08:10:32	8	for the record.	08:13:04
9	Recording will continue until parties	08:10:34	9	A. Yes. Dr. Margaret Jayne Lawrence of 62	08:13:04
10	agree to go off the record.	08:10:36	10	Wellington Road, Ashford, Middlesex, UK.	08:13:08
11	The deponent today is Dr. Jayne Lawrence	08:10:38	11	Q. How many times have you been deposed before?	08:13:11
12	in the matter of Senju Pharmaceutical	08:10:42	12	A. This is my first time.	08:13:14
13	Company, Ltd, et al, plaintiffs, versus	08:10:48	13	Q. Let me tell you how today's deposition will	08:13:16
14	Lupin, Ltd, et al, defendants, Civil Action	08:10:52	14	proceed. I represent the plaintiffs in this case.	08:13:18
15	Number 1:14-CV-00667, in the United States	08:11:00	15	Today I will ask you a series of questions, and I	08:13:20
16	District Court for the District of New	08:11:13	16	would ask that you answer my questions truthfully	08:13:23
17	Jersey.	08:11:23	17	and accurately.	08:13:25
18	This deposition is being taken at the	08:11:23	18	If you need a break, just let me know, but if	08:13:26
19	office of Goodwin Procter, the New York Times	08:11:25	19	I have asked a question I would ask that you first	08:13:29
20	Building, 620 Eighth Avenue, New York, New	08:11:30	20	answer the question and then we can take a break.	08:13:31
21	York, 10018. The time is approximately 8:12	08:11:33	21	If for any reason you do not understand a	08:13:34
22	a.m. Today is Friday, September 4, 2015.	08:11:44	22	question that I ask, please let me know. If you	08:13:36

Page 18		Page 20			
1	answer a question, I will assume that you understood	08:13:38	1	question again?	08:15:44
2	the question. Is that okay?	08:13:40	2	Q. Certainly. In what areas do you consider	08:15:44
3	A. Yes.	08:13:42	3	yourself an expert?	08:15:46
4	Q. Is there any reason why you cannot testify	08:13:42	4	MR. MARGOLIS: Same objection.	08:15:47
5	truthfully and accurately today?	08:13:45	5	THE WITNESS: In terms of scientific	08:15:49
6	A. No.	08:13:46	6	activities? In terms of professional	08:15:54
7	MR. HASFORD: I'm handing the court	08:13:49	7	activities? Could you please clarify a bit	08:15:56
8	reporter what I've asked to be marked as	08:13:50	8	more?	08:15:58
9	Lawrence Exhibit 1.	08:13:52	9	Q. In what areas do you hold yourself out as an	08:15:58
10	For the record, Lawrence Exhibit 1 is	08:13:53	10	expert?	08:16:01
11	the Declaration of Jayne Lawrence, Ph.D., and	08:13:55	11	MR. MARGOLIS: Objection. Vague.	08:16:01
12	Appendices and Exhibits.	08:13:59	12	THE WITNESS: It depends what -- I find	08:16:06
13	(Whereupon, Plaintiff's Deposition	08:14:30	13	that a very difficult question to answer	08:16:10
14	Exhibit No. Lawrence 1 was marked for	08:14:31	14	because you could be expert in lots of areas	08:16:12
15	Identification.)	08:14:33	15	and that's why I ask for clarification.	08:16:15
16	Q. Is Lawrence Exhibit 1 your claim construction	08:14:33	16	Q. In what scientific areas do you consider	08:16:17
17	declaration, appendices and exhibits in this case?	08:14:37	17	yourself an expert?	08:16:19
18	A. Yes.	08:14:45	18	A. Okay. I --	08:16:20
19	Q. Please turn to page 25. Does your signature	08:14:46	19	MR. MARGOLIS: Objection. Vague.	08:16:20
20	appear on page 25 of your claim construction	08:14:54	20	Q. You may answer.	08:16:21
21	declaration for this case?	08:14:57	21	A. Do you mean an expert in the context of this	08:16:23
22	A. It does.	08:14:58	22	particular case?	08:16:35
Page 19		Page 21			
1	Q. Who prepared your claim construction	08:14:58	1	Q. What's your understanding of an expert,	08:16:36
2	declaration for this case?	08:15:00	2	Doctor?	08:16:44
3	A. I did.	08:15:02	3	A. An expert is a person who has knowledge in a	08:16:44
4	Q. Take a look, if you would, at Appendix A. Is	08:15:03	4	particular area.	08:16:48
5	Appendix A to your claim construction declaration a	08:15:13	5	Q. Okay. And I'm asking the question based on	08:16:49
6	copy of your curriculum vitae?	08:15:16	6	your understanding. So I will ask it again. In	08:16:51
7	A. It is.	08:15:18	7	what areas do you consider yourself an expert?	08:16:53
8	Q. Does your curriculum vitae list your relevant	08:15:19	8	MR. MARGOLIS: Objection. Vague.	08:16:56
9	professional experience?	08:15:22	9	THE WITNESS: I think to answer that	08:17:06
10	A. It does.	08:15:23	10	question I'm going to have to qualify the	08:17:08
11	Q. In what areas do you consider yourself an	08:15:24	11	particular areas I'm talking about because I	08:17:12
12	expert?	08:15:26	12	have expertise in several areas.	08:17:15
13	MR. MARGOLIS: Objection. Vague.	08:15:27	13	Q. What areas?	08:17:17
14	BY MR. HASFORD:	08:15:30	14	A. I have expertise in respect to professional	08:17:19
15	Q. You may answer.	08:15:30	15	activities where I'm chair of -- I'm sorry -- where	08:17:27
16	MR. ABE: Counsel, will we agree that if	08:15:32	16	I'm Chief Scientist for Royal Pharmaceutical	08:17:30
17	counsel for Lupin objects it will apply for	08:15:35	17	Society, and so I have expertise, and surrounding my	08:17:36
18	Innopharma as well?	08:15:39	18	activities as a chief scientist in that context. I	08:17:43
19	MR. HASFORD: Sure. We can agree to	08:15:40	19	obviously have expertise surrounding my activities	08:17:47
20	that.	08:15:41	20	as an academic in King's College, London.	08:17:50
21	MR. ABE: Thank you. Please proceed.	08:15:42	21	Q. Are you an expert in any other areas?	08:17:56
22	THE WITNESS: Could you just repeat the	08:15:43	22	MR. MARGOLIS: Objection. Vague.	08:18:00

Page 22		Page 24			
1	Q. You may answer.	08:18:02	1	Q. What other areas?	08:20:04
2	A. I do find that really, really hard to answer.	08:18:06	2	A. Getting -- that's incredibly vague and	08:20:06
3	I can give you an expertise if you tell me what	08:18:09	3	probably not relevant to this particular case. For	08:20:12
4	particular areas you are referring to.	08:18:11	4	example, I'm an expert on neutron scattering, but	08:20:15
5	Q. I'm asking you for your understanding. In	08:18:13	5	it's probably irrelevant for this particular case.	08:20:20
6	what other areas do you hold yourself out as an	08:18:17	6	Q. Well, I'm asking you the question and, you	08:20:24
7	expert?	08:18:20	7	know, I'm not asking you to try to determine what's	08:20:27
8	MR. MARGOLIS: Objection. Vague.	08:18:20	8	relevant or not relevant for the case.	08:20:31
9	THE WITNESS: Well, I'm going to answer	08:18:36	9	Are you an expert in any other areas?	08:20:33
10	it this way. I have expertise in a number of	08:18:38	10	A. I consider I have expertise in a number of	08:20:59
11	scientific disciplines. I have expertise in	08:18:42	11	other areas, yes. For example, I'm a recognized	08:21:02
12	respect to my professional activities	08:18:47	12	expert on neutron scattering.	08:21:09
13	regarding my work at Pharmaceutical Society.	08:18:54	13	Q. And you just said that. What other areas	08:21:12
14	I think my main -- my main two areas of	08:18:56	14	besides neutron scattering?	08:21:15
15	expertise.	08:19:01	15	A. I think I'm expert in promoting of	08:21:18
16	Q. Take a look at paragraph 5 of your	08:19:02	16	pharmaceutical science.	08:21:23
17	declaration on page two.	08:19:05	17	Q. Any other areas?	08:21:25
18	A. Which is headed?	08:19:11	18	A. I'll qualify that, promoting to the public	08:21:27
19	Q. It's going to be page 2 of your declaration.	08:19:13	19	and other scientists. Can I look at my CV?	08:21:32
20	A. Yes.	08:19:13	20	Q. Oh, please.	08:21:40
21	Q. Paragraph 5 under Qualifications. I don't	08:19:16	21	A. I consider I'm an expert teacher with respect	08:21:48
22	think you're on the right page.	08:19:19	22	to pharmaceutical science. I've been given awards	08:21:54
Page 23		Page 25			
1	A. I'm sorry.	08:19:20	1	for that activity.	08:22:00
2	Q. It's your declaration.	08:19:21	2	I consider I'm an expert researcher, which	08:22:02
3	A. Sorry. Paragraph 5?	08:19:22	3	includes an expert in the areas you highlighted.	08:22:06
4	Q. So, I still don't believe you're on the right	08:19:26	4	Q. Any other areas?	08:22:10
5	page. It's your declaration, not your curriculum	08:19:28	5	A. Archaeology. Hobby.	08:22:14
6	vitae.	08:19:31	6	Q. Anything else?	08:22:22
7	A. I'm sorry. Five did you say? Page 5?	08:19:31	7	A. It's very hard to answer when asked are you	08:22:37
8	Q. Page 2, paragraph 5.	08:19:37	8	an expert in, not knowing what the point of the	08:22:40
9	A. Page 2. Okay.	08:19:39	9	question is.	08:22:44
10	Q. It says, "I am an expert in the field of	08:19:40	10	Q. Well, let me ask it this way. Are you an	08:22:45
11	formulation and drug delivery, specifically	08:19:42	11	expert in the field of pharmacy?	08:22:47
12	pharmaceutical formulation for oral and parenteral	08:19:44	12	A. Yes.	08:22:48
13	use (i.e., non-oral, including intravenous	08:19:48	13	Q. Have you ever practiced pharmacy?	08:22:49
14	intramuscular, nasal, respiratory and ophthalmic),	08:19:52	14	A. Yes.	08:22:51
15	including aqueous liquid preparations."	08:19:57	15	Q. When did you last practice pharmacy?	08:22:51
16	Do you see that?	08:19:58	16	A. I'm a practicing pharmacist.	08:22:53
17	A. Yes.	08:19:59	17	Q. When did you last dispense a medication to a	08:22:55
18	Q. Do you hold yourself out to the public as an	08:19:59	18	patient?	08:22:58
19	expert in any other areas?	08:20:01	19	A. Dispense medication? Probably 20 years ago.	08:22:58
20	A. In other areas?	08:20:02	20	Q. Are you an expert in pharmacology?	08:23:10
21	Q. Correct.	08:20:03	21	A. No.	08:23:12
22	A. Yes.	08:20:04	22	Q. Are you an expert in pharmacokinetics?	08:23:12



Page 26				Page 28			
1	MR. MARGOLIS: Objection. Vague.	08:23:18		1	A. As a pharmacist in the UK, that is not your	08:25:17	
2	Q. You may answer.	08:23:19		2	role.	08:25:21	
3	A. I have -- I have a good level of expertise in	08:23:23		3	Q. Is that a "no"?	08:25:22	
4	that.	08:23:28		4	A. In the UK, that would not be the role of a	08:25:24	
5	Q. Have you ever held yourself out to the public	08:23:29		5	pharmacist.	08:25:26	
6	as an expert in pharmacokinetics?	08:23:31		6	Q. Have you ever dispensed any bromfenac product	08:25:27	
7	A. No.	08:23:33		7	to a patient?	08:25:30	
8	Q. Have you ever held yourself out to the public	08:23:33		8	A. No.	08:25:32	
9	as an expert in pharmacodynamics?	08:23:36		9	Q. Have you ever dispensed any product	08:25:33	
10	MR. MARGOLIS: Objection. Vague.	08:23:40		10	containing tyloxapol to a patient?	08:25:35	
11	Q. You may answer.	08:23:41		11	A. Yes.	08:25:38	
12	A. I have not.	08:23:44		12	Q. What product?	08:25:39	
13	Q. Are you an expert in ophthalmology?	08:23:45		13	A. Exosurf.	08:25:40	
14	MR. MARGOLIS: Objection. Vague.	08:23:52		14	Q. You may have to spell that for the reporter.	08:25:42	
15	Q. You may answer.	08:23:54		15	A. E-X-O-S-U-R-F.	08:25:45	
16	A. I'm an expert in parenteral formulations of	08:23:57		16	Q. What is Exosurf?	08:25:50	
17	which ophthalmology -- ophthalmic formulations as	08:24:01		17	A. It's a product for respiratory distress	08:25:52	
18	well.	08:24:06		18	syndrome in pre-term infants.	08:25:59	
19	Q. Have you ever held yourself out to the public	08:24:06		19	Q. Is that an ophthalmic product?	08:26:03	
20	as an expert in ophthalmology?	08:24:09		20	A. It's not an ophthalmic product. I have	08:26:06	
21	MR. MARGOLIS: Objection. Vague.	08:24:11		21	dispensed many ophthalmic products.	08:26:08	
22	THE WITNESS: No.	08:24:12		22	Q. Have you ever dispensed an ophthalmic product	08:26:11	
Page 27				Page 29			
1	Q. Are you an expert in any field of medicine?	08:24:13		1	containing tyloxapol to a patient?	08:26:16	
2	MR. MARGOLIS: Objection. Vague.	08:24:17		2	A. Undoubtedly.	08:26:16	
3	THE WITNESS: Medicine is a huge area.	08:24:19		3	Q. Which one?	08:26:17	
4	And what are you covering? Are you covering	08:24:25		4	A. Many products contain tyloxapol. As a	08:26:19	
5	pharmaceutical medicine?	08:24:27		5	pharmacist, I have dispensed most ophthalmic	08:26:28	
6	Q. Have you ever held yourself out to the public	08:24:29		6	preparations.	08:26:32	
7	as an expert in any field of medicine?	08:24:31		7	Q. What ophthalmic product containing tyloxapol	08:26:32	
8	MR. MARGOLIS: Objection. Vague.	08:24:34		8	have you dispensed to a patient?	08:26:36	
9	THE WITNESS: I am a Registered	08:24:37		9	A. As a pharmacist, it is not normal you read	08:26:37	
10	Practicing Pharmacist in the UK.	08:24:39		10	the list of excipients.	08:26:40	
11	Q. Have you ever --	08:24:42		11	Q. Sitting here today, can you name any	08:26:41	
12	A. So, I am not a medic.	08:24:43		12	ophthalmic product containing tyloxapol that you	08:26:43	
13	Q. Well, when you say --	08:24:47		13	have dispensed to a patient?	08:26:46	
14	A. So, I would not claim to practice medicine.	08:24:48		14	A. No.	08:26:52	
15	Q. Have you ever prescribed medication to a	08:24:53		15	Q. Are you aware that the acronym EDTA stands	08:26:53	
16	patient?	08:24:56		16	for ethylenediaminetetraacetic acid?	08:26:59	
17	A. No.	08:24:58		17	A. I am.	08:27:02	
18	Q. Have you ever treated an inflammatory disease	08:24:59		18	Q. Have you ever administered any product	08:27:02	
19	of the eye?	08:25:02		19	containing EDTA or any salt or anion of EDTA to a	08:27:04	
20	A. No.	08:25:06		20	patient?	08:27:11	
21	Q. Have you ever administered any bromfenac	08:25:06		21	A. Undoubtedly, yes.	08:27:12	
22	product to a patient?	08:25:11		22	Q. Which product?	08:27:14	

Page 30			Page 32		
1	A. Eye drops that contain it.	08:27:15	1	Q. Have you ever conducted any research on any	08:29:37
2	Q. Which eye drops?	08:27:17	2	product containing EDTA or any salt or anion of	08:29:40
3	A. I don't recall.	08:27:19	3	EDTA?	08:29:45
4	Q. Have you ever conducted any research on any	08:27:21	4	A. Yes.	08:29:45
5	bromfenac product?	08:27:25	5	Q. What product?	08:29:45
6	MR. MARGOLIS: Objection. Vague.	08:27:27	6	A. It's frequently -- it's a compound that is	08:29:48
7	Q. You may answer.	08:27:28	7	frequently used in academic research for a variety	08:29:53
8	A. On a bromfenac product, no.	08:27:38	8	of purposes.	08:29:58
9	Q. Have you ever conducted any research on any	08:27:40	9	Q. When did you last use EDTA in your academic	08:29:58
10	product containing tyloxapol?	08:27:42	10	research?	08:30:02
11	A. Yes.	08:27:45	11	A. Personally, a while ago. My research group,	08:30:03
12	Q. What product?	08:27:45	12	all the time. So, I don't know how that answers	08:30:08
13	A. Exosurf, for example.	08:27:47	13	your question.	08:30:14
14	Q. Any others?	08:27:52	14	Q. No. Thank you for clarifying.	08:30:14
15	A. Formulations I have undertaken research in my	08:27:55	15	When personally did you last use EDTA in your	08:30:16
16	own laboratory.	08:27:59	16	academic research?	08:30:19
17	Q. Which formulations?	08:28:00	17	A. Probably about five years ago.	08:30:22
18	A. That I have made up in my own laboratory.	08:28:01	18	Q. When personally did you last use tyloxapol in	08:30:37
19	Q. How did you make a formulation in your	08:28:04	19	your academic research?	08:30:39
20	laboratory containing tyloxapol?	08:28:07	20	A. Very recently.	08:30:42
21	A. That is a very vague question. I have used	08:28:11	21	Q. Do you remember how recently?	08:30:45
22	tyloxapol much in my research.	08:28:16	22	A. Probably last year or so.	08:30:47
Page 31			Page 33		
1	Q. What did you use it for?	08:28:18	1	Q. Is bromfenac a water-soluble hydrophilic	08:30:52
2	A. To make a variety of formulations, of types	08:28:20	2	drug?	08:31:00
3	of formulations.	08:28:24	3	MR. MARGOLIS: Objection. Vague.	08:31:00
4	Q. Why did you use tyloxapol in the formulations	08:28:25	4	THE WITNESS: Can I ask you to clarify	08:31:02
5	that you made in your laboratory?	08:28:28	5	that? Do you mean the free acid or do you	08:31:02
6	MR. MARGOLIS: Objection. Vague.	08:28:30	6	mean the salt?	08:31:04
7	Compound.	08:28:31	7	Q. Well, let me ask it this way. Is the sodium	08:31:05
8	Q. You may answer.	08:28:32	8	salt of bromfenac a water-soluble hydrophilic drug?	08:31:07
9	A. I used it for several reasons. For example,	08:28:35	9	A. It is.	08:31:12
10	it is accepted pharmaceutically.	08:28:40	10	Q. Would a solution containing tyloxapol in	08:31:13
11	Q. What other reasons?	08:28:42	11	water be considered a water-based surfactant system?	08:31:16
12	A. It's a non-ionic surfactant.	08:28:45	12	MR. MARGOLIS: Objection. Vague.	08:31:19
13	Q. What other reasons?	08:28:51	13	THE WITNESS: Sorry. Repeat the	08:31:23
14	A. It is well-known to solubilize drugs. To	08:28:53	14	question?	08:31:25
15	solubilize, S-O-L-U-B-I-L-I-S-E, or Z-E.	08:29:05	15	Q. Certainly. I will repeat the question.	08:31:25
16	Q. Any other reasons?	08:29:07	16	Would a solution containing tyloxapol in	08:31:27
17	A. It's -- it stabilizes many formulations.	08:29:09	17	water be considered a water-based surfactant system?	08:31:30
18	Q. What do you mean by "it stabilizes many	08:29:26	18	MR. MARGOLIS: Objection. Vague.	08:31:34
19	formulations"?	08:29:29	19	THE WITNESS: It is vague because you	08:31:37
20	A. It depends on the formulation you're looking	08:29:29	20	don't give enough information as to regards	08:31:43
21	at, how it acts, but it is used to formulate many	08:29:31	21	to how much tyloxapol or what else is in	08:31:45
22	preparations.	08:29:35	22	there. So it's very -- it's difficult to	08:31:49

Page 34	<p>1 answer. 08:31:52</p> <p>2 Q. How would you make a water-based surfactant 08:31:52</p> <p>3 system with tyloxapol? 08:31:56</p> <p>4 A. Can I ask for clarification? 08:31:57</p> <p>5 Q. Sure. 08:31:59</p> <p>6 A. What do you mean by water-based? 08:32:00</p> <p>7 Q. What's your understanding of water-based? 08:32:01</p> <p>8 A. I don't know. I'm asking for clarification. 08:32:03</p> <p>9 Q. Have you ever used the term water-based? 08:32:06</p> <p>10 A. It's not a frequently used term -- a term I 08:32:09</p> <p>11 frequently use, no. 08:32:12</p> <p>12 Q. Have you ever used it in any of your 08:32:13</p> <p>13 publications? 08:32:15</p> <p>14 A. I don't know. I don't remember every single 08:32:17</p> <p>15 publication I've had. 08:32:24</p> <p>16 Q. Would a solution containing tyloxapol in 08:32:25</p> <p>17 water be considered an aqueous surfactant system? 08:32:28</p> <p>18 MR. MARGOLIS: Objection. Vague. 08:32:31</p> <p>19 THE WITNESS: Again, you need to tell me 08:32:32</p> <p>20 how much water and tyloxapol there are to 08:32:34</p> <p>21 answer that question. I'm sorry. 08:32:37</p> <p>22 Q. Why does it matter how much water and 08:32:37</p>	Page 36	<p>1 concentration, that would depend on what you would 08:33:48</p> <p>2 do next. 08:33:50</p> <p>3 Q. Would that be considered a water-based 08:33:51</p> <p>4 surfactant system? 08:33:53</p> <p>5 MR. MARGOLIS: Objection. Vague. 08:33:55</p> <p>6 THE WITNESS: Again, it depends on what 08:34:00</p> <p>7 the definition of based is. 08:34:04</p> <p>8 Q. Would that be considered an aqueous 08:34:06</p> <p>9 surfactant system? 08:34:09</p> <p>10 MR. MARGOLIS: Objection. Vague. 08:34:11</p> <p>11 THE WITNESS: It would depend on the 08:34:13</p> <p>12 relative -- depending on the relative 08:34:15</p> <p>13 proportions of surfactant and water. 08:34:16</p> <p>14 Q. If the water is in the greater proportion, 08:34:18</p> <p>15 would that be an aqueous surfactant system? 08:34:21</p> <p>16 A. Yes. 08:34:24</p> <p>17 Q. Are you an expert in clinical testing? 08:34:26</p> <p>18 A. No. I would consider myself somebody of 08:34:33</p> <p>19 ordinary skill in the art. 08:34:35</p> <p>20 Q. Have you ever conducted any clinical testing 08:34:36</p> <p>21 with a pharmaceutical product? 08:34:39</p> <p>22 A. When you mean conduct, again, that's very 08:34:47</p>
Page 35	<p>1 tyloxapol are there? 08:32:39</p> <p>2 A. Because you still haven't answered really 08:32:42</p> <p>3 what based is. So, when you say water-based, if you 08:32:45</p> <p>4 can clarify that, please? 08:32:49</p> <p>5 Q. No. I asked a different question. I 08:32:51</p> <p>6 asked -- 08:32:53</p> <p>7 A. I can't answer if you're talking about 08:32:53</p> <p>8 water-based and it's not clarified. So I can't 08:32:56</p> <p>9 answer. Sorry. 08:32:58</p> <p>10 Q. Okay. How would you make an aqueous 08:33:00</p> <p>11 surfactant system using tyloxapol? 08:33:03</p> <p>12 MR. MARGOLIS: Objection. Vague. 08:33:06</p> <p>13 Q. You may answer. 08:33:09</p> <p>14 A. The only way I can answer that is to make 08:33:12</p> <p>15 some assumptions. 08:33:15</p> <p>16 Q. Please do. 08:33:16</p> <p>17 A. Assuming you want a predominantly 08:33:17</p> <p>18 water-based -- water to be there in the biggest 08:33:25</p> <p>19 amount, largest amount, which I assume is what you 08:33:28</p> <p>20 are trying to say by based, you would add water, a 08:33:31</p> <p>21 known amount of water, to a pre-weighed amount of 08:33:42</p> <p>22 tyloxapol, and depending upon the particular 08:33:45</p>	Page 37	<p>1 vague because have I led a clinical trial, have I 08:34:54</p> <p>2 designed a clinical trial, have I analyzed a 08:34:58</p> <p>3 clinical trial? That's not -- 08:35:00</p> <p>4 Q. Have you ever led any clinical testing on a 08:35:02</p> <p>5 pharmaceutical product? 08:35:05</p> <p>6 A. No. 08:35:06</p> <p>7 Q. Have you ever designed any clinical testing 08:35:06</p> <p>8 on a pharmaceutical product? 08:35:09</p> <p>9 A. No. 08:35:10</p> <p>10 Q. Are you an expert in statistics or 08:35:10</p> <p>11 biostatistics? 08:35:12</p> <p>12 MR. MARGOLIS: Objection. Vague. 08:35:15</p> <p>13 THE WITNESS: I have a good 08:35:21</p> <p>14 understanding of statistics. 08:35:23</p> <p>15 Q. Do you hold yourself to the public as an 08:35:24</p> <p>16 expert in statistics or biostatistics? 08:35:26</p> <p>17 A. No, I would not. 08:35:30</p> <p>18 Q. Are you an expert in the U.S. Pharmacopeia 08:35:31</p> <p>19 criteria for antimicrobial effectiveness? 08:35:35</p> <p>20 MR. MARGOLIS: Objection. Vague. 08:35:39</p> <p>21 THE WITNESS: I'm very aware of what the 08:35:42</p> <p>22 criteria are. 08:35:48</p>

Page 38		Page 40		
1	Q. Do you hold yourself as an expert in the U.S.	08:35:49	1 question to answer that because I'm still	08:37:54
2	Pharmacopeia criteria for antimicrobial	08:35:52	2 uncertain -- I believe that expertise falls	08:38:00
3	effectiveness?	08:35:56	3 under my experience and expertise in	08:38:06
4	MR. MARGOLIS: Objection. Vague.	08:35:57	4 formulation.	08:38:09
5	THE WITNESS: I am unclear what an	08:35:58	5 Q. Have you ever told anyone that you were an	08:38:10
6	expert would need to do under those --	08:35:59	6 expert in the stability testing on aqueous liquid	08:38:12
7	somebody would need to do under those	08:36:02	7 preparations?	08:38:15
8	circumstances to be an expert.	08:36:05	8 A. Who would I need to have told?	08:38:18
9	Q. Have you ever conducted any tests measuring	08:36:06	9 Q. Is that a "no"?	08:38:20
10	antimicrobial effectiveness according to the U.S.	08:36:09	10 A. I don't know who you mean. I'm considered to	08:38:22
11	Pharmacopeia criteria?	08:36:13	11 be an expert in drug and gene delivery and all that	08:38:26
12	A. Yes.	08:36:15	12 entails. So that would be an integral part of that.	08:38:32
13	Q. What test did you conduct?	08:36:16	13 Q. Have you ever told anyone that you're an	08:38:35
14	A. A long time ago with some products that were	08:36:19	14 expert in stability testing on aqueous liquid	08:38:37
15	being prepared in the laboratory.	08:36:23	15 preparations?	08:38:40
16	Q. When did you last conduct a test measuring	08:36:25	16 MR. MARGOLIS: Objection. Asked and	08:38:44
17	antimicrobial effectiveness according to the U.S.	08:36:28	17 answered.	08:38:45
18	Pharmacopeia criteria?	08:36:31	18 THE WITNESS: I repeat again that is an	08:38:50
19	A. I can't recall.	08:36:34	19 integral part of my expertise in drug	08:38:53
20	Q. Are you an expert in the European	08:36:38	20 delivery.	08:39:01
21	Pharmacopeia criteria B standards?	08:36:42	21 Q. Have you ever conducted stability testing on	08:39:06
22	MR. MARGOLIS: Objection. Vague.	08:36:44	22 aqueous liquid preparations?	08:39:11
Page 39		Page 41		
1	THE WITNESS: Again, I am obviously	08:36:48	1 A. I have.	08:39:20
2	aware of those, being a pharmacist and a	08:36:51	2 Q. Why did you conduct stability testing on	08:39:22
3	researcher. I'm unclear what would be an	08:36:54	3 aqueous liquid preparations?	08:39:25
4	expert in that area.	08:36:58	4 A. Stability testing is a very large field and	08:39:28
5	Q. Have you ever held yourself out to the public	08:36:59	5 it would depend upon -- the tests you performed	08:39:39
6	as an expert in the European Pharmacopeia criteria B	08:37:02	6 would depend upon formulation and its ultimate	08:39:42
7	standards?	08:37:07	7 intended use.	08:39:47
8	A. No.	08:37:07	8 Q. How did you conduct stability testing on	08:39:48
9	MR. MARGOLIS: Objection. Vague.	08:37:08	9 aqueous liquid preparations?	08:39:50
10	Q. Are you an expert in stability testing of	08:37:09	10 MR. MARGOLIS: Objection. Vague.	08:39:52
11	aqueous liquid preparations?	08:37:12	11 THE WITNESS: I repeat my answer.	08:39:56
12	A. I believe I have a--	08:37:17	12 Stability testing is a very large area. The	08:39:58
13	MR. MARGOLIS: Objection. Vague.	08:37:17	13 tests you performed and how I perform them	08:40:04
14	THE WITNESS: I believe I have a very	08:37:18	14 would depend upon the formulation I was	08:40:07
15	good understanding of a large number of	08:37:21	15 looking at and the purpose, the intended	08:40:10
16	stability tests that would be appropriate for	08:37:26	16 purpose.	08:40:13
17	that.	08:37:28	17 Q. When did you last conduct stability testing	08:40:13
18	Q. Have you ever held yourself out to the public	08:37:28	18 on aqueous liquid preparations?	08:40:15
19	as an expert in stability testing of aqueous liquid	08:37:31	19 A. It's conducted all the time in my laboratory.	08:40:19
20	preparations?	08:37:34	20 Q. When did you last do it?	08:40:23
21	MR. MARGOLIS: Objection. Vague.	08:37:38	21 A. I conducted tests personally within the last	08:40:33
22	THE WITNESS: That's a really difficult	08:37:52	22 few weeks.	08:40:36

Page 42			Page 44		
1	Q. How did you conduct those tests?	08:40:37	1	the concept of solubility with respect to aqueous	08:43:32
2	A. This is a really impossible question to	08:40:43	2	liquid preparations?	08:43:37
3	answer. It's like how long is a piece of string.	08:40:51	3	MR. MARGOLIS: Objection. Vague.	08:43:39
4	Q. You've told me that you just conducted those	08:40:54	4	THE WITNESS: They are not synonymous at	08:43:41
5	tests and --	08:40:56	5	all.	08:43:49
6	A. I conducted some tests, yes.	08:40:56	6	Q. Why are they not synonymous at all?	08:43:49
7	Q. How did you conduct them?	08:40:58	7	A. Solubility is assessing the amount of the	08:43:51
8	A. Those particular tests? Okay. In this	08:40:59	8	material of interest that is molecularly dispersed	08:43:57
9	particular case, these tests were looking at	08:41:06	9	in solution. Stability always has to be defined.	08:44:03
10	stability of drug in micelle formulations.	08:41:09	10	There are different types of stability, and	08:44:12
11	Formulations were prepared to standard criteria in	08:41:18	11	that's -- and you want to ensure that your	08:44:17
12	my laboratory, and they were assayed over time using	08:41:22	12	formulation is unchanged in its use -- in use.	08:44:24
13	a variety of techniques which were appropriate	08:41:26	13	Q. Are you an expert in chemistry?	08:44:34
14	ranging from spectroscopic through to size stability	08:41:30	14	MR. MARGOLIS: Objection. Vague.	08:44:37
15	through to neutron scattering.	08:41:36	15	Q. You may answer.	08:44:38
16	Q. Why did you conduct those particular tests?	08:41:40	16	A. I'm going to ask you what you mean by	08:44:41
17	A. If you're working in drug delivery, gene	08:41:44	17	chemistry.	08:44:43
18	delivery, formulation stability is a prerequisite.	08:41:48	18	Q. Well, what's your understanding of chemistry?	08:44:43
19	Q. Why is formulation stability a prerequisite	08:41:53	19	A. Chemistry is a huge subject. That's my	08:44:47
20	for drug delivery?	08:41:56	20	understanding of chemistry.	08:44:50
21	A. A patient doesn't want an unstable	08:41:59	21	Q. Have you ever held yourself out to the public	08:44:52
22	formulation that's not going to behave in the	08:42:02	22	as an expert in the field of chemistry?	08:44:54
Page 43			Page 45		
1	appropriate way.	08:42:04	1	MR. MARGOLIS: Objection. Vague.	08:44:57
2	Q. Why is it important for a patient to have a	08:42:06	2	THE WITNESS: I have a known expertise	08:45:00
3	stable formulation that will behave in an	08:42:09	3	in physical chemistry. I have a good	08:45:02
4	appropriate way?	08:42:12	4	understanding of organic chemistry.	08:45:06
5	MR. MARGOLIS: Objection. Lacks	08:42:14	5	Q. Have you ever published anything in The	08:45:13
6	foundation.	08:42:16	6	Journal of the American Chemical Society?	08:45:15
7	Q. You may answer.	08:42:17	7	A. No.	08:45:18
8	A. There are a number of reasons. For example,	08:42:20	8	Q. Have you ever been qualified by any court as	08:45:18
9	to ensure the drug hasn't degraded into toxic	08:42:24	9	an expert in chemistry?	08:45:21
10	impurities.	08:42:29	10	A. Having only done two court cases prior, no.	08:45:28
11	Q. What other reasons?	08:42:31	11	Q. Are you an expert in patent law?	08:45:33
12	A. To ensure that the formulation hasn't changed	08:42:33	12	A. No.	08:45:37
13	its state.	08:42:39	13	Q. Are you a named inventor on any U.S. patents?	08:45:37
14	Q. Any other reasons?	08:42:42	14	A. Not U.S., no.	08:45:42
15	A. To ensure that the formulation is likely to	08:42:44	15	Q. Are you a named inventor on any U.S. patent	08:45:44
16	be stable under the condition of use of the patient,	08:42:47	16	applications?	08:45:47
17	to ensure the container you're putting the	08:42:53	17	A. No.	08:45:48
18	formulation in is appropriate for end use, ensure	08:42:59	18	Q. Prior to this case, have you ever provided	08:45:49
19	there's sufficient shelf-life, to ensure it's not	08:43:05	19	any opinion regarding the interpretation of the	08:45:52
20	contaminated with microbial contamination, to ensure	08:43:14	20	phrases sodium edetate or EDTA sodium salt in a	08:45:55
21	it's not affected by light. I could go on.	08:43:20	21	patent claim?	08:46:00
22	Q. How does the concept of stability differ from	08:43:30	22	MR. MARGOLIS: Objection. Vague.	08:46:06

Page 46	<p>1 THE WITNESS: I can't recall. I may 08:46:19</p> <p>2 have, but I can't recall definitely. 08:46:21</p> <p>3 Q. Prior to this case, have you provided any 08:46:23</p> <p>4 opinion regarding the interpretation of the term 08:46:28</p> <p>5 stable or any phrase concerning the term stabilized 08:46:30</p> <p>6 in a patent claim? 08:46:34</p> <p>7 A. I have. 08:46:35</p> <p>8 MR. MARGOLIS: Objection. Vague. 08:46:36</p> <p>9 Q. And what case was that? 08:46:36</p> <p>10 A. Novartis versus Ivax. Novartis versus Dixel. 08:46:44</p> <p>11 Q. What was your opinion? 08:46:49</p> <p>12 A. Very vague, that question. It was related to 08:46:52</p> <p>13 the particular formulation in the case. 08:46:55</p> <p>14 Q. Did the court accept your opinion? 08:46:58</p> <p>15 A. Yes. 08:47:00</p> <p>16 Q. Prior to this case, have you ever provided 08:47:02</p> <p>17 any opinion regarding the interpretation of any 08:47:05</p> <p>18 phrase dealing with preservative efficacy in a 08:47:08</p> <p>19 patent claim? 08:47:11</p> <p>20 MR. MARGOLIS: Objection. Vague. 08:47:13</p> <p>21 THE WITNESS: I may have, but I can't 08:47:22</p> <p>22 definitely recall. 08:47:24</p>	Page 48	<p>1 containing EDTA or any salt or anion of EDTA? 08:48:34</p> <p>2 A. I've used formulations in my laboratory with 08:48:39</p> <p>3 EDTA and the salts, yes. 08:48:43</p> <p>4 Q. Have you ever actually formulated any 08:48:45</p> <p>5 products containing EDTA? 08:48:47</p> <p>6 A. Can you explain what you mean by formulate? 08:48:48</p> <p>7 Q. Well, what's your understanding of 08:48:51</p> <p>8 formulation? 08:48:52</p> <p>9 A. A formulate is make up a preparation. 08:48:52</p> <p>10 Q. Okay. Well, I'm asking based on your 08:48:56</p> <p>11 understanding. 08:48:58</p> <p>12 Have you ever formulated any product 08:48:58</p> <p>13 containing EDTA or any salt or anion of EDTA? 08:49:00</p> <p>14 A. Okay. What do you mean by product? 08:49:04</p> <p>15 Q. Well, what's your understanding of a product? 08:49:06</p> <p>16 A. Do you mean something that got on to market? 08:49:09</p> <p>17 Q. I'm asking you more generally than that. Any 08:49:14</p> <p>18 formulation? 08:49:17</p> <p>19 A. I have made formulations in my laboratory 08:49:19</p> <p>20 using EDTA and its salts, yes. 08:49:23</p> <p>21 Q. And you mentioned the market -- excuse me. 08:49:26</p> <p>22 Have you ever formulated any marketed drug product? 08:49:29</p>
Page 47	<p>1 Q. Back to the Novartis case you mentioned, for 08:47:25</p> <p>2 which party in that case did you provide your 08:47:29</p> <p>3 opinion? 08:47:32</p> <p>4 A. Novartis. 08:47:33</p> <p>5 Q. In what court was that? 08:47:34</p> <p>6 A. The UK High Court. 08:47:37</p> <p>7 Q. Did you provide public testimony at trial in 08:47:40</p> <p>8 that case? 08:47:49</p> <p>9 A. Yes. 08:47:49</p> <p>10 Q. Did you provide testimony at a deposition in 08:47:50</p> <p>11 that case? 08:47:53</p> <p>12 A. They don't do deposition in the UK. 08:47:54</p> <p>13 Q. Have you ever formulated any bromfenac 08:47:57</p> <p>14 product? 08:48:02</p> <p>15 A. No, but formulated closely related molecules. 08:48:08</p> <p>16 Q. Have you ever formulated any product 08:48:14</p> <p>17 containing tyloxapol? 08:48:21</p> <p>18 A. I have formulated products in my laboratory, 08:48:23</p> <p>19 yes. 08:48:29</p> <p>20 Q. Containing tyloxapol? 08:48:29</p> <p>21 A. Yes. 08:48:31</p> <p>22 Q. Have you ever formulated any products 08:48:31</p>	Page 49	<p>1 A. Not as lead formulator, no. 08:49:33</p> <p>2 Q. Have you ever formulated any product for 08:49:37</p> <p>3 treating an inflammatory disease of the eye? 08:49:39</p> <p>4 A. No, not that's got to market. 08:49:43</p> <p>5 Q. Have you ever formulated any product 08:49:47</p> <p>6 containing multiple active ingredients? 08:49:49</p> <p>7 A. Yes. 08:49:51</p> <p>8 Q. What product? 08:49:52</p> <p>9 A. It's a combination formulation consisting of 08:49:53</p> <p>10 another particle and microemulsion. 08:50:01</p> <p>11 Q. How does the addition of a second active 08:50:03</p> <p>12 ingredient to a pharmaceutical formulation affect 08:50:06</p> <p>13 the physical and chemical properties of the 08:50:10</p> <p>14 formulation? 08:50:12</p> <p>15 MR. MARGOLIS: Objection. Lacks 08:50:13</p> <p>16 foundation. 08:50:14</p> <p>17 THE WITNESS: Again, that very much 08:50:16</p> <p>18 depends upon the two drugs and the 08:50:18</p> <p>19 formulation. 08:50:22</p> <p>20 Q. What else does it depend on? 08:50:23</p> <p>21 A. A huge amount of things. It would depend 08:50:25</p> <p>22 upon the two drugs. It would depend upon how the 08:50:32</p>

Page 50	<p>1 two drugs were formulated, relative amounts of the 08:50:38</p> <p>2 two drugs, the pH, the temperature of use, the 08:50:46</p> <p>3 presence of excipients. You would have to test to 08:50:55</p> <p>4 ensure whether or not it worked. 08:51:00</p> <p>5 Q. Is it fair to say that that's a complicated 08:51:04</p> <p>6 process? 08:51:07</p> <p>7 MR. MARGOLIS: Objection. Vague. 08:51:11</p> <p>8 THE WITNESS: It would depend upon the 08:51:15</p> <p>9 products you were interested in. 08:51:18</p> <p>10 Q. How so? 08:51:20</p> <p>11 A. I gave a potential landscape of problems that 08:51:32</p> <p>12 you would need to consider -- of considerations you 08:51:48</p> <p>13 would need to make when designing your study. 08:51:49</p> <p>14 Depending upon the two systems you're interested in, 08:51:53</p> <p>15 you may or may not have to do all of those, and I 08:51:58</p> <p>16 can't say without that knowledge. 08:52:01</p> <p>17 Q. Have you authored any papers dealing with the 08:52:04</p> <p>18 formulation of aqueous liquid preparations 08:52:07</p> <p>19 containing multiple active ingredients? 08:52:10</p> <p>20 A. Yes. 08:52:13</p> <p>21 Q. Have you authored or edited any book chapters 08:52:13</p> <p>22 dealing with formulation of aqueous liquid 08:52:16</p>	Page 52	<p>1 A. No. 08:53:13</p> <p>2 Q. Aside from your work in this case, have you 08:53:14</p> <p>3 ever consulted for any party concerning any 08:53:16</p> <p>4 bromfenac product? 08:53:21</p> <p>5 MR. MARGOLIS: Objection. Vague. 08:53:24</p> <p>6 THE WITNESS: I would like to state that 08:53:25</p> <p>7 I actually have written monographs in The 08:53:27</p> <p>8 Handbook for Pharmaceutical Excipients. 08:53:30</p> <p>9 Q. Did you write any monographs regarding 08:53:33</p> <p>10 bromfenac in the Handbook of Pharmaceutical -- 08:53:36</p> <p>11 A. No. It was on surfactants. 08:53:36</p> <p>12 Q. Did you write any monographs in The Handbook 08:53:40</p> <p>13 of Pharmaceutical Excipients regarding bromfenac? 08:53:42</p> <p>14 A. No. The Handbook of Excipients, and 08:53:46</p> <p>15 bromfenac is not an excipient, so I've written them 08:53:52</p> <p>16 on surfactants. 08:53:56</p> <p>17 Q. Aside from your work in this case, have you 08:53:57</p> <p>18 ever consulted for any party regarding any bromfenac 08:53:59</p> <p>19 product? 08:54:03</p> <p>20 MR. MARGOLIS: Objection. Vague. 08:54:04</p> <p>21 Q. You may answer. 08:54:06</p> <p>22 A. No. 08:54:10</p>
Page 51	<p>1 preparations containing multiple active ingredients? 08:52:18</p> <p>2 A. Have I edited a book or did I -- 08:52:22</p> <p>3 Q. Or authored any book chapter, correct. 08:52:30</p> <p>4 A. A book chapter, yes. I have, yes. 08:52:33</p> <p>5 Q. Have you ever contributed to the content of 08:52:35</p> <p>6 any edition of the European Pharmacopeia? 08:52:39</p> <p>7 A. No. 08:52:42</p> <p>8 Q. Have you ever contributed to the content of 08:52:43</p> <p>9 any edition of the United States Pharmacopeia? 08:52:45</p> <p>10 A. No. 08:52:49</p> <p>11 Q. Are you aware that the United States 08:52:49</p> <p>12 Pharmacopeia is a publication of the National 08:52:51</p> <p>13 Formulary? 08:52:54</p> <p>14 A. I am. 08:52:55</p> <p>15 Q. And have you ever consulted for the National 08:52:56</p> <p>16 Formulary? 08:52:59</p> <p>17 A. I have not. 08:52:59</p> <p>18 Q. Have you ever contributed to the content of 08:53:00</p> <p>19 any edition of the Japanese Pharmacopeia? 08:53:02</p> <p>20 A. I have not. 08:53:06</p> <p>21 Q. Have you ever contributed to the content of 08:53:08</p> <p>22 any edition of the Merck Index? 08:53:10</p>	Page 53	<p>1 Q. Aside from your work in this case, have you 08:54:11</p> <p>2 ever consulted for any party regarding any product 08:54:13</p> <p>3 containing tyloxapol? 08:54:16</p> <p>4 A. Yes. 08:54:20</p> <p>5 Q. In what context did you do that? 08:54:23</p> <p>6 A. I acted as an expert for a pharmaceutical 08:54:26</p> <p>7 company. 08:54:28</p> <p>8 Q. And what company was that? 08:54:28</p> <p>9 A. It's confidential. 08:54:30</p> <p>10 Q. Did you serve in that capacity in a court 08:54:31</p> <p>11 case? 08:54:37</p> <p>12 A. No. 08:54:37</p> <p>13 Q. Aside from your work in this case, have you 08:54:40</p> <p>14 ever consulted for any party regarding any product 08:54:42</p> <p>15 containing EDTA or a salt or anion of EDTA? 08:54:45</p> <p>16 MR. MARGOLIS: Objection. Vague. 08:54:50</p> <p>17 THE WITNESS: EDTA and its salts are 08:54:55</p> <p>18 excipients, so may be an integral part of a 08:54:59</p> <p>19 large number of formulations. It is unlikely 08:55:04</p> <p>20 you would be called upon to advise only on 08:55:08</p> <p>21 that particular ingredient. 08:55:11</p> <p>22 Q. Aside from your work in this case, have you 08:55:13</p>

Page 54		Page 56			
1	ever consulted for any party regarding EDTA in	08:55:15	1	funded by industry. So I have -- I could go on. I	08:57:45
2	particular or any salt or anion of EDTA?	08:55:19	2	have a lot more connections with industry.	08:57:49
3	MR. MARGOLIS: Objection. Vague.	08:55:26	3	Q. When was the last time you actually worked at	08:57:51
4	THE WITNESS: EDTA is a common excipient	08:55:32	4	a pharmaceutical company?	08:57:53
5	in lots of formulations. I have consulted a	08:55:34	5	A. About -- I was working as a consultant about	08:58:01
6	lot on formulations for companies. So it's	08:55:38	6	a year ago in the company.	08:58:11
7	highly likely EDTA has been a component of	08:55:42	7	Q. Have you ever been hired for a permanent	08:58:14
8	those.	08:55:46	8	position at a pharmaceutical company?	08:58:17
9	Q. Have you ever consulted on the chemistry of	08:55:46	9	A. I have been offered lots of jobs.	08:58:19
10	EDTA?	08:55:49	10	Q. Were you ever hired for one?	08:58:21
11	MR. MARGOLIS: Objection. Vague.	08:55:52	11	A. I never accepted them.	08:58:23
12	THE WITNESS: Again, I think it would be	08:55:57	12	Q. When was the last time you were offered a	08:58:24
13	unlikely anybody would be asked to consult	08:56:01	13	permanent position at a pharmaceutical company?	08:58:26
14	only on the chemistry of EDTA. That might be	08:56:05	14	A. Okay. Gosh. I can't remember now. I have	08:58:29
15	part of a formulation package.	08:56:08	15	to think on that one. I'm sorry. Let me just look.	08:58:50
16	Q. Have you ever consulted for the FDA?	08:56:11	16	I believe it was just prior to me taking up	08:59:14
17	A. No.	08:56:13	17	the role as Chief Scientist, Royal Pharmaceutical	08:59:17
18	Q. Take a look at your curriculum vitae, please.	08:56:14	18	Society. I haven't been offered a job since then.	08:59:22
19	A. I have consulted for the EMA though.	08:56:19	19	Q. What year was that?	08:59:26
20	Q. I'd like to direct your attention to page one	08:56:23	20	A. 2007.	08:59:28
21	under Previous Appointments.	08:56:27	21	Q. Have you ever worked in a full-time position	08:59:30
22	A. Yes.	08:56:33	22	at a pharmaceutical company?	08:59:35
Page 55		Page 57			
1	Q. And toward the bottom of that entry it says,	08:56:34	1	A. Explain full-time.	08:59:38
2	"6 months (total) sabbatical leave."	08:56:38	2	Q. Well, you currently work in a full-time	08:59:51
3	Do you see that?	08:56:40	3	position at King's College, correct?	08:59:54
4	A. Yes.	08:56:41	4	A. Okay. No. They've always been fixed	08:59:56
5	Q. Did you take six months of sabbatical leave	08:56:41	5	contracts.	08:59:58
6	from academia in 1993 to work in the Inhalation	08:56:44	6	Q. Have you ever founded or co-founded a	09:00:00
7	Research Group at Glaxo?	08:56:48	7	pharmaceutical services company?	09:00:02
8	A. Yes.	08:56:51	8	A. No.	09:00:04
9	Q. Aside from your six months of sabbatical	08:56:51	9	Q. Have you ever formulated an ophthalmic	09:00:05
10	leave from academia in 1993, have you ever worked at	08:56:53	10	product at a pharmaceutical company?	09:00:09
11	a pharmaceutical company?	08:56:57	11	MR. MARGOLIS: Objection. Vague.	09:00:11
12	A. Yes.	08:56:58	12	THE WITNESS: That is vague. I have --	09:00:14
13	Q. When was that?	08:56:58	13	again, please define product.	09:00:23
14	A. I've worked -- well, while a student, in my	08:57:01	14	Q. Well, let me ask it this way. Were you ever	09:00:24
15	summer vacations I've worked with Richardson and	08:57:06	15	responsible for formulating any ophthalmic product	09:00:27
16	Vicks. I spent six months working as a	08:57:10	16	at a pharmaceutical company?	09:00:30
17	pre-registration pharmacist in Richardson and Vicks,	08:57:15	17	MR. MARGOLIS: Objection. Vague.	09:00:32
18	which is under my Previous Appointments, and I have	08:57:18	18	THE WITNESS: We worked on, when I was	09:00:35
19	spent time in industry consulting with industrial	08:57:22	19	in GSK on my sabbatical, we also looked at	09:00:38
20	colleagues, running joint projects in my research	08:57:32	20	using the same platform for ophthalmic	09:00:44
21	laboratory, Ph.D. projects, post-doctoral projects.	08:57:36	21	preparations.	09:00:47
22	I have several students in my laboratory currently	08:57:42	22	Q. Have you ever formulated a marketed	09:00:47



Page 58		Page 60	
1	ophthalmic product -- 09:00:49	1	A. Yes. 09:02:55
2	A. No. 09:00:49	2	Q. Which grant did you receive for that? 09:02:56
3	Q. -- at a pharmaceutical company? 09:00:50	3	A. In the last ten years? Okay. So, the 09:02:58
4	A. No. 09:00:51	4	question was a non-ionic surfactant in a -- 09:03:04
5	Q. Take a look, if you would, at pages 9 through 09:00:52	5	Q. Pharmaceutical formulation? 09:03:08
6	10 of your CV. Let me direct your attention to the 09:00:57	6	A. -- pharmaceutical formulation? 09:03:09
7	section entitled Research Grants. 09:01:01	7	Q. Correct. 09:03:11
8	Do pages 9 through 10 of your curriculum 09:01:07	8	A. Okay. The novel microemulsion formulations. 09:03:12
9	vitae describe your research grants? 09:01:10	9	Q. That's the one for 17,000 pounds? 09:03:31
10	A. Not all of them, no. A selection. 09:01:11	10	A. Yes. The novel colloidal formulations, 09:03:34
11	Q. Okay. Which ones are not described here? 09:01:14	11	that's actually for more money, but we only get 09:03:38
12	A. Well, if you read the text, I have nothing 09:01:20	12	credited with the GSK side of the money. That's for 09:03:42
13	listed before, that started before 2005. And there 09:01:24	13	100,000. And there's been some other contracts and 09:03:45
14	will be some that are not listed if they are 09:01:30	14	there's been other projects. If you go to my -- let 09:03:49
15	confidential contracts as well. 09:01:32	15	me just find it -- current research students. 09:03:56
16	Q. Over the past ten years, what has been the 09:01:33	16	Q. What page is that? 09:04:03
17	focus of your scientific research? 09:01:36	17	A. Sorry. Page 11. 09:04:04
18	MR. MARGOLIS: Objection. Vague. 09:01:39	18	Q. Okay. 09:04:04
19	Q. You may answer. 09:01:41	19	A. And 12. 09:04:07
20	A. My focus of my scientific research has been 09:01:49	20	Q. Um-mm. 09:04:07
21	preparation of gene and drug delivery systems 09:01:53	21	A. And if you look at that one, two, three, four 09:04:08
22	intended for parenteral use in the correct way 09:01:58	22	of those students that are not on those grants you 09:04:13
Page 59		Page 61	
1	formulations. That's the focus. 09:02:02	1	just mentioned are using novel or using surfactants 09:04:17
2	Q. Has your scientific research focused on 09:02:04	2	for formulations. 09:04:21
3	studying various systems or formulating drugs for 09:02:07	3	Q. Have you ever received a research grant for 09:04:23
4	administration? 09:02:10	4	the use of tyloxapol in a pharmaceutical 09:04:25
5	MR. MARGOLIS: Objection. Vague. 09:02:15	5	formulation? 09:04:28
6	THE WITNESS: Repeat the question? 09:02:19	6	MR. MARGOLIS: Objection. Vague. 09:04:30
7	Q. Sure. Has your scientific research focused 09:02:20	7	THE WITNESS: Tyloxapol -- you receive 09:04:33
8	on the studying of various systems or formulating 09:02:22	8	grants for looking at non-ionic surfactants, 09:04:39
9	drugs for administration? 09:02:27	9	of which tyloxapol is a standard non-ionic 09:04:43
10	MR. MARGOLIS: Objection. 09:02:29	10	surfactant to use under these circumstances. 09:04:46
11	THE WITNESS: They are all part in the 09:02:30	11	Q. Have you ever received a research grant 09:04:48
12	same thing. 09:02:32	12	specifically to use tyloxapol in a pharmaceutical 09:04:50
13	Q. Well, which does your research focus more? 09:02:32	13	formulation? 09:04:54
14	A. No. No. No. No. That's part of the same 09:02:35	14	A. You would not get a grant in the UK to use 09:04:54
15	story. 09:02:37	15	tyloxapol because that's not how the grant system 09:04:57
16	Q. How so? 09:02:37	16	works in the UK. But have I used tyloxapol in my 09:05:00
17	A. Because if you're looking at systems, you 09:02:38	17	research? Yes, extensively. 09:05:04
18	obviously might want to know if they're appropriate 09:02:41	18	Q. Have you ever received a research grant for 09:05:06
19	for drugs. So they go together hand-in-hand. 09:02:43	19	the use of EDTA in a pharmaceutical formulation? 09:05:08
20	Q. In the past ten years, have you received a 09:02:47	20	A. The same comment would stand, you don't get 09:05:13
21	research grant for the use of a non-ionic surfactant 09:02:50	21	grants in the UK for that type of thing. I have 09:05:21
22	in a pharmaceutical formulation? 09:02:54	22	used EDTA in a product. So to say no is 09:05:26

Page 62		Page 64	
1	meaningless. 09:05:31	1	A. Yes. 09:08:20
2	Q. Have you ever received a research grant for 09:05:32	2	Q. Have you published a book chapter since 2002 09:08:21
3	formulating a stable aqueous liquid preparation? 09:05:34	3	dealing with non-ionic surfactants? 09:08:25
4	MR. MARGOLIS: Objection. Vague. 09:05:39	4	MR. MARGOLIS: Objection. Vague. 09:08:28
5	THE WITNESS: Yes. 09:05:39	5	THE WITNESS: It is vague, but 17 09:08:31
6	Q. What research grant did you receive for 09:05:40	6	includes non-ionic surfactants. 09:08:34
7	formulating a stable aqueous liquid preparation? 09:05:42	7	Q. Have you published a book chapter since 2008 09:08:36
8	A. Okay. For example, the novel microemulsion 09:05:51	8	dealing with non-ionic surfactants? 09:08:40
9	formulations. 09:05:58	9	A. I would have to check my records. 09:08:43
10	Q. That is on page 10 of your CV? 09:05:59	10	Q. Have you ever published a book chapter 09:08:45
11	A. That's on page 10 of the CV. And I've had a 09:06:02	11	dealing with the use of tyloxapol in a 09:08:48
12	large number of grants from Pharma, sometimes 09:06:05	12	pharmaceutical formulation? 09:08:50
13	confidential, sometimes not, looking at formulating 09:06:13	13	MR. MARGOLIS: Objection. Vague. 09:08:52
14	aqueous surfactant solutions. I think it is, 09:06:18	14	THE WITNESS: I would have to go and 09:08:59
15	without doubt, I'm acknowledged as an expert in the 09:06:23	15	check some of the references whether it was 09:09:00
16	use of surfactants for formulation in aqueous 09:06:27	16	mentioned in there. 09:09:02
17	systems. 09:06:31	17	Q. Have you ever published a book chapter 09:09:03
18	Q. Take a look, if you would, at pages 19 09:06:32	18	dealing with the use of EDTA in a pharmaceutical 09:09:06
19	through 20 of your CV. 09:06:35	19	formulation? 09:09:09
20	A. Yes. 09:06:36	20	MR. MARGOLIS: Objection. Vague. 09:09:10
21	Q. And let me direct your attention to the 09:06:39	21	THE WITNESS: I would have to look at 09:09:12
22	section entitled Chapters in Books. 09:06:46	22	the contents to see if there was any mention 09:09:19
Page 63		Page 65	
1	Do you see that? 09:06:47	1	of it. 09:09:21
2	A. I do. 09:06:48	2	Q. Have you ever published a book chapter 09:09:21
3	Q. Do pages 19 through 20 of your curriculum 09:06:48	3	dealing with formulating a stable aqueous liquid 09:09:23
4	vitae list all of your published book chapters? 09:06:51	4	preparation? 09:09:26
5	A. I would say most, not all. 09:07:01	5	MR. MARGOLIS: Objection. Vague. 09:09:27
6	Q. Which one or ones is or are missing? 09:07:06	6	THE WITNESS: It is very vague, but all 09:09:29
7	A. If I am honest, book chapters are not highly 09:07:27	7	of those chapters I believe contain work on 09:09:39
8	rated in the British academic system, so my 09:07:31	8	formulating aqueous-based, if that is the 09:09:46
9	recordkeeping of that is less good than my 09:07:34	9	word, a phrase, aqueous continuous phase 09:09:52
10	recordkeeping of academic journals. I have 09:07:36	10	systems. 09:09:56
11	certainly got something recently about neutron 09:07:40	11	Q. All 17 of your book chapters -- 09:09:57
12	scattering. 09:07:49	12	A. I -- just -- I believe set 15 does include 09:09:59
13	Q. Take a look at item 17 on page 20. That was 09:07:51	13	some -- set 5 doesn't because it's microemulsions. 09:10:02
14	published in 2008, correct? 09:07:55	14	But everything else I believe -- so, 5 is not -- is 09:10:07
15	A. Yes. 09:07:57	15	triglycerides. 9 is triglycerides. 10 is 09:10:15
16	Q. Have you published a book chapter since 2008? 09:07:57	16	surfactants. 11 is surfactants. But everything 09:10:19
17	A. I really can't remember. As I explained, 09:08:05	17	else is formulation of systems that have, at least 09:10:22
18	they're not particularly well-rated in the British 09:08:08	18	as part of the chapter, aqueous continuous phase. 09:10:27
19	academic system. You don't get credit for those. 09:08:10	19	Q. Take a look at pages 20 through 28 of your 09:10:30
20	You get credit for full academic papers. So I 09:08:12	20	curriculum vitae, the section entitled Articles in 09:10:35
21	really have not kept good records. 09:08:16	21	Academic Journals. 09:10:40
22	Q. Take a look at item number 12, if you would. 09:08:17	22	Do you see that? 09:10:42

Page 66		Page 68	
1	A. Yes. 09:10:43	1	preparation? 09:13:57
2	Q. Do pages 20 through 28 of your curriculum vitae list all of your published articles in academic journals? 09:10:46	2	MR. MARGOLIS: Objection. Vague. 09:13:59
3	09:10:48	3	THE WITNESS: I am looking at formulating for pharmaceutical use, so a goal of all the work is to try and make something that is stable. However, it may not report the whole range of stability tests that you would need for pharmaceutical formulation. 09:14:05
4	09:10:48	4	09:14:07
5	A. I believe so, yes. 09:10:49	5	09:14:11
6	Q. Take a look, if you would, at item number 73. Have you published a journal article since 2008 dealing with non-ionic surfactants? 09:10:50	6	09:14:14
7	09:10:58	7	09:14:18
8	09:11:01	8	09:14:20
9	A. Yes. 09:11:04	9	Q. Take a look, if you would, at page 28 of your curriculum vitae. 09:14:26
10	Q. Which one? 09:11:05	10	09:14:33
11	A. 108. 09:11:31	11	A. Yes. 09:14:35
12	Q. Any others? 09:11:33	12	Q. Does page 28 of your curriculum vitae list your only two patent applications? 09:14:40
13	A. I'm just looking. 102 is the -- it's a strange one. That's -- that's almost a citation classic that one. 93, 89, 84, 83, 82 has got something in it, I believe. I would have to check, but I believe it has. And the vast majority of the other ones are either cationic surfactants or lipids which are lipid molecules which behave in an analogous way to lot of non-ionic surfactants. 09:11:35	13	09:14:42
14	09:11:43	14	A. It does. 09:14:44
15	09:11:48	15	Q. Did either of your two patent applications issue as a patent? 09:14:45
16	09:12:23	16	09:14:47
17	09:12:25	17	A. The second one, no. The first one was taken over by a pharmaceutical company because they funded the work and I don't know. 09:14:49
18	09:12:30	18	09:14:54
19	09:12:35	19	09:14:57
20	09:12:39	20	Q. Do either of your two patent applications deal with non-ionic surfactants -- 09:14:59
21	09:12:42	21	09:15:03
22	09:12:45	22	A. Both do. 09:15:05
Page 67		Page 69	
1	is your last publication dealing with non-ionic surfactants? 09:12:48	1	Q. Okay. Have you ever filed a patent application dealing with the use of tyloxapol in a pharmaceutical formulation? 09:15:06
2	09:12:51	2	09:15:07
3	MR. MARGOLIS: Objection. Vague. 09:12:59	3	09:15:10
4	THE WITNESS: No. There are others. 117 deals with non-ionic surfactants. And they are all -- all the papers are related to each other. They all deal with lipids -- all deal with amphiphilic molecules or polymers. 09:13:01	4	A. No. 09:15:14
5	09:13:10	5	Q. Have you ever filed a patent application dealing with the use of EDTA in a pharmaceutical formulation? 09:15:15
6	09:13:14	6	09:15:17
7	09:13:17	7	09:15:20
8	09:13:20	8	A. No. 09:15:21
9	Q. Have you ever published a journal article dealing with the use of tyloxapol in a pharmaceutical formulation? 09:13:23	9	Q. Have you ever filed a patent application dealing with formulating a stable aqueous liquid preparation? 09:15:22
10	09:13:26	10	09:15:24
11	09:13:28	11	09:15:28
12	A. No, because that's normally been confidential information for the company. 09:13:29	12	A. Interestingly, no. The second patent application was to make those particles unstable. 09:15:35
13	09:13:31	13	09:15:38
14	Q. Have you ever published a journal article dealing with the use of EDTA in a pharmaceutical formulation? 09:13:33	14	Q. I understand. 09:15:42
15	09:13:38	15	Take a look, if you would, back to your declaration. Let me direct your attention to page 2, paragraph 4. It says, "I have not testified in any case in the previous four years." 09:15:45
16	09:13:41	16	09:15:48
17	MR. MARGOLIS: Objection. Vague. 09:13:45	17	09:15:59
18	THE WITNESS: I would have to look at the references, but EDTA will be in some of those papers definitely. 09:13:47	18	09:16:07
19	09:13:48	19	Do you see that? 09:16:09
20	09:13:51	20	A. Yes. 09:16:10
21	Q. Have you ever published a journal article dealing with formulating a stable aqueous liquid 09:13:52	21	Q. When was the case in which you testified in the UK? 09:16:11
22	09:13:54	22	09:16:15

Page 70	<p>1 A. That went to court 2006 and 2009. 09:16:17</p> <p>2 Q. Have you testified as an expert in any case 09:16:22</p> <p>3 since 2009? 09:16:26</p> <p>4 A. I've been consulted as an expert, but none 09:16:29</p> <p>5 have gone to court. 09:16:32</p> <p>6 Q. Have you ever been qualified by a court as an 09:16:33</p> <p>7 expert in any previous patent infringement case? 09:16:36</p> <p>8 A. I don't understand the question. 09:16:40</p> <p>9 Q. What don't you understand about it? 09:16:42</p> <p>10 A. I don't know how you get qualified as an 09:16:45</p> <p>11 expert. 09:16:49</p> <p>12 Q. So, do you understand that a court qualifies 09:16:50</p> <p>13 a particular -- 09:16:53</p> <p>14 A. I have been an expert in a court case, yes. 09:16:53</p> <p>15 Q. In -- 09:16:57</p> <p>16 A. As the main expert in those two -- in two 09:16:57</p> <p>17 court cases. 09:16:59</p> <p>18 Q. Okay. In two court cases. 09:17:00</p> <p>19 A. Novartis against Dexel, and Novartis against 09:17:02</p> <p>20 Ivax. 09:17:11</p> <p>21 Q. In those cases, in what field did the court 09:17:14</p> <p>22 qualify you as an expert? 09:17:19</p>
Page 71	<p>1 MR. MARGOLIS: Objection. Vague. 09:17:24</p> <p>2 THE WITNESS: I was the main expert in 09:17:27</p> <p>3 the case that was concerned with a novel 09:17:33</p> <p>4 non-ionic surfactant-based microemulsion 09:17:38</p> <p>5 formulation. 09:17:41</p> <p>6 Q. And what were your opinions, generally 09:17:42</p> <p>7 speaking, in that case? 09:17:43</p> <p>8 MR. MARGOLIS: Objection. Vague. 09:17:49</p> <p>9 THE WITNESS: What do you mean opinions? 09:17:50</p> <p>10 Q. Well, what opinions did you provide in that 09:17:52</p> <p>11 case to the court? 09:17:54</p> <p>12 MR. MARGOLIS: Objection. Vague. 09:17:56</p> <p>13 THE WITNESS: I was the main expert 09:17:58</p> <p>14 talking about -- it was a patent formulation, 09:18:01</p> <p>15 a formulation -- yes, a patent -- a 09:18:06</p> <p>16 formulation patent, and I was the sole expert 09:18:09</p> <p>17 in the first case to defend -- well, it's an 09:18:14</p> <p>18 infringement case, and the defendees came 09:18:18</p> <p>19 back and tried to invalidate the patent. So 09:18:24</p> <p>20 I was the expert for that. So, I dealt with 09:18:27</p> <p>21 the whole of the -- the opinions on the whole 09:18:30</p> <p>22 of the patent. 09:18:34</p>
Page 72	<p>1 Q. Did you provide opinions that the patent 09:18:34</p> <p>2 should or should not be invalidated? 09:18:36</p> <p>3 A. I said it shouldn't be invalidated. 09:18:39</p> <p>4 Q. Should not? Why was it your opinion that the 09:18:42</p> <p>5 patent in that case should not be invalidated? 09:18:44</p> <p>6 MR. MARGOLIS: Objection. Vague. 09:18:47</p> <p>7 THE WITNESS: It was a very novel, very 09:18:50</p> <p>8 effective formulation. 09:18:54</p> <p>9 Q. Was it a formulation containing a non-ionic 09:18:56</p> <p>10 surfactant? 09:19:00</p> <p>11 A. It was microemulsion formulation containing a 09:19:00</p> <p>12 non-ionic surfactant. 09:19:04</p> <p>13 Q. What was the active pharmaceutical ingredient 09:19:06</p> <p>14 in the formulation? 09:19:08</p> <p>15 A. Cyclosporin. 09:19:08</p> <p>16 Q. What other excipients were in the 09:19:10</p> <p>17 formulation? 09:19:12</p> <p>18 A. I would have to consult my notes. Sorry. 09:19:13</p> <p>19 Q. What non-ionic surfactant was in the 09:19:15</p> <p>20 formulation? 09:19:20</p> <p>21 A. I'd have to consult my notes. 09:19:20</p> <p>22 Q. Why was it your opinion in that case that the 09:19:22</p>
Page 73	<p>1 patent at issue was valid? 09:19:30</p> <p>2 MR. MARGOLIS: Objection. Vague. 09:19:33</p> <p>3 THE WITNESS: I was consulted as an 09:19:36</p> <p>4 expert in preparing microemulsions for 09:19:39</p> <p>5 pharmaceutical use, and the patent was 09:19:45</p> <p>6 concerned with a microemulsion formulation. 09:19:51</p> <p>7 So I was very expert in the area -- I was 09:19:58</p> <p>8 able to make a judgment, and the patent was 09:20:01</p> <p>9 upheld. 09:20:04</p> <p>10 Q. Why was it your opinion in that case that the 09:20:05</p> <p>11 patent dealing with a pharmaceutical formulation 09:20:08</p> <p>12 containing a non-ionic surfactant was valid? 09:20:13</p> <p>13 A. It was the first time anybody had prepared a 09:20:18</p> <p>14 microemulsion formulation to deliver a drug and it 09:20:25</p> <p>15 showed distinct improvements over the existing 09:20:31</p> <p>16 formulation. 09:20:39</p> <p>17 Q. What type of distinct improvements? 09:20:40</p> <p>18 A. Reproducibility of dose and total 09:20:45</p> <p>19 bioavailability, ease of use for the patients. 09:20:51</p> <p>20 Q. Anything else? 09:20:57</p> <p>21 A. Probably, but I can't remember. 09:20:58</p> <p>22 Q. Take a look, if you would, at paragraph 6 of 09:21:04</p>

Page 74		Page 76	
1	your declaration.	09:21:08	
2	A. Yes.	09:21:10	
3	Q. And in the second sentence you use the phrase	09:21:10	
4	"physic-chemical characterization" -- sorry. Are	09:21:15	
5	you there?	09:21:19	
6	A. Yes.	09:21:19	
7	Q. Okay. You use the phrase "physic-chemical	09:21:19	
8	characterization of novel, non-ionic surfactants."	09:21:24	
9	Do you see that?	09:21:26	
10	A. Yes.	09:21:26	
11	Q. What do you mean by "physic-chemical	09:21:27	
12	characterization"?	09:21:29	
13	A. Well, there should be an O after the C, but	09:21:30	
14	using standard physicochemical techniques, light	09:21:34	
15	scattering, viscosity, surface tension, behavior,	09:21:38	
16	characterization of the surfactants. Yep.	09:21:44	
17	Q. And you use the term novel non-ionic	09:21:51	
18	surfactants.	09:21:55	
19	Do you see that?	09:21:56	
20	A. Yes. I synthesis them.	09:21:56	
21	Q. What is a novel non-ionic surfactant?	09:21:58	
22	A. I designed and synthesized the surfactant.	09:22:00	
Page 75		Page 77	
1	Q. How many different non-ionic surfactants are	09:22:03	
2	known to exist?	09:22:06	
3	A. Sorry. As many as you want in your brain.	09:22:09	
4	Q. You used the term "physic" and you meant to	09:22:15	
5	say physicochemical --	09:22:21	
6	A. Yes.	09:22:21	
7	Q. -- characterization, correct?	09:22:21	
8	A. Yes.	09:22:22	
9	Q. What are some of the different physical and	09:22:23	
10	chemical properties that different non-ionic	09:22:25	
11	surfactants possess?	09:22:27	
12	A. It would depend in what state you were	09:22:31	
13	looking at them, whether you were looking at, the	09:22:37	
14	surfactant on its own, the surfactant with oil and	09:22:41	
15	water, et cetera.	09:22:45	
16	Q. Let me -- let me rephrase the question then.	09:22:46	
17	What are some of the different physical and chemical	09:22:53	
18	properties that different non-ionic surfactants	09:22:55	
19	possess in aqueous liquid preparations?	09:22:59	
20	MR. MARGOLIS: Objection. Vague.	09:23:05	
21	THE WITNESS: That would depend upon the	09:23:07	
22	structure of the surfactant you were looking	09:23:09	
1	at.	09:23:12	
2	Q. How would it depend on the structure of the	09:23:12	
3	surfactant?	09:23:15	
4	A. It would depend upon what the hydrophobic	09:23:22	
5	moiety was. It would depend upon what the head	09:23:30	
6	group was, for example.	09:23:35	
7	Q. Anything else?	09:23:37	
8	A. The way in which, the concentration in which	09:23:42	
9	it was present and its state of dispersal.	09:23:46	
10	Q. Anything else?	09:23:51	
11	A. pH, temperature, presence of excipients,	09:23:55	
12	other excipients, presence of salts.	09:24:05	
13	Q. Anything else?	09:24:10	
14	A. I can't think of all the ones I've	09:24:15	
15	listed already. Presence of -- if you're using as a	09:24:17	
16	formulation, presence of drug.	09:24:22	
17	Q. Anything else?	09:24:27	
18	A. I think I might have listed excipients, pH,	09:24:35	
19	temperature, electrolytes, drug, concentration --	09:24:39	
20	they're the main ones.	09:24:48	
21	Q. Why do different non-ionic surfactants have	09:24:49	
22	different chemical and physical properties?	09:24:53	
1	MR. MARGOLIS: Objection. Vague.	09:24:56	
2	Compound. Lack of foundation.	09:24:59	
3	Q. You may answer.	09:25:02	
4	A. Because the structure of the surfactants can	09:25:06	
5	vary, so the balance between the hydrophobic and the	09:25:14	
6	hydrophilic can vary.	09:25:20	
7	Q. Can the physical and chemical properties of a	09:25:20	
8	non-ionic surfactant be predicted from the physical	09:25:22	
9	and chemical properties of a different non-ionic	09:25:26	
10	surfactant with a different chemical structure?	09:25:30	
11	MR. MARGOLIS: Objection. Vague.	09:25:33	
12	THE WITNESS: That's very vague. The	09:25:34	
13	best answer I can give you is in a	09:25:37	
14	structurally related series or a closely	09:25:41	
15	related series of molecules. You can have a	09:25:44	
16	good estimate, yes.	09:25:52	
17	Q. Have you ever accurately predicted the	09:25:54	
18	physical and chemical properties of a non-ionic	09:25:57	
19	surfactant based on the physical and chemical	09:25:59	
20	properties of a different non-ionic surfactant with	09:26:02	
21	a different chemical structure?	09:26:05	
22	MR. MARGOLIS: Objection. Vague.	09:26:07	

Page 78	Page 80
<p>1 THE WITNESS: That's vague. I'm unclear 09:26:09</p> <p>2 when you say accurately what you mean, what 09:26:23</p> <p>3 level of accuracy you're talking about? 09:26:28</p> <p>4 Q. Have you ever with any level of accuracy 09:26:32</p> <p>5 predicted the physical and chemical properties of a 09:26:34</p> <p>6 non-ionic surfactant based on the physical and 09:26:37</p> <p>7 chemical properties of a different non-ionic 09:26:40</p> <p>8 surfactant with a different chemical structure? 09:26:43</p> <p>9 MR. MARGOLIS: Objection. Vague. 09:26:47</p> <p>10 Compound. 09:26:48</p> <p>11 THE WITNESS: A different 09:26:48</p> <p>12 chemical structure. I explained that if 09:26:51</p> <p>13 there is, for example, a relationship between 09:26:53</p> <p>14 the head group used and -- yes, you can 09:26:59</p> <p>15 predict with reasonable accuracy. 09:27:04</p> <p>16 Q. Have you ever done that? 09:27:07</p> <p>17 A. Yes. 09:27:09</p> <p>18 Q. Did you publish your findings? 09:27:09</p> <p>19 A. I don't know. I would have to -- sorry. I 09:27:13</p> <p>20 would have to look. I don't know. 09:27:16</p> <p>21 No. I have got students in laboratory doing 09:27:58</p> <p>22 that at the moment. 09:28:00</p>	<p>1 expect the same amount of two different non-ionic 09:29:13</p> <p>2 surfactants having different chemical structures to 09:29:18</p> <p>3 have the same stabilizing effect or different 09:29:21</p> <p>4 stabilizing effects in an aqueous liquid preparation 09:29:24</p> <p>5 of a nonsteroidal anti-inflammatory drug? 09:29:27</p> <p>6 MR. MARGOLIS: Objection. Vague. 09:29:31</p> <p>7 THE WITNESS: You couldn't -- I couldn't 09:29:32</p> <p>8 answer that on the vagueness of the question. 09:29:34</p> <p>9 You would have to do tests under those 09:29:38</p> <p>10 circumstances. 09:29:41</p> <p>11 Q. Take a look, if you would, at page 3 of your 09:29:42</p> <p>12 declaration. 09:29:47</p> <p>13 MR. HASFORD: Oh, you know what? That 09:29:49</p> <p>14 might actually be a good time for a break 09:29:50</p> <p>15 because we need to do a tape change. 09:29:53</p> <p>16 THE VIDEOGRAPHER: The time is 09:29:57</p> <p>17 approximately 9:31 a.m., Friday, September 4, 09:29:59</p> <p>18 2015. This is the end of tape number one of 09:30:09</p> <p>19 the videotaped deposition of Dr. Jayne 09:30:12</p> <p>20 Lawrence. We are off the record. 09:30:15</p> <p>21 (Recess from 9:31 to 9:46.) 09:30:18</p> <p>22 THE VIDEOGRAPHER: The time is 09:45:18</p>
Page 79	Page 81
<p>1 Q. Is it fair to say that the physical and 09:28:01</p> <p>2 chemical properties of a non-ionic surfactant cannot 09:28:05</p> <p>3 be predicted from the physical and chemical 09:28:08</p> <p>4 properties of a different non-ionic surfactant with 09:28:10</p> <p>5 a different chemical structure? 09:28:13</p> <p>6 MR. MARGOLIS: Objection. Vague. 09:28:16</p> <p>7 Compound. 09:28:18</p> <p>8 THE WITNESS: Yes. It depends how 09:28:18</p> <p>9 different they were. 09:28:21</p> <p>10 Q. How does it depend how different they are? 09:28:22</p> <p>11 A. Again, that's very vague. There is quite a 09:28:26</p> <p>12 lot of understanding available, for example, in the 09:28:30</p> <p>13 literature about the relationship between the 09:28:33</p> <p>14 hydrophobic chain and the relationship if it -- the 09:28:38</p> <p>15 non-ionic, if it's a -- yeah, if it's a -- if it's a 09:28:44</p> <p>16 straight chain, or a single chain I should say, 09:28:49</p> <p>17 hydrophobic group -- actually, there's quite a lot 09:28:53</p> <p>18 of information about the effect of the head group. 09:28:59</p> <p>19 and the head group often dominates. So it would 09:29:02</p> <p>20 really depend on the structure how differently in 09:29:07</p> <p>21 order to be able to say that. 09:29:09</p> <p>22 Q. Would a person of ordinary skill in the art 09:29:11</p>	<p>1 approximately 9:46 a.m., Friday, September 4, 09:45:33</p> <p>2 2015. This is tape number two of the 09:45:45</p> <p>3 videotaped deposition of Dr. Jayne Lawrence. 09:45:48</p> <p>4 We are back on the record. 09:45:50</p> <p>5 BY MR. HASFORD: 09:45:52</p> <p>6 Q. Doctor, could you please turn to page 3, 09:45:52</p> <p>7 paragraph 10 of your declaration, and take a look at 09:45:55</p> <p>8 the second sentence, if you would. 09:46:00</p> <p>9 And do you see where it says, "Novel, 09:46:05</p> <p>10 non-ionic and zwitterionic surfactants"? 09:46:09</p> <p>11 A. Oh, yes. 09:46:11</p> <p>12 Q. What novel non-ionic surfactants have you 09:46:13</p> <p>13 synthesized and characterized? 09:46:17</p> <p>14 A. Quite a few. Some of them -- do you want me 09:46:27</p> <p>15 to describe them or -- 09:46:32</p> <p>16 Q. Sure. Please. 09:46:33</p> <p>17 A. Some of them have different head groups, not 09:46:35</p> <p>18 having polyethylene oxide head groups that have 09:46:39</p> <p>19 alternative polymers. Some have been used for 09:46:44</p> <p>20 production of vesicles. They've got two chains. 09:46:49</p> <p>21 Some have been used to solubilize drug in micelles. 09:47:00</p> <p>22 Q. How have you characterized the physical and 09:47:07</p>

Page 82	<p>1 chemical properties of the new non-ionic surfactants 09:47:09</p> <p>2 that you've synthesized? 09:47:13</p> <p>3 MR. MARGOLIS: Objection. Vague. Lacks 09:47:16</p> <p>4 foundation. 09:47:21</p> <p>5 THE WITNESS: Well, the first -- the 09:47:25</p> <p>6 first thing to say is how you characterize 09:47:29</p> <p>7 them is partially dependent upon what they 09:47:32</p> <p>8 are going to be used for. So that would 09:47:36</p> <p>9 vary. Micelle-forming surfactants we'd 09:47:42</p> <p>10 characterize analytically the surfactants, 09:47:46</p> <p>11 checking it's the structure we think it is. 09:47:50</p> <p>12 We would then typically put it through a 09:47:54</p> <p>13 whole battery of studies, looking at surface 09:47:58</p> <p>14 tension, viscosity, aggregation using light 09:48:04</p> <p>15 and neutron scattering, solubilization 09:48:10</p> <p>16 capacity, and then further studies depending 09:48:15</p> <p>17 on how they're going to -- how you're going 09:48:18</p> <p>18 to use them. 09:48:22</p> <p>19 Q. How do the physical and chemical properties 09:48:24</p> <p>20 of the new non-ionic surfactants you have 09:48:27</p> <p>21 synthesized differ from the physical and chemical 09:48:31</p> <p>22 properties of other non-ionic surfactants in the 09:48:34</p>	Page 84	<p>1 depends in what way you mean complex. 09:49:56</p> <p>2 Q. How do you view it? 09:49:59</p> <p>3 MR. MARGOLIS: Objection. Vague. 09:50:04</p> <p>4 THE WITNESS: We have been concerned 09:50:08</p> <p>5 with trying to design surfactants with 09:50:10</p> <p>6 improved properties for particular uses. 09:50:13</p> <p>7 It's not that complicated because we 09:50:20</p> <p>8 rationally design them. So, by understanding 09:50:22</p> <p>9 rules, we've managed to design them. 09:50:26</p> <p>10 Q. Why would a person of ordinary skill in the 09:50:29</p> <p>11 art want to synthesize a new non-ionic surfactant? 09:50:32</p> <p>12 A. It didn't say that they would. 09:50:37</p> <p>13 MR. MARGOLIS: Objection. Calls for 09:50:37</p> <p>14 speculation. 09:50:39</p> <p>15 THE COURT REPORTER: I didn't get your 09:50:39</p> <p>16 answer. 09:50:39</p> <p>17 THE WITNESS: No, I don't -- I don't -- 09:50:43</p> <p>18 I'm unsure why somebody ordinary skilled in 09:50:50</p> <p>19 the art would necessarily want to do what I 09:50:56</p> <p>20 have been doing, designing new surfactants. 09:51:00</p> <p>21 Q. Well, let me ask it this way. Under what 09:51:03</p> <p>22 circumstances would a person of ordinary skill in 09:51:05</p>
Page 83	<p>1 art? 09:48:39</p> <p>2 MR. MARGOLIS: Objection. Vague. Lack 09:48:39</p> <p>3 of foundation. 09:48:42</p> <p>4 THE WITNESS: It's quite a complicated 09:48:44</p> <p>5 story, if you want me to tell you the story? 09:48:46</p> <p>6 Q. Please do. 09:48:48</p> <p>7 A. One way to improve drug solubilization would 09:48:51</p> <p>8 be to make larger micelles. In brief, the 09:49:01</p> <p>9 non-ionic -- the PEG head group is not good at 09:49:09</p> <p>10 making huge -- I'm talking about very large micelles 09:49:14</p> <p>11 here. These are not things that are commercially 09:49:18</p> <p>12 available. And that's because PEG mixes with a 09:49:21</p> <p>13 hydrocarbon chain and destroys the capacity of 09:49:25</p> <p>14 micelle to solubilize the drug. We use a different 09:49:29</p> <p>15 polymer to overcome that property. So we have 09:49:33</p> <p>16 rationally designed. I could go on and give you 09:49:35</p> <p>17 other examples, but it's a rationale design of the 09:49:38</p> <p>18 surfactant for a particular purpose. 09:49:41</p> <p>19 Q. Is it fair to say that this is a complex 09:49:43</p> <p>20 field? 09:49:45</p> <p>21 MR. MARGOLIS: Objection. Vague. 09:49:46</p> <p>22 THE WITNESS: It depends how -- it 09:49:51</p>	Page 85	<p>1 the art want to synthesize a new non-ionic 09:51:07</p> <p>2 surfactant? 09:51:11</p> <p>3 A. Again -- 09:51:21</p> <p>4 MR. MARGOLIS: Objection. Lack of 09:51:21</p> <p>5 foundation. 09:51:22</p> <p>6 THE WITNESS: That's vague. A vague 09:51:22</p> <p>7 answer would be if there isn't a surfactant 09:51:26</p> <p>8 available to do what they want. 09:51:29</p> <p>9 Q. Why would a person of ordinary skill in the 09:51:31</p> <p>10 art want to characterize the physical and chemical 09:51:34</p> <p>11 properties of a new non-ionic surfactant that he or 09:51:37</p> <p>12 she has synthesized? 09:51:41</p> <p>13 MR. MARGOLIS: Objection. Lack of 09:51:43</p> <p>14 foundation. Vague. 09:51:45</p> <p>15 THE WITNESS: Anybody receiving a novel 09:51:56</p> <p>16 excipient for use in formulation would want 09:51:58</p> <p>17 to understand the properties. So they would 09:52:02</p> <p>18 do some basic characterization that was 09:52:06</p> <p>19 appropriate for their use. 09:52:08</p> <p>20 Q. What characterization would they do? 09:52:11</p> <p>21 A. Again, that would be dependent on how they 09:52:14</p> <p>22 wanted to use the surfactant. 09:52:17</p>

Page 86	<p>1 Q. What if they wanted to use it in a stable 09:52:21                  2 aqueous liquid preparation, what characterization 09:52:24                  3 would they do? 09:52:26                  4 MR. MARGOLIS: Objection. Vague. 09:52:28                  5 THE WITNESS: There's a plethora of 09:52:29                  6 stable -- of surfactants in water. So it 09:52:32                  7 would depend upon the aggregation state, the 09:52:38                  8 formulation state. 09:52:42                  9 Q. What else would it depend on? 09:52:44                  10 A. The tests the person would do with any 09:52:49                  11 unfamiliar or novel excipients, or non-ionic 09:52:56                  12 surfactant here, would depend on their ultimate use. 09:53:00                  13 Q. How so? 09:53:07                  14 A. If you wanted to make a water continuous 09:53:09                  15 semi-solid formulation would be characterized using 09:53:22                  16 rheology, for example. If you were using it -- if 09:53:33                  17 you wanted to inject your aqueous formulation, you 09:53:42                  18 would want it to be low viscosity. You would use 09:53:46                  19 viscometric techniques. So, it's impossible to say 09:53:50                  20 unless you are much more specific. 09:53:54                  21 Q. What if a person of ordinary skill in the art 09:53:57                  22 wanted to formulate a stable aqueous liquid 09:54:00</p>	Page 88	<p>1 MR. MARGOLIS: Objection. Vague. 09:55:25                  2 THE WITNESS: There's a lot of 09:55:29                  3 conditions you would have to put on to that 09:55:31                  4 statement. So, could somebody who is 09:55:34                  5 ordinary skilled in the art with the same 09:55:44                  6 formulation but just different amounts of 09:55:46                  7 surfactant be able to form a stability -- an 09:55:49                  8 assessment on stability? 09:55:53                  9 Q. A different type of surfactant. So let me 09:55:54                  10 ask it -- 09:55:56                  11 A. Yes. 09:55:56                  12 Q. -- again just to be clear. 09:55:57                  13 A. Yeah. No. In hypothetical, yes, of course. 09:55:57                  14 Q. Could a person of ordinary skill in the art 09:56:00                  15 conduct an experiment comparing the stability of two 09:56:02                  16 different aqueous liquid preparations with identical 09:56:05                  17 compositions where only the amount of surfactant was 09:56:09                  18 varied? 09:56:13                  19 MR. MARGOLIS: Objection. Vague. 09:56:15                  20 THE WITNESS: Hypothetically, yes. 09:56:19                  21 Q. Take a look, if you would, at page 4 of your 09:56:23                  22 declaration, paragraph 12. 09:56:27</p>
Page 87	<p>1 preparation for ophthalmic use, how would that 09:54:04                  2 person characterize the physical and chemical 09:54:09                  3 properties of the formulation? 09:54:11                  4 MR. MARGOLIS: Objection. Vague. Lacks 09:54:14                  5 foundation. Calls for speculation. 09:54:15                  6 THE WITNESS: It would depend upon the 09:54:21                  7 drug you're using and the drug dose, and that 09:54:24                  8 may determine the formulation type you would 09:54:28                  9 prepare. 09:54:32                  10 Q. Could a person of ordinary skill in the art 09:54:32                  11 conduct an experiment comparing the stability of two 09:54:54                  12 different aqueous liquid preparations with identical 09:54:58                  13 compositions where only the type of surfactant is 09:55:01                  14 varied? 09:55:04                  15 MR. MARGOLIS: Objection. Vague. 09:55:09                  16 THE WITNESS: Can you repeat the 09:55:10                  17 question? 09:55:11                  18 Q. Certainly. Could a person of ordinary skill 09:55:12                  19 in the art conduct an experiment comparing the 09:55:13                  20 stability of two different aqueous liquid 09:55:16                  21 preparations with identical compositions where only 09:55:19                  22 the type of surfactant is varied? 09:55:22</p>	Page 89	<p>1 A. Yes. 09:56:31                  2 Q. And in the first sentence it says, "As listed 09:56:32                  3 in my curriculum vitae, I have also received 09:56:36                  4 numerous awards pertaining to my research and 09:56:38                  5 teaching." 09:56:41                  6 Do you see that? 09:56:41                  7 A. Yes. 09:56:42                  8 Q. Do you currently teach pharmaceuticals classes 09:56:42                  9 at King's College? 09:56:45                  10 A. I teach some pharmaceuticals, yes. 09:56:46                  11 Q. Have you ever taught your students that the 09:56:48                  12 phrases EDTA sodium salt and sodium edetate are 09:56:50                  13 limited to the tetrasodium salt of EDTA? 09:56:55                  14 A. I don't recall. 09:57:02                  15 Q. Have you ever taught your students the term 09:57:03                  16 stable in the context of pharmaceutical formulations 09:57:06                  17 is indefinite? 09:57:08                  18 A. I have told them -- I have -- I lecture on 09:57:11                  19 stability, so I explain to my students what 09:57:16                  20 stability is and the need to define stability. 09:57:20                  21 Q. Have you ever actually taught your students 09:57:22                  22 the term stable in the context of pharmaceutical 09:57:25</p>



Page 90	<p>1 formulations as indefinite? 09:57:28</p> <p>2 A. No. I haven't used the word indefinite, no. 09:57:30</p> <p>3 Q. Take a look, if you would, at your 09:57:35</p> <p>4 declaration back at page 1, paragraph 2. And it 09:57:37</p> <p>5 says, "I have been asked to provide my opinion on 09:57:46</p> <p>6 the meaning of several claim terms in U.S. Patents," 09:57:48</p> <p>7 and then you list the patents-in-suit. 09:57:53</p> <p>8 Do you see that? 09:57:55</p> <p>9 A. Yes. 09:57:55</p> <p>10 Q. Let me just go through each of them, if 09:57:56</p> <p>11 that's okay with you. Did you review U.S. Patent 09:58:01</p> <p>12 No. 8,129,431 in connection with your declaration in 09:58:04</p> <p>13 this case? 09:58:08</p> <p>14 A. I did. 09:58:08</p> <p>15 Q. If I refer to U.S. Patent No. 8,129,431 as 09:58:09</p> <p>16 the '431 patent, will you understand what I mean? 09:58:13</p> <p>17 A. Yes. 09:58:16</p> <p>18 Q. Did you also review U.S. Patent No. 8,669,290 09:58:16</p> <p>19 in connection with your declaration in this case? 09:58:21</p> <p>20 A. I did. 09:58:23</p> <p>21 Q. If I refer to U.S. Patent No. 8,669,290 as 09:58:24</p> <p>22 the '290 patent. will you understand what I mean? 09:58:29</p>	Page 92	<p>1 will you understand what I mean? 09:59:36</p> <p>2 A. Yes. 09:59:37</p> <p>3 Q. Did you review the patents-in-suit in 09:59:38</p> <p>4 connection with your opinions in this case? 09:59:40</p> <p>5 A. I did. 09:59:42</p> <p>6 Q. And you state in paragraph 2 that you have 09:59:43</p> <p>7 been asked to provide your opinion on the meaning of 09:59:45</p> <p>8 several claim terms in the patents-in-suit. 09:59:48</p> <p>9 Do you see that? 09:59:50</p> <p>10 A. Yes. 09:59:51</p> <p>11 Q. Did you consider the entirety of the claims 09:59:51</p> <p>12 of the patents-in-suit or did you focus on certain 09:59:54</p> <p>13 terms? 09:59:57</p> <p>14 MR. MARGOLIS: Objection. Vague. 09:59:58</p> <p>15 THE WITNESS: I read -- when I was 10:00:06</p> <p>16 preparing this document, I read the whole 10:00:08</p> <p>17 patents very carefully -- all the patents 10:00:12</p> <p>18 very carefully, but -- 10:00:15</p> <p>19 Q. And my question -- 10:00:16</p> <p>20 A. -- I took it in whole. 10:00:16</p> <p>21 Q. Okay. My question is slightly different. 10:00:18</p> <p>22 Did you consider the entirety of the claims 10:00:20</p>
Page 91	<p>1 A. Yes. 09:58:32</p> <p>2 Q. Did you also review U.S. Patent No. 8,754,131 09:58:32</p> <p>3 in connection with your declaration in this case? 09:58:38</p> <p>4 A. I did. 09:58:40</p> <p>5 Q. If I refer to U.S. Patent No. 8,754,131 as 09:58:41</p> <p>6 the '131 patent, will you understand what I mean? 09:58:46</p> <p>7 A. Yes. 09:58:49</p> <p>8 Q. Did you also review U.S. Patent No. 8,871,813 09:58:50</p> <p>9 in connection with your declaration in this case? 09:58:55</p> <p>10 A. I did. 09:58:57</p> <p>11 Q. If I refer to U.S. Patent No. 8,871,813 as 09:58:58</p> <p>12 the '813 patent, will you understand what I mean? 09:59:03</p> <p>13 A. Yes. 09:59:07</p> <p>14 Q. And did you also review U.S. Patent No. 09:59:07</p> <p>15 8,927,606 in connection with your declaration in 09:59:09</p> <p>16 this case? 09:59:14</p> <p>17 A. I did. 09:59:15</p> <p>18 Q. If I refer to U.S. Patent No. 8,927,606 as 09:59:15</p> <p>19 the '606 patent, will you understand what I mean? 09:59:21</p> <p>20 A. Yes. 09:59:24</p> <p>21 Q. If I refer to the '431, '290, '131, '813 and 09:59:25</p> <p>22 '606 patents collectively as the patents-in-suit, 09:59:32</p>	Page 93	<p>1 of the patents-in-suit or did you focus on certain 10:00:22</p> <p>2 terms in those claims? 10:00:24</p> <p>3 MR. MARGOLIS: Objection. Asked and 10:00:27</p> <p>4 answered. 10:00:28</p> <p>5 Q. You may answer. 10:00:29</p> <p>6 A. Can you repeat the specific wording of the 10:00:33</p> <p>7 question you asked me? 10:00:36</p> <p>8 Q. Certainly. Did you consider the entirety of 10:00:37</p> <p>9 the claims of the patents-in-suit or did you focus 10:00:39</p> <p>10 on certain terms in the claims? 10:00:43</p> <p>11 A. Okay. 10:00:45</p> <p>12 MR. MARGOLIS: Objection. Vague. 10:00:47</p> <p>13 THE WITNESS: Perhaps you can explain 10:00:48</p> <p>14 what you mean by the entirety of the claims? 10:00:52</p> <p>15 Q. Do you understand what the claims of the 10:00:55</p> <p>16 patents-in-suit are? 10:00:56</p> <p>17 A. Yes. 10:00:58</p> <p>18 Q. Okay. Did you consider the entirety of the 10:00:58</p> <p>19 claims of the patents-in-suit or did you focus on 10:01:01</p> <p>20 certain terms in those claims? 10:01:04</p> <p>21 MR. MARGOLIS: Objection. Vague. 10:01:06</p> <p>22 THE WITNESS: I'm assuming entirety is 10:01:09</p>

Page 94		Page 96			
1	not a legal word in this context? No? Is	10:01:12	1	engineering in this country is more related to what	10:03:16
2	it?	10:01:16	2	I would term industrial pharmacy.	10:03:21
3	Q. I'm not using any particular legal meaning.	10:01:16	3	Is that your understanding before I answer?	10:03:25
4	A. No. So, did I --	10:01:19	4	Q. Well, so, I'm asking based on your	10:03:28
5	Q. Let me just --	10:01:22	5	understanding, but I will ask the question both ways	10:03:30
6	A. I read the whole -- I considered the whole	10:01:23	6	just to be clear.	10:03:32
7	patent, all the patents, the whole -- all the	10:01:26	7	Do the patents-in-suit relate to chemical	10:03:33
8	claims, yes.	10:01:29	8	engineering as you use the term?	10:03:35
9	Q. Okay. Did you focus on certain terms in	10:01:29	9	A. No.	10:03:36
10	those claims?	10:01:31	10	MR. MARGOLIS: Objection. Objection.	10:03:37
11	MR. MARGOLIS: Objection. Vague.	10:01:33	11	Vague.	10:03:39
12	THE WITNESS: My report focuses on	10:01:38	12	Q. Do the patents-in-suit relate to gene	10:03:39
13	several terms, but they were made in	10:01:40	13	formulation?	10:03:43
14	relationship to reading the whole entirety of	10:01:44	14	A. No.	10:03:46
15	the patent.	10:01:47	15	Q. Take a look, if you would, at page 8 of your	10:03:47
16	Q. In your opinion, would a person with a Ph.D.	10:01:48	16	declaration. Skip ahead a bit, and I want to direct	10:03:55
17	and several years of experience in pharmaceutical	10:01:53	17	your attention to footnote 2. Just read that to	10:03:58
18	sciences be considered an expert in the field of the	10:01:55	18	yourself and let me know when you're ready.	10:04:04
19	patents-in-suit?	10:01:58	19	A. Okay.	10:04:18
20	A. I believe I have defined that as somebody --	10:02:00	20	Q. Is it your understanding that the	10:04:18
21	just let me turn to the -- as somebody of ordinary	10:02:05	21	patents-in-suit all have essentially the same	10:04:20
22	skill.	10:02:09	22	specification?	10:04:22
Page 95		Page 97			
1	Q. Would you consider that person an expert in	10:02:09	1	A. They have very similar claims, yes.	10:04:28
2	the field of the patents-in-suit?	10:02:11	2	Q. And so that -- my question is slightly	10:04:31
3	MR. MARGOLIS: Objection. Vague.	10:02:13	3	different. I want to focus on the specification as	10:04:34
4	THE WITNESS: Unlikely.	10:02:23	4	opposed to the claims.	10:04:36
5	Q. Do the patents-in-suit relate to gene	10:02:25	5	Is it your understanding that the	10:04:37
6	delivery?	10:02:28	6	patents-in-suit all have essentially the same	10:04:38
7	A. No.	10:02:30	7	specification?	10:04:41
8	Q. Do the patents-in-suit relate to gene	10:02:30	8	A. Broadly, yes.	10:04:45
9	formulation?	10:02:33	9	Q. Turn, if you would, to the '606 patent. It's	10:04:47
10	A. They have learnings that would be useful for	10:02:42	10	going to be I believe Exhibit 16 to your	10:04:51
11	gene delivery.	10:02:47	11	declaration.	10:04:56
12	Q. Do the patents-in-suit relate to chemical	10:02:47	12	A. There are obviously some differences between	10:04:58
13	engineering?	10:02:50	13	the patents, which is what I say there.	10:05:00
14	MR. MARGOLIS: Objection. Vague.	10:02:52	14	Q. Take a look, if you would, at column 11,	10:05:06
15	THE WITNESS: I have probably a	10:02:54	15	claim 1 of the '606 patent.	10:05:11
16	different definition of chemical engineering	10:02:56	16	Did you consider claim 1 of the '606 patent	10:05:22
17	than you.	10:02:58	17	in connection with your opinions in this case?	10:05:25
18	Q. What is your definition?	10:02:59	18	MR. MARGOLIS: Objection. Vague.	10:05:27
19	A. The British definition.	10:03:00	19	THE WITNESS: As far as I understand	10:05:43
20	Q. Okay. Please.	10:03:02	20	what you mean by consider, yes.	10:05:45
21	A. Which is much more focused on engineering in	10:03:03	21	Q. How would a person of ordinary skill in the	10:05:46
22	a sort of industrial context. I understand chemical	10:03:10	22	art carry out the method of claim 1 of the '606	10:05:48

Page 98			Page 100		
1	patent?	10:05:52	1	Q. What other information do you think they	10:08:50
2	MR. MARGOLIS: Objection. Vague.	10:05:56	2	would need?	10:08:53
3	THE WITNESS: It's vague. There really	10:05:56	3	A. They would need to know the range of	10:08:55
4	isn't a method.	10:05:59	4	materials of the ingredients that they could be	10:09:03
5	Q. Please turn now to the '431 patent, if you	10:06:01	5	used. They ideally should be told whether there's	10:09:09
6	would?	10:06:24	6	any specific order of mixing of the materials. This	10:09:14
7	A. Yes.	10:06:24	7	also includes no water, as far as I can see, but	10:09:27
8	Q. And let me direct your attention to column 13	10:06:25	8	it's supposed to be an aqueous formulation. They	10:09:32
9	and in particular claim 18. Did you consider claim	10:06:29	9	couldn't make it just on that information alone.	10:09:38
10	18 of the '431 patent in connection with your	10:06:34	10	Q. How would a person of ordinary skill in the	10:09:41
11	opinions in this case?	10:06:38	11	art use the aqueous liquid preparation of claim 18	10:09:43
12	MR. MARGOLIS: Objection. Vague.	10:06:42	12	of the '431 patent?	10:09:46
13	THE WITNESS: I will say again, as far	10:06:45	13	MR. MARGOLIS: Objection. Vague.	10:09:49
14	as I understand what you mean by consider, of	10:06:48	14	THE WITNESS: Use under what	10:09:50
15	course.	10:06:51	15	circumstances?	10:09:52
16	Q. How would a person of ordinary skill in the	10:06:51	16	Q. Use in an ophthalmic product or use as an	10:09:52
17	art make the aqueous liquid preparation of claim 18	10:06:54	17	ophthalmic product. Actually, let me rephrase the	10:10:00
18	of the '431 patent?	10:06:57	18	question so it's clear.	10:10:04
19	MR. MARGOLIS: Objection. Vague. Calls	10:07:01	19	How would a person of ordinary skill in the	10:10:05
20	for speculation.	10:07:02	20	art use the aqueous liquid preparation of claim 18	10:10:07
21	THE WITNESS: There isn't a	10:07:10	21	of the '431 patent as an ophthalmic product?	10:10:10
22	formulation -- there isn't a formulation as	10:07:14	22	MR. MARGOLIS: Objection. Vague.	10:10:28
Page 99			Page 101		
1	such. It's just a list of ingredients. It	10:07:18	1	THE WITNESS: I am struggling here to	10:10:28
2	wouldn't give anybody who is skilled in the	10:07:21	2	understand that. That on its own doesn't	10:10:30
3	art based on that list how to make it.	10:07:24	3	give somebody enough information to be able	10:10:36
4	Q. Do you have an understanding as to how a	10:07:28	4	to formulate the preparation.	10:10:38
5	person of ordinary skill in the art would make the	10:07:30	5	Q. In interpreting claim 18 of the '431 patent,	10:10:44
6	aqueous liquid preparation of claim 18 of the '431	10:07:32	6	would a person of ordinary skill in the art look to	10:10:47
7	patent?	10:07:36	7	the specification of the patent for guidance?	10:10:50
8	A. Please explain to me why it's a preparation	10:07:43	8	A. They would, yes.	10:10:52
9	because there is no formulation there.	10:07:46	9	Q. Based on the teachings of the '431 patent,	10:10:53
10	Q. Do you see the words "an aqueous liquid	10:07:49	10	how would a person of ordinary skill in the art use	10:10:59
11	preparation"?	10:07:51	11	the aqueous liquid preparation of claim 18 of the	10:11:01
12	A. Yes.	10:07:52	12	'431 patent?	10:11:04
13	Q. All right. So, my question is do you	10:07:52	13	A. Sorry. Say that again? I'm sorry.	10:11:07
14	understand how a person of ordinary skill in the art	10:07:56	14	Q. Based on the teachings of the '431 patent,	10:11:09
15	would make the aqueous liquid preparation specified	10:07:58	15	how would a person of ordinary skill in the art use	10:11:12
16	in claim 18 of the '431 patent?	10:08:02	16	the aqueous liquid preparation of claim 18 of the	10:11:14
17	MR. MARGOLIS: Objection. Vague.	10:08:30	17	'431 patent?	10:11:18
18	THE WITNESS: I don't believe anybody of	10:08:34	18	A. Based on this -- based on the teaching in the	10:11:22
19	or the skill could make a liquid -- easily	10:08:38	19	patent, they would be able to get some indication of	10:11:30
20	make or rationally make a liquid preparation	10:08:44	20	the amounts of material that are needed to make the	10:11:39
21	based on that particular formula. They would	10:08:47	21	preparation.	10:11:43
22	need other information.	10:08:49	22	Q. Based on the teachings of the '431 patent,	10:11:43

Page 102	<p>1 how would a person of ordinary skill in the art make 10:11:46</p> <p>2 then aqueous liquid preparation of claim 18 of the 10:11:50</p> <p>3 '431 patent? 10:11:53</p> <p>4 A. Well, as far as I can remember, there's no 10:11:55</p> <p>5 specific instructions about how you actually make 10:12:00</p> <p>6 it. 10:12:06</p> <p>7 Q. Based on the general teachings of the '431 10:12:07</p> <p>8 patent, how would a person of ordinary skill in the 10:12:10</p> <p>9 art make the aqueous liquid preparation of claim 18 10:12:12</p> <p>10 of the '431 patent? 10:12:15</p> <p>11 A. I assume they would take an example and try 10:12:23</p> <p>12 adding the ingredients in the order in which they 10:12:31</p> <p>13 are listed on an example. 10:12:34</p> <p>14 Q. Does the plain language of claim 18 of the 10:12:36</p> <p>15 '431 patent restrict the phrase EDTA sodium salt to 10:12:39</p> <p>16 the tetrasodium form? 10:12:44</p> <p>17 MR. MARGOLIS: Objection. Vague. 10:12:46</p> <p>18 THE WITNESS: But it doesn't say -- 10:12:56</p> <p>19 sodium edetate has a strict meaning, just 10:12:58</p> <p>20 like polyvinylpyrrolidone has. 10:13:02</p> <p>21 Q. I'm just asking based on the plain language 10:13:05</p> <p>22 of the claim. Let me ask it again. 10:13:05</p>	Page 104	<p>1 '431 patent restrict the phrase sodium edetate to 10:14:15</p> <p>2 the tetrasodium form? 10:14:18</p> <p>3 MR. MARGOLIS: Objection. Vague. Asked 10:14:21</p> <p>4 and answered. 10:14:23</p> <p>5 Q. You may answer. 10:14:23</p> <p>6 A. All I can say -- again, I'm really, really 10:14:27</p> <p>7 sorry -- my understanding of what sodium edetate is 10:14:29</p> <p>8 is quite clear. So, I don't understand the question 10:14:33</p> <p>9 why somebody would consider it might refer to 10:14:36</p> <p>10 something else. 10:14:42</p> <p>11 Q. Do you understand the plain language of the 10:14:42</p> <p>12 claims of the patents-in-suit? 10:14:44</p> <p>13 A. I believe I do. 10:14:51</p> <p>14 Q. Does the plain language of any claim of the 10:14:52</p> <p>15 patent-in-suit, or the patents-in-suit rather -- 10:14:54</p> <p>16 strike that and try again. 10:14:57</p> <p>17 Does the plain language of any claim of the 10:14:59</p> <p>18 patents-in-suit restrict the phrase sodium edetate 10:15:01</p> <p>19 to the tetrasodium form? 10:15:04</p> <p>20 A. I believe the way it's written, yes. 10:15:06</p> <p>21 Q. Did you review the specification of the 10:15:09</p> <p>22 patents-in-suit in connection with your opinions in 10:15:11</p>
Page 103	<p>1 Does the plain language of claim 18 of the 10:13:08</p> <p>2 '431 patent restrict the phrase EDTA sodium salt to 10:13:11</p> <p>3 the tetrasodium form? 10:13:14</p> <p>4 A. I believe it does. It's telling you only 10:13:16</p> <p>5 that you're using sodium edetate. 10:13:19</p> <p>6 Q. Take a look, if you would, at claim 8 of the 10:13:22</p> <p>7 '431 patent. 10:13:26</p> <p>8 A. Okay. 10:13:29</p> <p>9 Q. Does the plain language of claim 8 of the 10:13:30</p> <p>10 '431 patent restrict the phrase sodium edetate to 10:13:33</p> <p>11 the tetrasodium form? 10:13:37</p> <p>12 MR. MARGOLIS: Objection. Vague. 10:13:40</p> <p>13 THE WITNESS: I'm struggling here 10:13:43</p> <p>14 because sodium edetate has a strict meaning. 10:13:45</p> <p>15 So it would be like saying, I don't know, 10:13:49</p> <p>16 does sodium hydroxide -- does this patent 10:13:57</p> <p>17 restrict sodium hydroxide -- does it include 10:14:02</p> <p>18 calcium hydroxide. It's not applicable in my 10:14:05</p> <p>19 understanding. 10:14:08</p> <p>20 Q. I'm just asking about the plain language of 10:14:09</p> <p>21 the claim for the time being. 10:14:11</p> <p>22 Does the plain language of claim 8 of the 10:14:12</p>	Page 105	<p>1 this case? 10:15:13</p> <p>2 A. Yes. 10:15:14</p> <p>3 Q. Does the specification of the patents-in-suit 10:15:15</p> <p>4 in any place limit the phrases sodium edetate or 10:15:18</p> <p>5 EDTA sodium salt to the tetrasodium form? 10:15:22</p> <p>6 MR. MARGOLIS: Objection. Vague. 10:15:26</p> <p>7 THE WITNESS: I'm really struggling with 10:15:31</p> <p>8 this because there was no reason to because 10:15:35</p> <p>9 it's a known specific compound. You wouldn't 10:15:38</p> <p>10 say, you know, E. coli becomes some other 10:15:42</p> <p>11 gram negative bacteria. To me, it's very, 10:15:45</p> <p>12 very clear what they're telling you is sodium 10:15:49</p> <p>13 edetate. 10:15:51</p> <p>14 Q. Does the specification of the patents-in-suit 10:15:52</p> <p>15 in any place refer to edetic acid, tetrasodium salt 10:15:54</p> <p>16 or tetrasodium edetate? 10:16:00</p> <p>17 A. Sorry. Does? 10:16:02</p> <p>18 Q. Sure. Does the specification -- 10:16:04</p> <p>19 A. Yes. 10:16:04</p> <p>20 Q. -- of the patents-in-suit in any place refer 10:16:06</p> <p>21 to edetic acid, tetrasodium salt or tetrasodium 10:16:09</p> <p>22 edetate? 10:16:14</p>

Page 106		Page 108			
1	A. I would have to read to check that.	10:16:15	1	1 of the '290 patent for ophthalmic administration?	10:19:24
2	Q. Sitting here today, do you know that?	10:16:17	2	A. In a patient -- they would -- I guess, take	10:19:30
3	A. I don't know whether it says it in my -- I	10:16:20	3	the example which they felt was of interest or more	10:19:38
4	can look at my declaration or my -- I'm sorry. I	10:16:32	4	likely take a range of formulations, prepare them,	10:19:42
5	would have to re-read them to answer you	10:16:44	5	and then have to test them appropriately for	10:19:54
6	categorically.	10:16:46	6	stability.	10:20:00
7	Q. Please turn -- actually, please turn back to	10:16:48	7	Q. Take a look, if you would, at column 14 of	10:20:00
8	the '606 patent. I want to direct your attention	10:16:52	8	the '290 patent and let me direct your attention to	10:20:05
9	again to claim 1.	10:16:56	9	claim 26.	10:20:09
10	A. '606?	10:17:03	10	Did you consider claim 26 of the '290 patent	10:20:13
11	Q. Yes, '606. Are you there?	10:17:04	11	in connection with your opinions in this case?	10:20:15
12	A. Yes.	10:17:10	12	A. I certainly did, yes.	10:20:17
13	Q. Based on the teachings of the '606 patent,	10:17:11	13	Q. Okay. Based on the teachings of the '290	10:20:18
14	how would a person of ordinary skill in the art	10:17:14	14	patent, how would a person of ordinary skill in the	10:20:20
15	carry out the method of claim 1 of the '606 patent?	10:17:16	15	art make the aqueous liquid preparation of claim 26	10:20:23
16	MR. MARGOLIS: Objection. Vague.	10:17:21	16	of the '290 patent?	10:20:26
17	THE WITNESS: The same way we discussed	10:17:52	17	A. I don't know if "make" is the word I would	10:20:32
18	before. You turn to an example that's taught	10:17:54	18	use. I believe that is a test. Once they have made	10:20:34
19	and use that to try and make it up.	10:18:00	19	the preparation, they would have to, according to	10:20:38
20	Q. Take a look, if you would, now at the '290	10:18:05	20	this, make a preparation for claim 1. We've	10:20:43
21	patent. I believe it's Exhibit 13 in your binder.	10:18:10	21	discussed that. And then check that that	10:20:47
22	A. Thank you.	10:18:15	22	preparation fulfills the EP. criteria B of the	10:20:50
Page 107		Page 109			
1	Q. Let me direct your attention to column 12,	10:18:15	1	European Pharmacopeia.	10:21:02
2	claim 1. Did you consider claim 1 of the '290	10:18:18	2	Q. Would that be a fairly straightforward test?	10:21:08
3	patent in connection with your opinions in this	10:18:25	3	MR. MARGOLIS: Objection. Vague.	10:21:11
4	case?	10:18:28	4	THE WITNESS: I don't know what a fairly	10:21:15
5	A. I read all the claims, yes.	10:18:28	5	straightforward test is. It's a standard	10:21:17
6	Q. Based on the teachings of the '290 patent,	10:18:30	6	test.	10:21:20
7	how would a person of ordinary skill in the art make	10:18:33	7	Q. Would it be a fairly straightforward or	10:21:20
8	the aqueous liquid preparation of claim 1 of the	10:18:35	8	standard test based on the teachings of the	10:21:22
9	'290 patent?	10:18:39	9	patents-in-suit?	10:21:24
10	MR. MARGOLIS: Objection. Vague.	10:18:40	10	A. Well, somebody ordinary skilled in the art	10:21:25
11	THE WITNESS: They would have to turn to	10:18:48	11	would obviously go to the European Pharmacopeia and	10:21:30
12	the teachings in the patent and use that as a	10:18:49	12	check the criteria, because that would obviously be	10:21:36
13	starting point.	10:18:53	13	their responsibility, and follow the protocol that's	10:21:40
14	Q. Based on the teachings of the '290 patent,	10:18:53	14	there, the more detailed protocol. This is only an	10:21:46
15	how would a person of ordinary skill in the art use	10:18:56	15	abstract of the protocol.	10:21:49
16	the aqueous liquid preparation of claim 1 of the	10:18:59	16	Q. Based on the teachings of the '290 patent,	10:21:51
17	'290 patent?	10:19:02	17	how would a person of ordinary skill in the art use	10:21:54
18	MR. MARGOLIS: Objection. Vague.	10:19:05	18	the aqueous liquid preparation of claim 26 of the	10:21:56
19	THE WITNESS: Used in what context?	10:19:13	19	'290 patent as an ophthalmic formulation?	10:22:00
20	Q. I apologize. Based on the teachings of the	10:19:15	20	MR. MARGOLIS: Objection. Vague. Lacks	10:22:06
21	'290 patent, how would a person of ordinary skill in	10:19:18	21	foundation.	10:22:09
22	the art use the aqueous liquid preparation of claim	10:19:21	22	THE WITNESS: I don't believe anybody	10:22:10

Page 110			Page 112		
1	would use that formulation in isolation of	10:22:26	1	MR. MARGOLIS: Objection. Vague.	10:25:04
2	just doing that test. They would have to do	10:22:29	2	THE WITNESS: I think somebody who is	10:25:21
3	a test to satisfy themselves that it is	10:22:33	3	ordinary skilled in the art would be	10:25:23
4	suitable for ophthalmic use.	10:22:35	4	concerned that the formulation doesn't have	10:25:29
5	Q. And what test would they do?	10:22:38	5	the full raft of stability tests that you	10:25:32
6	A. We've already discussed a little bit about	10:22:42	6	would need to ensure something was suitable	10:25:39
7	the necessary range of stability tests that they	10:22:47	7	for ophthalmic use.	10:25:42
8	would have to do. This preservative test would	10:22:52	8	Q. Based on the specification of the '131	10:25:45
9	complement the whole raft of stability tests that	10:22:58	9	patent, how would a person of ordinary skill in the	10:25:48
10	would be needed.	10:23:01	10	art make the aqueous liquid preparation of claim 25	10:25:51
11	Q. Take a look, if you would, at the '131 patent	10:23:01	11	of the '131 patent?	10:25:53
12	now. It should be the next exhibit in your binder.	10:23:05	12	MR. MARGOLIS: Objection. Vague.	10:25:57
13	Let me direct your attention to column 14, claim 25.	10:23:10	13	THE WITNESS: I thought I answered this.	10:26:05
14	A. Okay.	10:23:19	14	They would go to claim 1, make some	10:26:07
15	Q. How would a person of ordinary skill in the	10:23:20	15	formulations which falls within the	10:26:11
16	art make the aqueous liquid preparation of claim 25	10:23:23	16	specification that they were interested in.	10:26:15
17	of the '131 patent?	10:23:26	17	Assuming some of those formulations looked	10:26:20
18	MR. MARGOLIS: Objection. Vague.	10:23:30	18	promising from the initial screen, they would	10:26:23
19	THE WITNESS: Well, the answer -- if	10:23:36	19	do a more detailed screening and do some	10:26:25
20	somebody was using this patent, they would go	10:23:39	20	stability tests which would include the	10:26:28
21	to the examples, produce a variety of	10:23:41	21	preservative tests.	10:26:31
22	formulations to their preferred	10:23:46	22	Q. So, could you turn back to the '290 patent	10:26:38
Page 111			Page 113		
1	specification. If they looked promising,	10:23:50	1	please?	10:26:42
2	they would then start to test those	10:23:52	2	A. Yes.	10:26:43
3	formulations with respect to stability which	10:23:54	3	Q. Let me direct your attention to column 7 and	10:26:56
4	would include, but not totally be,	10:23:57	4	Experimental Example 1. Did you review Experimental	10:27:0
5	preservative stability. And they would go to	10:24:02	5	Example 1 in connection with your opinions in this	10:27:10
6	the European -- uh, the U.S. Pharmacopeia and	10:24:05	6	case?	10:27:12
7	get the full detailed methods for -- because	10:24:10	7	A. I did.	10:27:12
8	these are not detailed methods. These are	10:24:16	8	Q. Under Table 1, the paragraph reads, "The	10:27:13
9	incomplete. And then they would realize	10:24:18	9	remaining rate percent in the above Table 1	10:27:17
10	there was some discrepancy here.	10:24:21	10	indicates values obtained by correcting moisture	10:27:21
11	Q. How would a person of ordinary skill in the	10:24:23	11	vaporization from the container. As is apparent	10:27:24
12	art use the aqueous liquid preparation of claim 25	10:24:25	12	from Table 1, stability test was carried out under	10:27:27
13	of the '131 patent as an ophthalmic formulation?	10:24:29	13	the conditions of pH 7.0 at 60 degrees Celsius for	10:27:31
14	MR. MARGOLIS: Objection. Vague.	10:24:34	14	four weeks, and sodium 2-amino-3-(4-bromobenzoyl)	10:27:36
15	THE WITNESS: They wouldn't use it	10:24:39	15	phenylacetate in each eye drop was stable in the	10:27:45
16	unless they performed a whole raft of other	10:24:44	16	order of tyloxapol-containing preparation greater	10:27:47
17	tests to ensure that it is suitable for	10:24:47	17	than polyoxyl 40 stearate-containing preparation	10:27:51
18	ophthalmic use.	10:24:50	18	greater than polysorbate 80-containing preparation."	10:27:56
19	Q. Based on the teachings of the '131 patent,	10:24:52	19	Do you see that?	10:27:59
20	how would a person of ordinary skill in the art use	10:24:56	20	A. I do.	10:28:00
21	the aqueous liquid preparation of claim 25 of the	10:24:58	21	Q. Does Experimental Example 1 of the '290	10:28:01
22	'131 patent?	10:25:01	22	patent teach that formulation A-03 was stable within	10:28:04

Page 114	<p>1 the meaning of the claims? 10:28:07</p> <p>2 A. It's my understanding from the claims, no, 10:28:12</p> <p>3 because they're quite -- it's difficult to follow. 10:28:18</p> <p>4 Just let me turn to my -- so, as I've said in my 10:28:23</p> <p>5 report, it discusses an order of stability, but it 10:28:40</p> <p>6 doesn't discuss an absolute stability. It doesn't 10:28:44</p> <p>7 say in the -- in this patent here, it doesn't say 10:28:53</p> <p>8 what remaining rate is required for stability. 10:28:57</p> <p>9 Q. Let me direct your attention then to claim 8 10:29:01</p> <p>10 of the '290 patent. Do you see that claim 8 of the 10:29:05</p> <p>11 '290 patent has a clause that says, "Wherein the 10:29:11</p> <p>12 stable aqueous liquid preparation is characterized 10:29:14</p> <p>13 in that greater than about 90 percent of the 10:29:17</p> <p>14 original amount of the first component remains in 10:29:20</p> <p>15 the preparation after storage at about 60 degrees 10:29:23</p> <p>16 Celsius for four weeks"? 10:29:27</p> <p>17 A. Okay. 10:29:28</p> <p>18 Q. Do you see that? 10:29:29</p> <p>19 A. Yes. 10:29:31</p> <p>20 Q. Does Experimental Example 1 of the '290 10:29:31</p> <p>21 patent teach that formulation A-03 was a stable 10:29:35</p> <p>22 within the meaning of claim 8 of the '290 patent? 10:29:38</p>	Page 116	<p>1 Q. Well, let's take a look at Table 2 in 10:32:06</p> <p>2 Experimental Example 2 and formulation A-04. 10:32:11</p> <p>3 Does Experimental Example 2 of the '290 10:32:16</p> <p>4 patent teach that formulation A-04 was stable within 10:32:19</p> <p>5 the meaning of claim 8 of the '290 patent? 10:32:23</p> <p>6 A. I believe it does. 10:32:34</p> <p>7 Q. Is the concept of stability in the 10:32:36</p> <p>8 patents-in-suit directed to the physical stability 10:32:39</p> <p>9 or the chemical stability of the claimed aqueous 10:32:41</p> <p>10 liquid preparations? 10:32:45</p> <p>11 A. It's quite vague because it does -- just let 10:32:51</p> <p>12 me find something. I'm sorry. 10:32:58</p> <p>13 Q. Tell me when you're ready. I'll be happy to 10:33:27</p> <p>14 reask the question. 10:33:29</p> <p>15 A. Sorry. 10:33:30</p> <p>16 Q. That's all right. 10:33:31</p> <p>17 A. I can't find in this patent the bit I'm 10:33:32</p> <p>18 looking for. I'm sorry. 10:33:36</p> <p>19 Q. Take your time. Tell me when you're ready. 10:33:37</p> <p>20 A. I think this patent is vague with respect to 10:34:11</p> <p>21 stability. I don't think it's explicit in what it 10:34:15</p> <p>22 teaches because part of the goal was to ensure that 10:34:20</p>
Page 115	<p>1 MR. MARGOLIS: Objection. Vague. 10:29:43</p> <p>2 THE WITNESS: I'm really, really sorry. 10:29:46</p> <p>3 You were too quick for me then. 10:29:48</p> <p>4 Q. Okay. 10:29:48</p> <p>5 A. Can you say it again? 10:29:50</p> <p>6 Q. I can repeat. 10:29:50</p> <p>7 A. Thank you. 10:29:51</p> <p>8 Q. Certainly. Does Experimental Example 1 of 10:29:52</p> <p>9 the '290 patent teach that formulation A-03 was 10:29:54</p> <p>10 stable within the meaning of claim 8 of the '290 10:29:59</p> <p>11 patent? 10:30:03</p> <p>12 MR. MARGOLIS: Objection. Vague. 10:30:09</p> <p>13 THE WITNESS: Okay. So, ask me the 10:31:23</p> <p>14 question again? Sorry. 10:31:24</p> <p>15 Q. Sure. Does Experimental Example 1 of the 10:31:26</p> <p>16 '290 patent teach that formulation A-03 was stable 10:31:29</p> <p>17 within the meaning of claim 8 of the '290 patent? 10:31:33</p> <p>18 MR. MARGOLIS: Objection. Vague. 10:31:38</p> <p>19 THE WITNESS: A-03, you said? Yes. I 10:31:43</p> <p>20 thought you said example one before. I'm 10:31:51</p> <p>21 sorry. Okay. It is vague, the lower limit, 10:31:52</p> <p>22 but I would say that probably. 10:31:59</p>	Page 117	<p>1 the preservative kept its -- its intended, or 10:34:26</p> <p>2 disclosure was that they found the preservative kept 10:34:31</p> <p>3 its effect. And there was no precipitate, which is 10:34:35</p> <p>4 possibly chemical, possibly physical stability. 10:34:40</p> <p>5 There is some indication of chemical stability here, 10:34:44</p> <p>6 but it doesn't define properly under what conditions 10:34:48</p> <p>7 you're looking at it. I think it's vague. 10:34:53</p> <p>8 Q. Do Experimental Examples 1 and -- sorry -- 10:34:56</p> <p>9 let me strike that and try again. 10:34:59</p> <p>10 Do Experimental Example 1 and Experimental 10:35:01</p> <p>11 Example 2 in the patents-in-suit deal with physical 10:35:05</p> <p>12 or chemical stability? 10:35:07</p> <p>13 A. Sorry. This is Experimental -- this is on 10:35:15</p> <p>14 page 7 -- column 7? 10:35:18</p> <p>15 Q. Correct. Columns 7 and 8. 10:35:20</p> <p>16 A. Okay. That deals with chemical stability, 10:35:24</p> <p>17 but only as far as it does also indicate there's 10:35:48</p> <p>18 some physical component to it because it's 10:35:54</p> <p>19 correcting for moisture vaporization from the 10:36:03</p> <p>20 container. 10:36:08</p> <p>21 Q. Aside from the correction for moisture 10:36:09</p> <p>22 vaporization from the container, do Experimental 10:36:12</p>

Page 118	Page 120
<p>1 Example 1 and Experimental Example 2 in the 10:36:17</p> <p>2 patents-in-suit deal with chemical stability? 10:36:19</p> <p>3 A. I guess so, yes. 10:36:37</p> <p>4 Q. Do you know how the aqueous liquid 10:36:38</p> <p>5 preparations disclosed and claimed in the 10:36:41</p> <p>6 patents-in-suit regulate the dose of drug to the 10:36:43</p> <p>7 patient? 10:36:46</p> <p>8 MR. MARGOLIS: Objection. Vague. 10:36:47</p> <p>9 THE WITNESS: I don't understand that 10:36:53</p> <p>10 question anyway. 10:36:54</p> <p>11 Q. What don't you understand about it? 10:36:55</p> <p>12 A. How can the formulation -- how can the 10:36:59</p> <p>13 formulation that is regulate the dose. I don't 10:37:03</p> <p>14 understand. I'm sorry. 10:37:06</p> <p>15 Q. Take a look at the first sentences above 10:37:07</p> <p>16 Tables 1 and 2 of the '290 patent. 10:37:17</p> <p>17 A. Um-mm. 10:37:20</p> <p>18 Q. And it says, "Four eye drops of sodium 10:37:21</p> <p>19 2-amino-3-(4-bromobenzoyl) phenylacetate comprising 10:37:24</p> <p>20 the components as shown in Table 1 were prepared, 10:37:29</p> <p>21 filled respectively into a polypropylene container 10:37:32</p> <p>22 and subjected to stability test at 60 degrees 10:37:35</p>	<p>1 obviously. It's a type of plastic. It would be 10:38:42</p> <p>2 normal for eye drops to be in a -- if they're in a 10:38:47</p> <p>3 plastic container, normally in one that you could 10:38:52</p> <p>4 use to squeeze -- to drop out the eye drops. I 10:38:54</p> <p>5 don't know. It doesn't say what type of 10:38:58</p> <p>6 polypropylene. I don't know what plasticizers are 10:38:59</p> <p>7 there or anything. 10:39:01</p> <p>8 Q. Would a person of ordinary skill in the art 10:39:01</p> <p>9 readily understand how to use a polypropylene 10:39:04</p> <p>10 container to carry out Experimental Examples 1 and 10:39:06</p> <p>11 2? 10:39:11</p> <p>12 MR. MARGOLIS: Objection, Vague. 10:39:16</p> <p>13 THE WITNESS: These are not standard 10:39:19</p> <p>14 tests. They're not standard stability tests. 10:39:20</p> <p>15 A standard ICH stability test or regulatory 10:39:26</p> <p>16 test would have a very prescribed way of 10:39:32</p> <p>17 doing a stability test. There was no mention 10:39:36</p> <p>18 here about controlling external humidity, how 10:39:40</p> <p>19 you heat them up or anything. So, it is 10:39:45</p> <p>20 vague. 10:39:49</p> <p>21 Q. Well, my question is a little simpler -- 10:39:49</p> <p>22 A. Yeah. 10:39:49</p>
Page 119	Page 121
<p>1 Celsius." 10:37:35</p> <p>2 And then the sentence above Table 2 says, 10:37:39</p> <p>3 "Five eye drops of sodium 2-amino-3-(4- 10:37:43</p> <p>4 bromobenzoyl) phenylacetate comprising the 10:37:46</p> <p>5 components as shown in Table 2 were prepared, filled 10:37:50</p> <p>6 respectively into a polypropylene container and 10:37:54</p> <p>7 preserved at 60 degrees Celsius for four weeks, and 10:37:57</p> <p>8 then the content of 2-amino-3-(4-bromobenzoyl) 10:38:01</p> <p>9 phenylacetic acid and the pH in each eye drop were 10:38:07</p> <p>10 measured." 10:38:09</p> <p>11 Do you see those sentences? 10:38:10</p> <p>12 A. Yes. 10:38:12</p> <p>13 Q. Do the -- does -- sorry. Let me strike that 10:38:12</p> <p>14 and try again. 10:38:14</p> <p>15 Does the specification of the patents-in-suit 10:38:14</p> <p>16 state that Experimental Examples 1 and 2 were 10:38:17</p> <p>17 carried out using polypropylene containers? 10:38:21</p> <p>18 A. Yes. 10:38:24</p> <p>19 Q. What are polypropylene containers? 10:38:25</p> <p>20 A. They're effectively a plastic container. I 10:38:29</p> <p>21 assume -- there are different types of 10:38:36</p> <p>22 polypropylene, so you would need more information 10:38:38</p>	<p>1 Q. -- actually. 10:39:51</p> <p>2 Would a person of ordinary skill in the art 10:39:51</p> <p>3 readily understand how to use a polypropylene 10:39:53</p> <p>4 container to carry out Experimental Examples 1 and 10:39:56</p> <p>5 2? 10:40:00</p> <p>6 MR. MARGOLIS: Objection. Vague. 10:40:00</p> <p>7 THE WITNESS: I thought I answered that. 10:40:01</p> <p>8 Sorry. There's no specification on the 10:40:05</p> <p>9 polypropylene bottle, so that would be 10:40:14</p> <p>10 initial concern. There's no discussion when 10:40:20</p> <p>11 you make these formulations as to whether you 10:40:28</p> <p>12 sterilize them before you put them in the 10:40:31</p> <p>13 bottle or -- so, there are things that are 10:40:33</p> <p>14 not available so you could not be a hundred 10:40:40</p> <p>15 percent certain that you were completely 10:40:42</p> <p>16 using the same protocol. 10:40:47</p> <p>17 Q. Would a person of ordinary skill in the art 10:40:48</p> <p>18 with several years of experience know how to find 10:40:50</p> <p>19 the information necessary to use a polypropylene 10:40:54</p> <p>20 container to carry out Experimental Examples 1 and 10:40:57</p> <p>21 2? 10:41:01</p> <p>22 MR. MARGOLIS: Objection. Vague. Lack 10:41:01</p>



Page 122		Page 124	
1	of foundation. 10:41:03	1	paragraph under "Disclosure of the Invention" that 10:43:19
2	THE WITNESS: I'm struggling with your 10:41:06	2	goes from line 16 through line 23? 10:43:22
3	use of the word use. I'm sorry. How would 10:41:09	3	A. I do. 10:43:25
4	they use as in -- would they just put it into 10:41:13	4	Q. Could you just read that to yourself and let 10:43:25
5	an -- I don't know. Is that what you mean by 10:41:19	5	me know when you're ready. 10:43:31
6	use? 10:41:22	6	A. Okay. 10:43:42
7	Q. Well, let me ask it this way. Would a person 10:41:23	7	Q. And you understand that the chemical name 10:43:43
8	of ordinary skill in the art readily understand how 10:41:25	8	2-amino-3-(4-bromobenzoyl) phenylacetic acid is the 10:43:45
9	to obtain a polypropylene container to carry out 10:41:27	9	chemical name for bromfenac, correct? 10:43:52
10	Experimental Examples 1 and 2? 10:41:31	10	A. Correct. 10:43:55
11	A. Yes. There are, of course, the 10:41:36	11	Q. Okay. I'll refer to it as bromfenac because 10:43:55
12	manufacturers. 10:41:39	12	that chemical name is a bit of a mouthful. 10:43:57
13	Q. Okay. What size polypropylene container 10:41:40	13	Does the specification of the patents-in-suit 10:43:59
14	would a person of ordinary skill in the art want to 10:41:42	14	state that it is an object of the present invention 10:44:01
15	select when carrying out Experimental Examples 1 and 10:41:44	15	to provide an aqueous liquid preparation comprising 10:44:04
16	2? 10:41:48	16	bromfenac or a pharmacologically acceptable salt 10:44:07
17	A. It would suggest a hundred mil, but that 10:41:49	17	thereof or a hydrate thereof, which is stable within 10:44:11
18	would seem ridiculous for an eye drop formulation. 10:41:52	18	a pH range giving no irritation to eyes and in 10:44:13
19	Q. Why would it seem ridiculous for an eye drop 10:41:58	19	which, when a preservative such as benzalkonium 10:44:17
20	formulation? 10:42:03	20	chloride is incorporated therein, preservative 10:44:21
21	A. As you only administer one or two drops into 10:42:03	21	effect of the preservative does not substantially 10:44:23
22	the eye possibly twice a day, you would not need a 10:42:06	22	deteriorate? 10:44:26
Page 123		Page 125	
1	hundred mil. You would obviously want to do this on 10:42:09	1	A. Yes. 10:44:27
2	a much smaller scale. 10:42:11	2	Q. Take a look, if you would, now down at column 10:44:27
3	Q. Why do Experimental Examples 1 and 2 suggest 10:42:14	3	6, lines 38 through 40. So, over to column 6, it's 10:44:32
4	using a one hundred milliliter polypropylene 10:42:17	4	going to be the sentence that starts "The pH"? 10:44:37
5	container to carry out those examples? 10:42:20	5	A. Yes. 10:44:41
6	MR. MARGOLIS: Objection. 10:42:23	6	Q. Can you read that to yourself and let me know 10:44:42
7	Mischaracterizes her testimony. 10:42:24	7	when you're ready? 10:44:44
8	Q. You may answer. 10:42:27	8	A. Yes. 10:44:47
9	A. It doesn't say anything else. I mean, it 10:42:29	9	Q. Does the specification of the patents-in-suit 10:44:48
10	doesn't even say polypropylene dropper bottle, which 10:42:32	10	state that the pH of the aqueous liquid preparation 10:44:52
11	is what I -- or container, which is what I would 10:42:35	11	of the present invention can be adjusted to about 6 10:44:55
12	normally expect. 10:42:38	12	to 9, preferably about 7 to 9, especially about 7.5 10:44:59
13	Q. What shape polypropylene container would a 10:42:39	13	to 8.5? 10:45:04
14	person of ordinary skill in the art want to select 10:42:42	14	A. Yes. 10:45:05
15	when carrying out Experimental Examples 1 and 2? 10:42:44	15	Q. Based on the specification of the 10:45:06
16	MR. MARGOLIS: Objection. Lacks 10:42:50	16	patents-in-suit, would a person of ordinary skill in 10:45:07
17	foundation. 10:42:51	17	the art expect that the claimed aqueous liquid 10:45:10
18	THE WITNESS: Something that is the same 10:42:52	18	preparations are stable within the especially 10:45:13
19	shape as a normal eye drop bottle. 10:42:57	19	preferred pH range of about 7.5 to 8.5? 10:45:15
20	Q. Take a look, if you would, at the '290 10:42:59	20	MR. MARGOLIS: Objection. Vague. 10:45:20
21	patent, column 2, line 16. And I want to read to 10:43:03	21	THE WITNESS: Ask the question again? 10:45:24
22	you the paragraph-- well, actually, do you see the 10:43:18	22	Sorry. 10:45:26

Page 126	<p>1 Q. Sure. Based on the specification of the 10:45:26</p> <p>2 patents-in-suit, would a person of ordinary skill in 10:45:28</p> <p>3 the art expect that the claimed aqueous liquid 10:45:30</p> <p>4 preparations are stable within the especially 10:45:33</p> <p>5 preferred pH range of about 7.5 to 8.5? 10:45:36</p> <p>6 MR. MARGOLIS: Objection. Vague. Calls 10:45:41</p> <p>7 for speculation. Compound. 10:45:43</p> <p>8 THE WITNESS: Not necessarily, no. 10:45:55</p> <p>9 Q. Take a look, if you would, at the Abstract. 10:45:58</p> <p>10 And if you would just read the entirety of the 10:46:10</p> <p>11 Abstract to yourself and just let me know when 10:46:13</p> <p>12 you're ready. 10:46:15</p> <p>13 A. Okay. 10:46:43</p> <p>14 Q. Does the first sentence of the Abstract of 10:46:44</p> <p>15 the patents-in-suit state that an aqueous liquid 10:46:47</p> <p>16 preparation of the present invention containing 10:46:50</p> <p>17 bromfenac and tyloxapol is stable? 10:46:52</p> <p>18 A. Yes. 10:47:01</p> <p>19 Q. Do you have any basis to disagree with that 10:47:02</p> <p>20 statement? 10:47:05</p> <p>21 A. At the moment with an Abstract there's 10:47:06</p> <p>22 insufficient information to make that, so no. 10:47:10</p>	Page 128	<p>1 Q. Do you have any basis at all to disagree with 10:49:24</p> <p>2 that statement? 10:49:27</p> <p>3 A. I don't think this -- that I have enough 10:49:34</p> <p>4 information here to say one way or another. 10:49:36</p> <p>5 Q. Take a look, if you would, at lines 63 to 64 10:49:39</p> <p>6 in column 2. It starts with a number 3 and it says, 10:49:44</p> <p>7 "The aqueous liquid preparation" -- I apologize. 10:49:52</p> <p>8 A. Yeah. 10:49:52</p> <p>9 Q. So, it's actually 62 to 64. 10:49:56</p> <p>10 A. That's okay. 10:49:58</p> <p>11 Q. And read that to yourself, if you would, and 10:49:59</p> <p>12 let me know when you're ready. 10:50:01</p> <p>13 A. Yes. 10:50:10</p> <p>14 Q. Is tyloxapol an example of an alkyl aryl 10:50:11</p> <p>15 polyether alcohol type polymer? 10:50:16</p> <p>16 A. Yes. That's one way you can call it, one way 10:50:18</p> <p>17 of describing it. 10:50:22</p> <p>18 Q. Is tyloxapol a polyoxyethylene sorbitan 10:50:23</p> <p>19 n-acyl ester? 10:50:30</p> <p>20 A. No. 10:50:30</p> <p>21 Q. Take a look actually, if you would, at 10:50:31</p> <p>22 paragraph 60 of your declaration. It's on page 16. 10:50:34</p>
Page 127	<p>1 Q. Take a look, if you would, at the '290 10:47:13</p> <p>2 patent, column 2, lines 6 through 12. Read that to 10:47:19</p> <p>3 yourself and let me know when you're ready. 10:47:31</p> <p>4 A. Okay. 10:47:49</p> <p>5 Q. Does the specification of the patents-in-suit 10:47:50</p> <p>6 state that the prior art references identified in 10:47:54</p> <p>7 the patents-in-suit provide no disclosure that alkyl 10:47:58</p> <p>8 aryl polyether alcohol type polymers or polyethylene 10:48:02</p> <p>9 glycol fatty acid esters are able to stabilize an 10:48:08</p> <p>10 aqueous liquid preparation of bromfenac and inhibit 10:48:11</p> <p>11 decrease in preservative effect of benzalkonium 10:48:15</p> <p>12 chloride and other quaternary ammonium compounds? 10:48:19</p> <p>13 MR. MARGOLIS: Objection. 10:48:21</p> <p>14 Mischaracterizing the documents. 10:48:23</p> <p>15 THE WITNESS: It does. 10:48:24</p> <p>16 Q. Do you have any basis to disagree with that 10:48:25</p> <p>17 statement? 10:48:28</p> <p>18 A. Let me just have a think. 10:48:29</p> <p>19 So, the question was do I have any -- 10:49:07</p> <p>20 Q. Basis to disagree with that statement? 10:49:09</p> <p>21 A. When you say "basis," based on this 10:49:16</p> <p>22 information here or other information? 10:49:20</p>	Page 129	<p>1 A. Okay. I've got it. 10:50:47</p> <p>2 Q. Okay. And just a minute ago we read the 10:50:48</p> <p>3 Abstract of the '290 patent. 10:50:50</p> <p>4 Do you remember that? 10:50:52</p> <p>5 A. Yes. 10:50:53</p> <p>6 Q. And in paragraph 60 you quote the Abstract in 10:50:53</p> <p>7 your "See e.g." citation and you say, "An aqueous 10:50:58</p> <p>8 liquid preparation of the present invention 10:51:02</p> <p>9 containing 2-amino-3-(4-bromobenzoyl) phenylacetic 10:51:04</p> <p>10 acid or its pharmacologically acceptable salt or a 10:51:09</p> <p>11 hydrate thereof, an alkyl aryl polyether alcohol 10:51:13</p> <p>12 type polymer such as tyloxapol, or a polyethylene 10:51:17</p> <p>13 glycol fatty acid ester such as polyethylene glycol 10:51:21</p> <p>14 monostearate is staple." 10:51:25</p> <p>15 Do you see that? 10:51:26</p> <p>16 A. Yes. 10:51:27</p> <p>17 Q. You provide no basis for disagreement with 10:51:27</p> <p>18 that statement. 10:51:29</p> <p>19 Do you see that? 10:51:30</p> <p>20 MR. MARGOLIS: Objection. Vague. 10:51:37</p> <p>21 THE WITNESS: I provide no basis -- that 10:51:38</p> <p>22 was not the point of that statement. 10:51:40</p>

Page 130	Page 132
<p>1 Q. You provide no basis for disagreement with 10:51:42                  2 that, do you? 10:51:44                  3 A. That's just bizarre because the point of the 10:51:45                  4 statement was to talk about there's no clarity 10:51:49                  5 around the meaning of stability. I wasn't dealing 10:51:52                  6 with whether or not that statement is correct. I'm 10:51:57                  7 just saying that statement has no definition of 10:52:00                  8 stability. 10:52:04                  9 Q. Do you provide any basis for disagreement 10:52:04                  10 with that statement anywhere in your declaration? 10:52:06                  11 A. I would have to have a look. 10:52:11                  12 Okay. I was asked to particularly look at 10:53:26                  13 claim construction. I don't consider that to be 10:53:30                  14 part of claim construction. It is in my report 10:53:32                  15 because it's actually demonstrating that it's a 10:53:35                  16 supporting statement that indicates they don't 10:53:38                  17 define stability clearly. 10:53:41                  18 Q. You provide no basis for disagreement with 10:53:42                  19 that statement anywhere in your declaration, 10:53:44                  20 correct? 10:53:47                  21 A. The statement is only there because it's to 10:53:48                  22 support the discussion about stability. 10:53:51</p>	<p>1 preparations of the patents-in-suit? 10:55:09                  2 A. Not specifically, no. 10:55:12                  3 Q. Could an aqueous liquid preparation of 10:55:17                  4 bromfenac have sufficient preservative efficacy as 10:55:22                  5 an eye drop without containing benzalkonium 10:55:25                  6 chloride? 10:55:31                  7 MR. MARGOLIS: Objection. Vague. Lack 10:55:31                  8 of foundation. 10:55:47                  9 THE WITNESS: I'm sorry. I'm going to 10:55:48                  10 have to take my time answering this one. 10:55:55                  11 Apologies. Without reference to what is 10:55:58                  12 written in the patents elsewhere, I would say 10:56:37                  13 that without a preservative in the 10:56:42                  14 formulation, it would not be possible to 10:56:46                  15 produce an eyedrop that's preserved 10:56:50                  16 bromfenac. 10:56:55                  17 Q. My question is a little different. Could an 10:56:55                  18 aqueous liquid preparation of bromfenac have 10:56:56                  19 sufficient preservative efficacy as an eye drop 10:56:58                  20 without containing benzalkonium chloride? 10:57:01                  21 MR. MARGOLIS: Objection. Vague. 10:57:05                  22 THE WITNESS: The simple answer, which 10:57:07</p>
Page 131	Page 133
<p>1 Q. You provide no basis for disagreement with 10:53:53                  2 that statement, correct? 10:53:55                  3 A. The point of this declaration was to look at 10:54:00                  4 claim construction. 10:54:04                  5 Q. Doctor, I will ask you again. You provide no 10:54:05                  6 basis for disagreement with that statement, correct? 10:54:07                  7 A. I provide no basis for agreement with that 10:54:09                  8 statement either. 10:54:13                  9 Q. Okay. Take a look, if you would, at the -- 10:54:13                  10 back to the '290 patent, Experimental Example 3. 10:54:17                  11 You considered Experimental Example 3 in connection 10:54:30                  12 with your opinions in this case, correct? 10:54:33                  13 A. Yes. 10:54:35                  14 Q. Does Experimental Example 3 address 10:54:39                  15 preservative efficacy of the aqueous liquid 10:54:41                  16 preparations of the patents-in-suit? 10:54:44                  17 A. Sorry. This is Experimental Example 3? 10:54:48                  18 Q. Correct. 10:54:51                  19 A. You're asking me does it address preservative 10:54:52                  20 efficacy? 10:54:55                  21 Q. Correct. Does Experimental Example 3 10:54:56                  22 address preservative efficacy of the aqueous liquid 10:54:59</p>	<p>1 sounds a bit facetious, is if you had a 10:57:15                  2 different preservative, of course. 10:57:18                  3 Q. How would a person of ordinary skill in the 10:57:20                  4 art determine whether an aqueous liquid preparation 10:57:22                  5 of bromfenac without benzalkonium chloride have 10:57:25                  6 sufficient preservative efficacy as an eye drop? 10:57:29                  7 MR. MARGOLIS: Objection. Vague. 10:57:32                  8 THE WITNESS: There are several answers 10:57:36                  9 to that question. The most -- if you were 10:57:54                  10 going to optimize your formulation, you would 10:57:58                  11 do formulation optimization and test it with 10:58:01                  12 preservative -- against appropriate -- 10:58:04                  13 sorry -- doing appropriate -- doing 10:58:08                  14 appropriate compendial tests to ensure it has 10:58:12                  15 appropriate preservative activity. 10:58:17                  16 Q. Did you have anything else to provide? 10:58:26                  17 A. Well, the bottom line is it is vague and 10:58:28                  18 answering, you know, if it's -- perhaps if you took 10:58:35                  19 an example they took the preservative out, 10:58:38                  20 benzalkonium chloride out, you would have to do 10:58:41                  21 tests to ensure it had preservative activity. 10:58:44                  22 Q. Take a look back now at your declaration, if 10:58:47</p>

Page 134	<p>1 you would, on page 5, paragraph 17, please. If you 10:58:50</p> <p>2 would just read that paragraph to yourself. 10:59:04</p> <p>3 Actually, I'm sorry, I think you're on the wrong 10:59:07</p> <p>4 page. 10:59:09</p> <p>5 A. Oh, sorry. 10:59:09</p> <p>6 Q. So, page 5? 10:59:10</p> <p>7 A. Oh, right. Okay. Sorry. What number did 10:59:10</p> <p>8 you say? 10:59:14</p> <p>9 Q. Paragraph 17. It's Section III, Materials 10:59:14</p> <p>10 Reviewed. Just read that to yourself and let me 10:59:17</p> <p>11 know when you're ready. 10:59:20</p> <p>12 A. Ready. 10:59:34</p> <p>13 Q. Okay. Which document or documents do you 10:59:35</p> <p>14 consider most important to your opinions in this 10:59:37</p> <p>15 case? 10:59:40</p> <p>16 MR. MARGOLIS: Objection. Vague. 10:59:42</p> <p>17 Compound. 10:59:44</p> <p>18 Q. You may answer. 10:59:45</p> <p>19 MR. MARGOLIS: And lacks foundation. 10:59:50</p> <p>20 THE WITNESS: In terms of the court, 11:00:01</p> <p>21 it's obviously the intrinsic evidence, which 11:00:03</p> <p>22 would be the claims themselves and patent 11:00:06</p>
Page 135	<p>1 specification and the prosecution history. 11:00:08</p> <p>2 Q. Which document or documents do you consider 11:00:10</p> <p>3 least important to your opinions in this case? 11:00:13</p> <p>4 MR. MARGOLIS: Objection. Vague. 11:00:16</p> <p>5 Compound. Lacks foundation. 11:00:18</p> <p>6 Q. You may answer. 11:00:20</p> <p>7 A. That would be very difficult because that 11:00:21</p> <p>8 would depend what the intrinsic evidence was. 11:00:24</p> <p>9 Q. Which document did you consider first in 11:00:27</p> <p>10 connection with your opinions in this case? 11:00:30</p> <p>11 MR. MARGOLIS: Objection. Vague. 11:00:33</p> <p>12 Compound. 11:00:35</p> <p>13 THE WITNESS: The first documents to do 11:00:40</p> <p>14 with this case that I read were the patents 11:00:43</p> <p>15 themselves, the whole specifications. 11:00:46</p> <p>16 Q. From whom did you obtain the documents that 11:00:48</p> <p>17 you considered in connection with your opinions in 11:00:51</p> <p>18 this case? 11:00:53</p> <p>19 MR. MARGOLIS: Objection. Compound. 11:00:54</p> <p>20 Vague. 11:00:56</p> <p>21 Q. You may answer. 11:00:58</p> <p>22 A. The attorneys. 11:01:02</p>
Page 136	<p>1 Q. And in your previous answer when you said the 11:01:04</p> <p>2 patents themselves with the whole specifications 11:01:09</p> <p>3 were the documents that you considered first in 11:01:13</p> <p>4 connection with your opinions in this case, you are 11:01:15</p> <p>5 referring to the patents-in-suit, correct? 11:01:17</p> <p>6 A. I am. 11:01:19</p> <p>7 MR. HASFORD: It looks like we're about 11:01:22</p> <p>8 ready for another tape change. Is this a 11:01:23</p> <p>9 good time for a break? 11:01:26</p> <p>10 A. This is an excellent time for a break. 11:01:27</p> <p>11 THE VIDEOGRAPHER: The time is 11:01:31</p> <p>12 approximately 11:02 a.m., Friday, September 11:01:36</p> <p>13 4, 2015. This is the end of tape number two 11:01:45</p> <p>14 of the videotaped deposition of Dr. Jayne 11:01:48</p> <p>15 Lawrence. We are off the record. 11:01:51</p> <p>16 (Recess from 11:02 to 11:21.) 11:01:53</p> <p>17 THE VIDEOGRAPHER: The time is 11:19:18</p> <p>18 approximately 11:21 a.m., Friday, September 11:19:58</p> <p>19 4, 2015. This is tape number three of the 11:20:05</p> <p>20 videotaped deposition of Dr. Jayne Lawrence. 11:20:08</p> <p>21 We are back on the record. 11:20:11</p> <p>22 BY MR. HASFORD: 11:20:13</p>
Page 137	<p>1 Q. Turn if you would, Doctor, to page 5 of your 11:20:13</p> <p>2 declaration and look at paragraph 18. It says, "I 11:20:16</p> <p>3 understand that for claim construction purposes, the 11:20:21</p> <p>4 Court will look to the meaning a person having 11:20:23</p> <p>5 ordinary skill in the art at the time of the 11:20:25</p> <p>6 invention would have ascribed to disputed claim 11:20:28</p> <p>7 terms, in view of the specification and prosecution 11:20:31</p> <p>8 history." 11:20:34</p> <p>9 Do you see that? 11:20:34</p> <p>10 A. I do. 11:20:35</p> <p>11 Q. Do you have an understanding of the 11:20:35</p> <p>12 significance of the plain language of the claims for 11:20:37</p> <p>13 claim construction purposes? 11:20:40</p> <p>14 A. I do. 11:20:43</p> <p>15 Q. What is your understanding? 11:20:44</p> <p>16 A. I thought I put it in there. I'm not an 11:20:52</p> <p>17 attorney. So I have an understanding, but I -- I 11:21:14</p> <p>18 thought I had written it down, but I don't have it 11:21:17</p> <p>19 written down. 11:21:21</p> <p>20 Q. What is your general understanding of the 11:21:23</p> <p>21 significance of the plain language of the claims for 11:21:25</p> <p>22 claim construction purposes? 11:21:28</p>

Page 138	Page 140
<p>1 MR. MARGOLIS: Objection. Vague. 11:21:30</p> <p>2 THE WITNESS: Explain -- to me, it means 11:21:39</p> <p>3 the plain and ordinary means what anybody who 11:21:50</p> <p>4 is skilled in the art would understand to be 11:21:54</p> <p>5 correct. Is that okay? 11:21:57</p> <p>6 Q. I'm just asking for your understanding. Take 11:21:59</p> <p>7 a look at paragraph 19, if you would. And the first 11:22:06</p> <p>8 sentence says, "With respect to the level of 11:22:10</p> <p>9 ordinary skill in the art at the relevant times 11:22:12</p> <p>10 applicable to the subject patents, I understand that 11:22:15</p> <p>11 factors such as the education level of those working 11:22:17</p> <p>12 in the field, the sophistication of the technology, 11:22:20</p> <p>13 the types of problems encountered in the art, the 11:22:23</p> <p>14 prior art solutions to those problems, and the speed 11:22:25</p> <p>15 at which innovations are made may help establish the 11:22:28</p> <p>16 level of skill in the art." 11:22:31</p> <p>17 Do you see that? 11:22:33</p> <p>18 A. I do. 11:22:33</p> <p>19 Q. What is your understanding of the 11:22:34</p> <p>20 sophistication of the technology of the 11:22:36</p> <p>21 patents-in-suit? 11:22:38</p> <p>22 A. Can I just check I've got the correct 11:22:49</p>	<p>1 A. Okay. 11:23:53</p> <p>2 Q. So, let me ask the question again just to be 11:23:53</p> <p>3 clear. 11:23:56</p> <p>4 How complex are the types of problems 11:23:56</p> <p>5 encountered in the art of the patents-in-suit? 11:24:00</p> <p>6 MR. MARGOLIS: Objection. Vague. 11:24:04</p> <p>7 THE WITNESS: I could list some examples 11:24:07</p> <p>8 of formulations that are encountered. 11:24:10</p> <p>9 Q. Please do. 11:24:15</p> <p>10 A. If it's a solution formulation, it's 11:24:18</p> <p>11 important that there are no large particulate 11:24:25</p> <p>12 contaminants in the formulation. If it's a 11:24:30</p> <p>13 suspension formulation, it's important that the 11:24:34</p> <p>14 particles or the suspension are small enough and not 11:24:37</p> <p>15 too large. That could be a problem due to poor 11:24:42</p> <p>16 stability of the formulation. So that's an example 11:24:47</p> <p>17 of a type of problem encountered. 11:24:49</p> <p>18 Q. Are there any other examples? 11:24:52</p> <p>19 A. One very practical problem is getting the 11:24:56</p> <p>20 formulation viscous enough to stay in the eye but 11:25:03</p> <p>21 not too viscous to come out of the eye drop bottle, 11:25:08</p> <p>22 for example. 11:25:13</p>
Page 139	Page 141
<p>1 understanding? So, you're asking me what I think of 11:22:52</p> <p>2 the formulations that are contained in the patents 11:22:55</p> <p>3 at the time of the patents? 11:23:00</p> <p>4 Q. I think that is generally correct. I'm just 11:23:01</p> <p>5 looking for your understanding because you used the 11:23:04</p> <p>6 phrase sophistication of technology here. So then 11:23:06</p> <p>7 my question is what is your understanding of the 11:23:09</p> <p>8 sophistication of the technology of the 11:23:12</p> <p>9 patents-in-suit? 11:23:13</p> <p>10 A. They are relatively simple ophthalmic 11:23:15</p> <p>11 preparations, nothing particularly sophisticated 11:23:22</p> <p>12 about the formulation at all. It contains standard 11:23:25</p> <p>13 ingredients. 11:23:31</p> <p>14 Q. How complex are the types of problems 11:23:31</p> <p>15 encountered in the art of the patents-in-suit? 11:23:33</p> <p>16 MR. MARGOLIS: Objection. Vague. 11:23:38</p> <p>17 THE WITNESS: Could you give me some 11:23:40</p> <p>18 examples of the problems? 11:23:41</p> <p>19 Q. Well, I'm trying to get at your statement 11:23:43</p> <p>20 here. In paragraph 19 you say the types of problems 11:23:46</p> <p>21 encountered in the art. 11:23:49</p> <p>22 Do you see that? 11:23:51</p>	<p>1 Q. Are there any other examples? 11:25:13</p> <p>2 A. We spoke about stability in respect to 11:25:16</p> <p>3 particulates, but there might be stability in the 11:25:24</p> <p>4 container that you choose to put the formulation in, 11:25:26</p> <p>5 there might be problems once you -- there's two 11:25:31</p> <p>6 types of stability. There's the shelf-life 11:25:34</p> <p>7 stability, and then there's the stability once the 11:25:39</p> <p>8 formulation is opened, and they may be -- opened and 11:25:41</p> <p>9 in use, and they may be different, and that is 11:25:44</p> <p>10 something else that you need to consider. 11:25:47</p> <p>11 You need to make sure you're not introducing 11:25:50</p> <p>12 anything damaging that's going to irritate into the 11:25:53</p> <p>13 eye. 11:25:56</p> <p>14 Q. Are there any other examples? 11:25:57</p> <p>15 A. I'm sure there are, but they are the ones 11:26:01</p> <p>16 that I can think of at the moment. 11:26:03</p> <p>17 Q. Take a look at the last sentence in the 11:26:05</p> <p>18 paragraph, and it's going to be at the top of page 11:26:09</p> <p>19 6. The last sentence in paragraph 19 of your 11:26:13</p> <p>20 declaration at the top of page 6, it says, "A person 11:26:16</p> <p>21 of ordinary skill in the art is also a person of 11:26:18</p> <p>22 ordinary creativity, not a robot." 11:26:20</p>

Page 142	<p>1 Do you see that? 11:26:23</p> <p>2 A. I do. 11:26:23</p> <p>3 Q. Why is it significant that a person of 11:26:24</p> <p>4 ordinary skill in the art of the patents-in-suit is 11:26:26</p> <p>5 a person of ordinary creativity, not a robot? 11:26:28</p> <p>6 MR. MARGOLIS: Objection. Lack of 11:26:32</p> <p>7 foundation. 11:26:34</p> <p>8 Q. You may answer. 11:26:35</p> <p>9 A. The person who is skilled in the art has to 11:26:37</p> <p>10 have some ability to problem-solve once problems are 11:26:41</p> <p>11 encountered with the formulation. They should also 11:26:47</p> <p>12 be able to take ideas perhaps from one field and 11:26:52</p> <p>13 apply it to another field. 11:26:57</p> <p>14 Q. And when you say problem-solve, are you 11:26:58</p> <p>15 referring to the problems about which you just 11:27:01</p> <p>16 testified? 11:27:04</p> <p>17 A. It could be wider than that, but yes, that is 11:27:05</p> <p>18 included. 11:27:07</p> <p>19 Q. Okay. Take a look at page 6 of your 11:27:08</p> <p>20 declaration, paragraph 20. 11:27:12</p> <p>21 A. Yes. 11:27:14</p> <p>22 Q. Read that to yourself and let me know when 11:27:15</p>	Page 144	<p>1 definitions that any courts have adopted in other 11:28:16</p> <p>2 cases? 11:28:19</p> <p>3 A. I did not. 11:28:21</p> <p>4 Q. In proposing your definition of a person of 11:28:22</p> <p>5 ordinary skill in the art, did you consider the 11:28:24</p> <p>6 education level of the inventors of the 11:28:26</p> <p>7 patents-in-suit? 11:28:28</p> <p>8 A. Not explicitly. 11:28:38</p> <p>9 Q. What art do you consider relevant to the 11:28:41</p> <p>10 patents-in-suit? 11:28:42</p> <p>11 MR. MARGOLIS: Objection. Vague. 11:28:44</p> <p>12 THE WITNESS: So, "what arts" did you 11:29:01</p> <p>13 say? 11:29:03</p> <p>14 Q. Yes. What art do you consider relevant to 11:29:03</p> <p>15 the patents-in-suit? 11:29:06</p> <p>16 MR. MARGOLIS: Objection. Vague. 11:29:08</p> <p>17 THE WITNESS: It's important that the 11:29:10</p> <p>18 person has a high level of understanding of 11:29:13</p> <p>19 pharmaceutical science, has expertise in 11:29:17</p> <p>20 formulating products, pharmaceuticals in 11:29:22</p> <p>21 general, has experience of conducting a 11:29:29</p> <p>22 research, ideally has experience of 11:29:32</p>
Page 143	<p>1 you're ready. 11:27:23</p> <p>2 A. Yes. 11:27:24</p> <p>3 Q. Do you cite anything in support of your 11:27:24</p> <p>4 proposed definition of a person of ordinary skill in 11:27:27</p> <p>5 the art of the patents-in-suit? 11:27:30</p> <p>6 A. No. 11:27:33</p> <p>7 Q. In proposing your definition of a person of 11:27:34</p> <p>8 ordinary skill in the art, did you consider the 11:27:36</p> <p>9 definitions that any other experts have provided in 11:27:38</p> <p>10 other cases? 11:27:41</p> <p>11 A. I thought very long and hard about this 11:27:45</p> <p>12 definition. It comes from having experience of 11:27:50</p> <p>13 something like the pharmaceutical industry at that 11:27:56</p> <p>14 period and the average qualifications of somebody. 11:27:58</p> <p>15 Q. Okay. My question is just a little 11:28:01</p> <p>16 different. In proposing your definition of a person 11:28:03</p> <p>17 of ordinary skill in the art, did you consider the 11:28:05</p> <p>18 definitions that any other experts have provided in 11:28:07</p> <p>19 other cases? 11:28:10</p> <p>20 A. I did not. 11:28:11</p> <p>21 Q. In proposing your definition of a person of 11:28:12</p> <p>22 ordinary skill in the art, did you consider the 11:28:14</p>	Page 145	<p>1 conducting a research program, which is why 11:29:36</p> <p>2 we talk about the ordinary creativity because 11:29:39</p> <p>3 somebody with a Ph.D. is proven to have those 11:29:43</p> <p>4 skills, and somebody who has experience in 11:29:47</p> <p>5 parenteral -- ideally parenteral formulation. 11:29:52</p> <p>6 Q. As of 2003, would a person of ordinary skill 11:29:55</p> <p>7 in the art of the patents-in-suit have been 11:29:59</p> <p>8 generally aware of U.S. Food &amp; Drug Administration 11:30:01</p> <p>9 regulations? 11:30:04</p> <p>10 A. They would. 11:30:05</p> <p>11 Q. In your opinion, would the inventors of the 11:30:06</p> <p>12 patents-in-suit be considered persons of ordinary 11:30:08</p> <p>13 skill in the art? 11:30:11</p> <p>14 MR. MARGOLIS: Objection. Lack of 11:30:12</p> <p>15 foundation. 11:30:14</p> <p>16 THE WITNESS: I can't answer that 11:30:14</p> <p>17 question. 11:30:16</p> <p>18 Q. In your opinion, would the patent examiner 11:30:17</p> <p>19 who allowed the patents-in-suit be considered a 11:30:19</p> <p>20 person of ordinary skill in the art? 11:30:22</p> <p>21 MR. MARGOLIS: Objection. Lacks 11:30:24</p> <p>22 foundation. 11:30:25</p>

Page 146		Page 148			
1	THE WITNESS: I have no experience of	11:30:29	1	claims and put them into context of the correct --	11:32:19
2	the education level of the person working in	11:30:32	2	I'm not going to explain this very well -- in the	11:32:23
3	the patents office, so I can't answer.	11:30:35	3	correct science or understanding at that time.	11:32:26
4	Q. Would a biomedical engineer be a person of	11:30:37	4	Q. And what is the correct science or	11:32:33
5	ordinary skill in the art of the patents-in-suit?	11:30:40	5	understanding as of 2003 in your view with respect	11:32:35
6	MR. MARGOLIS: Objection. Vague. Calls	11:30:43	6	to the patents-in-suit?	11:32:39
7	for speculation.	11:30:45	7	A. That is a very wide question. It would	11:32:42
8	THE WITNESS: I would have to look at	11:30:47	8	depend, obviously, on the particular aspect of the	11:32:46
9	his CV or her CV to be able to answer that	11:30:50	9	patents you're looking at.	11:32:50
10	one. I'm sorry.	11:30:53	10	Q. What aspects could it touch on?	11:32:51
11	Q. Would a medical doctor be a person of	11:30:54	11	A. Again, that is very wide. I don't know what	11:33:04
12	ordinary skill in the art of the patents-in-suit?	11:30:55	12	you mean by what aspects could it touch on? Sorry.	11:33:08
13	MR. MARGOLIS: Objection. Vague. Calls	11:30:58	13	It's just too vague for me to answer. You need to	11:33:11
14	for speculation.	11:31:00	14	be more specific.	11:33:14
15	THE WITNESS: I really can't answer that	11:31:01	15	Q. Well, as of 2003, what is -- let me strike	11:33:14
16	one either. I suspect most medics won't be,	11:31:04	16	that.	11:33:18
17	but then some medics could be. So I just	11:31:07	17	What is your understanding of the state of	11:33:18
18	can't answer. I don't have the information	11:31:10	18	the art as of 2003 with respect to the	11:33:21
19	in front of me to do that.	11:31:14	19	patents-in-suit?	11:33:24
20	Q. Do you know Dr. Robert O. Williams, III?	11:31:15	20	MR. MARGOLIS: Objection. Vague.	11:33:27
21	A. No.	11:31:19	21	THE WITNESS: That is really hard to	11:33:34
22	Q. Take a look, if you would, at again page 6 of	11:31:19	22	answer. I'm not certain what you are asking	11:33:36
Page 147		Page 149			
1	your declaration, at now paragraph 23. In paragraph	11:31:25	1	me. What aspect of the patents you are	11:33:40
2	23 you state, "I understand that to determine how	11:31:28	2	asking me about.	11:33:42
3	the skilled person would have understood disputed	11:31:30	3	Q. Well, I'm asking you about the patents as a	11:33:43
4	claim language, courts first look to the 'intrinsic	11:31:34	4	whole now. What is your understanding of the state	11:33:46
5	evidence,' the words of the claims themselves, the	11:31:37	5	of the art as of 2003 with respect to the	11:33:48
6	patent specification and the prosecution history. I	11:31:40	6	patents-in-suit?	11:33:50
7	understand that statements in related patent	11:31:44	7	MR. MARGOLIS: Objection. Vague.	11:33:53
8	applications can also be relevant to claim	11:31:46	8	THE WITNESS: It seems like you're	11:34:00
9	construction."	11:31:48	9	asking me about the sophistication and the	11:34:02
10	Do you see that?	11:31:49	10	technology.	11:34:04
11	A. I do.	11:31:49	11	Q. Is that your understanding of the state of	11:34:06
12	Q. Do you have an understanding of the plain and	11:31:50	12	the art?	11:34:08
13	ordinary meaning of the claims of the	11:31:53	13	A. That is part of the state of the art. It's	11:34:09
14	patents-in-suit?	11:31:55	14	not completely the state of the art.	11:34:16
15	A. I thought you already asked that -- I	11:31:56	15	Q. So, what is your understanding of the state	11:34:18
16	answered that. I believe I do.	11:31:59	16	of the art as of 2003 with respect to	11:34:21
17	Q. What is your understanding of the plain and	11:32:01	17	patents-in-suit?	11:34:24
18	ordinary mean of the claims of the patents-in-suit?	11:32:04	18	MR. MARGOLIS: Objection. Vague.	11:34:25
19	MR. MARGOLIS: Objection. Compound.	11:32:07	19	THE WITNESS: I'm really not too sure to	11:34:54
20	Vague.	11:32:09	20	what you are trying to get me to answer. I	11:34:58
21	Q. You may answer.	11:32:10	21	can talk about whether the patents were	11:35:01
22	A. My understanding of that is you take the	11:32:14	22	particularly ground-breaking or whether they	11:35:03

Page 150			Page 152		
1	were more pedestrian, whether they were	11:35:07	1	patents-in-suit in light of the prosecution	11:37:30
2	advancement in the knowledge. I can talk	11:35:10	2	histories?	11:37:32
3	about that, but I don't know if that's what	11:35:13	3	A. Sorry. You have to ask that question again.	11:37:36
4	you mean.	11:35:15	4	Q. Okay. Well, actually, let me -- you	11:37:38
5	Q. My question is a little bit more basic.	11:35:15	5	mentioned the prosecution --	11:37:40
6	Do you have an understanding of the state of	11:35:18	6	A. Yes.	11:37:40
7	the art as of 2003 --	11:35:19	7	Q. -- history in paragraph 23. Do you see that?	11:37:41
8	A. What people were doing formulations with	11:35:21	8	Is it proper for a person of ordinary skill in the	11:37:43
9	ophthalmic, yeah.	11:35:24	9	art to interpret the claims of the patents-in-suit	11:37:45
10	Q. -- with respect to the patents-in-suit?	11:35:24	10	in light of the prosecution histories?	11:37:48
11	A. What people -- I understand what people were	11:35:26	11	A. I believe it is, yes.	11:37:50
12	doing with ophthalmic preparations, yes.	11:35:28	12	Q. And then in the last sentence in that	11:37:52
13	Q. And what is your understanding?	11:35:30	13	paragraph you talk about related patent	11:37:54
14	MR. MARGOLIS: Objection. Vague.	11:35:32	14	applications.	11:37:58
15	THE WITNESS: So, the state of the art	11:35:35	15	Do you see that?	11:37:59
16	at the time, people were really starting to	11:35:37	16	A. Yes.	11:37:59
17	look at more novel formulations to improve	11:35:40	17	Q. And do you understand that claims in related	11:38:00
18	delivery to the eye. The formulation we have	11:35:44	18	patents can also be relevant to claim construction?	11:38:02
19	here is not particularly exciting in terms of	11:35:47	19	A. Yes.	11:38:05
20	novelty.	11:35:52	20	Q. Take a look now at paragraph 24. I want to	11:38:05
21	Q. Do you have any reason to dispute that the	11:35:53	21	direct your attention to the second sentence in that	11:38:11
22	formulations of the patents-in-suit are novel?	11:35:57	22	paragraph, which is the first full sentence at the	11:38:13
Page 151			Page 153		
1	MR. MARGOLIS: Objection. Vague.	11:36:01	1	top of page 7. It says, "I understand that while	11:38:16
2	THE WITNESS: I don't know how to answer	11:36:15	2	courts may rely on extrinsic evidence, it is less	11:38:19
3	that. So the question was specifically do I	11:36:17	3	significant than the patent and prosecution history	11:38:23
4	have any reasons to -- at the time of the	11:36:19	4	in determining the meaning of claim language."	11:38:26
5	patent, there were a large number of aqueous	11:36:22	5	Why is it your understanding that extrinsic	11:38:31
6	continuous phase formulations that contained	11:36:30	6	evidence is less significant than the patent and	11:38:34
7	surfactant, the ingredients of the patent and	11:36:33	7	prosecution history in determining the meaning of	11:38:36
8	drug. That was not -- that was a fairly	11:36:39	8	claim language?	11:38:39
9	typical ophthalmic preparation at the time.	11:36:43	9	A. That's what I've been advised by the	11:38:40
10	Q. Let me go back, actually, to page 6 of your	11:36:54	10	attorneys.	11:38:43
11	declaration, paragraph 23. You refer to the	11:36:57	11	Q. Take a look now at paragraph 25 on page 7.	11:38:44
12	specification in that paragraph.	11:37:02	12	The first sentence says, "I understand that a claim	11:38:50
13	Do you see that?	11:37:04	13	term is indefinite, and therefore the claim is	11:38:53
14	A. 23 or 22?	11:37:05	14	invalid, when the claim read in light of the	11:38:56
15	Q. 23.	11:37:07	15	specification and the prosecution history, fail to	11:38:59
16	A. 23, yes, I do. I do, yes.	11:37:08	16	inform, with a reasonable certainty, those skilled	11:39:01
17	Q. Is it proper for a person of ordinary skill	11:37:10	17	in the art about the scope of the claimed	11:39:05
18	in the art to interpret the claims of the	11:37:13	18	invention."	11:39:08
19	patents-in-suit in light of the specification?	11:37:15	19	Do you see that?	11:39:08
20	A. I think that would be commonly done, yes.	11:37:23	20	A. I do.	11:39:09
21	Q. Is it proper for a person of ordinary skill	11:37:26	21	Q. Is the standard for definiteness whether a	11:39:10
22	in the art to interpret the claims of the	11:37:28	22	claim makes sense to you or whether a claim informs	11:39:13



Page 154		Page 156			
1	with reasonable certainty those skilled in the art	11:39:17	1	Do you see that?	11:41:13
2	about the scope of the claimed invention?	11:39:19	2	A. I do.	11:41:14
3	MR. MARGOLIS: Objection. Vague. Calls	11:39:22	3	Q. What does it mean that bromfenac is a	11:41:14
4	for a legal conclusion.	11:39:25	4	non-steroidal anti-inflammatory drug or NSAID?	11:41:17
5	Q. You may answer.	11:39:28	5	A. That's quite a descriptive name. It is an	11:41:22
6	A. Say it again to make sure I get it correct?	11:39:37	6	anti-inflammatory drug, so it reduces inflammation	11:41:26
7	Q. Well, let me ask it more simply. Is the	11:39:39	7	in the body, so it's very good for things like	11:41:30
8	standard for definiteness whether a claim makes	11:39:41	8	muscle damage, for example. Non-steroidal means it	11:41:35
9	sense to you?	11:39:44	9	is not a steroid. Simple as that.	11:41:39
10	MR. MARGOLIS: Objection. Vague. Calls	11:39:45	10	Q. Do you have an understanding of the physical	11:41:42
11	for a legal conclusion.	11:39:46	11	and chemical properties of bromfenac?	11:41:44
12	THE WITNESS: To me personally?	11:39:48	12	MR. MARGOLIS: Objection. Vague.	11:41:48
13	Q. Correct.	11:39:49	13	THE WITNESS: It is vague. I have some	11:41:50
14	A. If I am somebody that is -- if I know about	11:39:51	14	understanding of the physical properties,	11:41:58
15	the art, it should make sense to me, but it should	11:39:55	15	yes.	11:42:02
16	also make sense to those skilled in the art.	11:39:59	16	Q. With what physical properties of bromfenac	11:42:02
17	Q. Are you a person of ordinary skill in the art	11:40:01	17	are you familiar?	11:42:04
18	or are you a person of something higher than	11:40:03	18	A. I'm familiar with its structure, I'm familiar	11:42:06
19	ordinary skill in the art?	11:40:06	19	with its aqueous solubility are the main two.	11:42:11
20	MR. MARGOLIS: Objection. Vague.	11:40:08	20	Q. What is your understanding of the aqueous	11:42:16
21	THE WITNESS: I consider myself to be an	11:40:10	21	solubility of bromfenac?	11:42:18
22	expert, but I have to understand -- I	11:40:13	22	A. I'm just looking at that definition there.	11:42:20
Page 155		Page 157			
1	obviously still have to understand the terms.	11:40:15	1	and bromfenac sodium salt is actually very water	11:42:23
2	Q. Well, let me go back to the original question	11:40:19	2	soluble. The free acid is far less so. In the	11:42:29
3	then. Is the standard for definiteness whether a	11:40:22	3	literature, there's a lot of debate about the	11:42:35
4	claim makes sense to you personally or whether a	11:40:24	4	absolute levels of those solubilities, but certainly	11:42:39
5	claim informs with reasonable certainty those	11:40:26	5	the free acid is very insoluble compared to the	11:42:42
6	skilled in the art about the scope of the claimed	11:40:29	6	salt.	11:42:47
7	invention?	11:40:31	7	Q. How many different NSAIDs are known to exist?	11:42:47
8	A. It has to inform with reasonable certainty to	11:40:32	8	A. Quite a lot.	11:42:52
9	those skilled in the art about the claimed	11:40:35	9	Q. Do you know how many?	11:42:53
10	invention.	11:40:37	10	A. 20, 30, that sort of number.	11:42:55
11	Q. Take a look, if you would, at page 8,	11:40:37	11	Q. What are some of the different physical and	11:42:58
12	paragraph 32.	11:40:40	12	chemical properties that different NSAIDs possess?	11:43:01
13	A. Yes.	11:40:42	13	MR. MARGOLIS: Objection. Vague. Lack	11:43:05
14	Q. The first sentence says, "The patents-in-suit	11:40:43	14	of foundation.	11:43:07
15	are generally directed to anti-inflammatory	11:40:46	15	THE WITNESS: That is really difficult	11:43:08
16	ophthalmic formulations containing (1)	11:40:49	16	to talk about because there are sub-classes	11:43:10
17	2-amino-3-(4-bromobenzoyl) phenylacetic acid (also	11:40:53	17	of NSAIDs anyway, and they have different	11:43:15
18	known as bromfenac), a non-steroidal	11:40:59	18	structures. So it's slightly open-ended.	11:43:21
19	anti-inflammatory drug ('NSAID'), and (2) tyloxapol,	11:40:59	19	You need to be a little bit more specific.	11:43:25
20	a non-ionic surfactant, and methods for treating an	11:41:07	20	Q. Well -- and thank you for pointing out that	11:43:27
21	inflammatory disease by administering such	11:41:10	21	they have different structures.	11:43:30
22	formulations."	11:41:12	22	Can the physical and chemical properties of	11:43:32

Page 158		Page 160			
1	an NSAID be predicted from the physical and chemical	11:43:34	1	So if it's in water, you may not.	11:45:54
2	properties of a different NSAID with a different	11:43:38	2	There are packages for predicting pKa	11:45:56
3	chemical structure?	11:43:41	3	and log P, not very reliably, but there are	11:45:59
4	MR. MARGOLIS: Objection. Vague. Calls	11:43:42	4	packages. Based on that information, coupled	11:46:03
5	for speculation.	11:43:43	5	with what your dose of the drug is intended,	11:46:07
6	THE WITNESS: It is very vague, but	11:43:46	6	wanted, desired dose of the drug, plus an	11:46:11
7	somebody who is experienced in formulating	11:43:50	7	intended route of administration, you could	11:46:16
8	would be able to look at a drug and the first	11:43:53	8	start to select some solvents and look at	11:46:20
9	approximation be able to expect its	11:44:00	9	solubility.	11:46:24
10	solubility to be insoluble, soluble, very	11:44:03	10	Q. Why would a person of ordinary skill in the	11:46:24
11	soluble.	11:44:08	11	art want to formulate new aqueous liquid	11:46:26
12	Q. Have you ever accurately predicted the	11:44:08	12	preparations of NSAIDs?	11:46:29
13	physical and chemical properties of an NSAID based	11:44:10	13	MR. MARGOLIS: Objection. Lack of	11:46:31
14	on the physical and chemical properties of a	11:44:13	14	foundation. Calls for speculation.	11:46:33
15	different NSAID with a different chemical structure?	11:44:15	15	THE WITNESS: There may be re-purposing	11:46:37
16	A. You would not need to do that.	11:44:17	16	of the drug. They might have decided that	11:46:43
17	Q. Why do different NSAIDs have different	11:44:19	17	the drug could be used for some other	11:46:45
18	physical and chemical properties?	11:44:23	18	purpose, or repositioning. It may be that	11:46:48
19	MR. MARGOLIS: Objection. Lack of	11:44:25	19	the company wants to extend a product line.	11:46:52
20	foundation.	11:44:27	20	There's sort of a whole variety of reasons.	11:46:55
21	THE WITNESS: Because if the drug, if	11:44:32	21	Q. And are all of those part of the innovative	11:46:59
22	the NSAID is going to exert its effect, it's	11:44:41	22	scientific process of drug companies?	11:47:02
Page 159		Page 161			
1	got to work at a particular site in the body,	11:44:44	1	A. They would like to think so, yes.	11:47:04
2	and some structural properties of the drug	11:44:48	2	Q. Is there any limit -- sorry. Let me strike	11:47:08
3	may be important for that interaction. The	11:44:53	3	that and try again.	11:47:12
4	rest of the molecule might not be important.	11:44:55	4	Is there a limit to the number of different	11:47:13
5	Q. How would a person of ordinary skill in the	11:44:59	5	possible ways to formulate aqueous liquid	11:47:16
6	art go about formulating new aqueous liquid	11:45:01	6	preparations of NSAIDs?	11:47:19
7	preparations of NSAIDs?	11:45:05	7	MR. MARGOLIS: Objection. Vague.	11:47:21
8	MR. MARGOLIS: Objection. Vague. Calls	11:45:06	8	THE WITNESS: It is vague, but there are	11:47:24
9	for speculation.	11:45:08	9	a large number of ways you can try to	11:47:29
10	THE WITNESS: Okay. So the question was	11:45:11	10	formulate, some more successful than others.	11:47:32
11	to look at formulating in water?	11:45:13	11	It would depend upon the dose and the route	11:47:42
12	Q. Yes. So, how would a person of ordinary	11:45:17	12	of administration you needed.	11:47:44
13	skill in the art go about formulating new aqueous	11:45:19	13	Q. Would it depend on anything else?	11:47:46
14	liquid preparations of NSAIDs?	11:45:23	14	A. Well, it obviously depends -- well, it	11:47:56
15	MR. MARGOLIS: Objection. Vague. Calls	11:45:26	15	potentially depends upon whether you wanted a salt	11:47:58
16	for speculation.	11:45:28	16	or a free acid or base, but there are other	11:48:02
17	THE WITNESS: Yeah, I can speculate	11:45:29	17	considerations.	11:48:07
18	vaguely. It's the same as any drug. NSAIDs	11:45:32	18	Q. How would a person of ordinary skill in the	11:48:08
19	are no different than any other drug molecule	11:45:37	19	art go about characterizing the physical and	11:48:10
20	you would be looking at. You may have some	11:45:40	20	chemical properties of aqueous liquid preparations	11:48:13
21	physical data such as the measured log P, the	11:45:46	21	of NSAIDs?	11:48:16
22	pKa, its solubility, for instance, in water.	11:45:50	22	MR. MARGOLIS: Objection. Vague.	11:48:19

Page 162		Page 164	
1	Compound.	11:48:22	
2	THE WITNESS: This is -- what you're	11:48:27	1 MR. MARGOLIS: Objection. Vague.
3	asking me to describe effectively is the	11:48:29	2 THE WITNESS: That is vague, and it
4	pre-formulation process. If you wanted to	11:48:31	3 would depend on the formulation route of
5	formulate your drug in aqueous solution, you	11:48:41	4 administration anyway, so.
6	would mix the ingredients that you're	11:48:46	5 Q. Do you have an understanding of the
7	interested in and then assay it in some way	11:48:48	6 pharmacokinetic properties of any aqueous liquid
8	generally as a function of time to see	11:48:54	7 preparations of bromfenac?
9	whether the drug has remained intact, whether	11:49:00	8 MR. MARGOLIS: Objection. Vague.
10	the physical state of the formulation hasn't	11:49:08	9 THE WITNESS: No.
11	changed, et cetera. We've discussed some of	11:49:11	10 Q. Do you have an understanding of the
12	them before, basically. It's no different	11:49:16	11 pharmacodynamic properties of any aqueous liquid
13	than the ones we discussed before.	11:49:17	12 preparations of bromfenac?
14	Q. Any others?	11:49:20	13 MR. MARGOLIS: Objection. Vague.
15	A. I can't remember what I discussed before, to	11:49:21	14 THE WITNESS: No, I don't believe -- no,
16	be honest.	11:49:24	15 I don't believe I do.
17	Q. Okay. Why would a person of ordinary skill	11:49:24	16 Q. Do you have an understanding of the
18	in the art want to characterize the physical and	11:49:29	17 toxicological properties of bromfenac?
19	chemical properties of aqueous liquid preparations	11:49:32	18 MR. MARGOLIS: Objection. Vague.
20	of NSAIDs?	11:49:35	19 THE WITNESS: Again, that really does
21	MR. MARGOLIS: Objection. Lacks	11:49:36	20 depend upon how you're going to formulate it
22	foundation.	11:49:39	21 and route of administration, whether -- about
			22 the toxicology.
Page 163		Page 165	
1	THE WITNESS: If you were formulating an	11:49:42	1 Q. Do you have an understanding of the
2	NSAID or other drug with a view to getting a	11:49:47	2 toxicological properties of any formulation of
3	marketing authorization, you would obviously	11:49:52	3 bromfenac?
4	have to have done the appropriate studies	11:49:55	4 MR. MARGOLIS: Objection. Vague.
5	beforehand to submit to the regulatory	11:49:58	5 THE WITNESS: No. But I have experience
6	authorities to get it on the market. So, at	11:50:01	6 of working off other steroids, and it's not a
7	the very least, you have to do it from a	11:50:03	7 particularly unusual steroid. I'm sorry.
8	regulatory point of view.	11:50:05	8 NSAID. Sorry. I didn't mean to say steroid,
9	Q. Any other reasons?	11:50:07	9 did I.
10	A. By understanding stability or lack of and	11:50:10	10 Q. Do you have an understanding of the
11	what type of lack of stability, you might be able to	11:50:15	11 toxicological properties of any oral formulation of
12	improve your formulation.	11:50:20	12 bromfenac?
13	Q. Any other reasons?	11:50:23	13 A. No.
14	A. I think it gives you an understanding and	11:50:31	14 Q. Do you know the oil and water partition
15	knowledge of the systems you're looking at, and then	11:50:33	15 coefficient of bromfenac?
16	that is building up your database to be able to	11:50:35	16 A. No. I couldn't find it in the search.
17	better formulate. That's what gives somebody skill	11:50:38	17 Q. Do you have -- I'm sorry. Were you finished
18	in the art.	11:50:42	18 with your answer?
19	Q. Any other reasons?	11:50:43	19 A. No. No. I searched for it and I couldn't
20	A. I can't think of any offhand.	11:50:47	20 find it.
21	Q. Do you have an understanding of the	11:50:49	21 Q. Okay. Do you have an understanding of the
22	pharmacokinetic properties of bromfenac?	11:50:51	22 properties of any oral formulations of bromfenac?

Page 166	Page 168
1 MR. MARGOLIS: Objection. Vague. 11:52:35	1 not fact, but that's sort of up to say 15, 20 11:55:12
2 THE WITNESS: Such as? 11:52:40	2 percent for micelles. 11:55:16
3 Q. Any of the properties? 11:52:42	3 Q. What is the critical micelle concentration of 11:55:18
4 MR. MARGOLIS: Objection. Vague. 11:52:53	4 tyloxapol in aqueous liquid preparations? 11:55:20
5 THE WITNESS: I have some understanding 11:52:54	5 A. I can't remember that. I would have to look 11:55:23
6 of some issues around stability and of the 11:52:55	6 that up. 11:55:25
7 solubility as a function of pH, that sort of 11:53:02	7 Q. Have you ever determined the solubilizing 11:55:25
8 thing. That's fairly obvious. 11:53:05	8 capacity of tyloxapol based on the liquid nature of 11:55:28
9 Q. Take a look, if you would, in paragraph 32 11:53:07	9 the micellar core? 11:55:32
10 again of your declaration, page 8. We've talked a 11:53:14	10 A. On the liquid nature of the micellar core? 11:55:35
11 lot about non-ionic surfactants today and tyloxapol, 11:53:20	11 Okay. I have determined the solubility of drugs in 11:55:38
12 and you referred to tyloxapol in paragraph 32 as a 11:53:24	12 tyloxapol micelles. 11:55:44
13 non-ionic surfactant. 11:53:27	13 Q. What drugs? 11:55:44
14 Do you see that? 11:53:29	14 A. Particularly steroids, but a range of drugs, 11:55:46
15 A. Yes. 11:53:30	15 phenylbutazone, which is an anti-inflammatory, 11:55:52
16 Q. What does it mean that tyloxapol is a 11:53:30	16 aspirin, a whole variety of drugs. 11:55:55
17 non-ionic surfactant? 11:53:34	17 Q. Have you ever done that for bromfenac? 11:55:58
18 A. Surfactants are amphiphilic molecules that 11:53:36	18 A. No. 11:56:00
19 have a hydrophobic and a hydrophilic head group and 11:53:42	19 Q. Does tyloxapol form vesicles in aqueous 11:56:01
20 self-assembling solution. They are classified on 11:53:49	20 liquid preparations? 11:56:06
21 the basis and natures of the head group. Two main 11:53:54	21 MR. MARGOLIS: Objection. Vague. 11:56:07
22 classifications are non-ionic and ionic. Ionic can 11:54:00	22 THE WITNESS: No, not to my knowledge. 11:56:12
Page 167	Page 169
1 be positive and negative charged. Non-ionic has no 11:54:08	1 Q. Do you have an understanding of the physical 11:56:14
2 charge. Sometimes lipids are included as non-ionic 11:54:12	2 and chemical properties of tyloxapol? 11:56:15
3 surfactants. These are molecules that have -- are 11:54:16	3 A. Yes, I do. 11:56:18
4 zwitterionic, they're positive and negative charge 11:54:22	4 Q. With what physical and chemical properties of 11:56:19
5 in close proximity. 11:54:24	5 tyloxapol are you familiar? 11:56:21
6 Q. Is tyloxapol a polyethylene oxide surfactant? 11:54:26	6 A. I'm familiar with its -- I don't have the 11:56:25
7 A. Yes, it is. 11:54:31	7 figures in front of me, but I'm familiar with 11:56:29
8 Q. Does tyloxapol form micelles in aqueous 11:54:32	8 properties such as its ability to form micelles, the 11:56:31
9 liquid preparations? 11:54:36	9 size of the micelles, the viscosity, the behavior of 11:56:36
10 A. Yes. 11:54:36	10 those micelles, the upper limit before it changes 11:56:40
11 MR. MARGOLIS: Objection. Vague. 11:54:37	11 phase behavior, its cloud points. 11:56:45
12 Q. Under what circumstances does tyloxapol form 11:54:38	12 Q. How do those properties affect aqueous liquid 11:56:53
13 micelles in aqueous liquid preparations? 11:54:42	13 preparations of NSAIDs that contain tyloxapol? 11:56:58
14 A. At relatively low concentrations it will 11:54:45	14 MR. MARGOLIS: Objection. Lack of 11:57:02
15 self-assemble into micelles. 11:54:48	15 foundation. Vague. 11:57:04
16 Q. At what concentrations will it do that? 11:54:50	16 THE WITNESS: It would be very much 11:57:04
17 MR. MARGOLIS: Objection. Vague. 11:54:54	17 looking on a case-by-case basis. 11:57:08
18 THE WITNESS: I don't have that, but 11:54:56	18 Q. And why would it be very much looking on a 11:57:10
19 certainly it will be -- I don't have the 11:54:58	19 case-by-case basis? 11:57:13
20 exact figures, but I can certainly make an 11:55:02	20 A. Because an understanding of interaction 11:57:16
21 estimate. It will be between point 0, 11:55:04	21 between surfactants and drugs is quite complex. So 11:57:20
22 perhaps 0 one percent, but I don't -- that's 11:55:09	22 you could predict possibly this drug's got low 11:57:27

Page 170		Page 172			
1	solubility, so it may solubilize or it may coat the	11:57:35	1	A. Yes.	11:59:30
2	drug, but you would have to check to prove it	11:57:38	2	Q. Do you see that?	11:59:31
3	unambiguously	11:57:41	3	A. Yes.	11:59:31
4	Q. Can the physical and chemical properties of	11:57:43	4	Q. Is EDTA also known as edetic acid or	11:59:32
5	tyloxapol be predicted from the physical and	11:57:45	5	ethylenediaminetetraacetic acid?	11:59:36
6	chemical properties of a different non-ionic	11:57:48	6	A. Yes.	11:59:37
7	surfactant with a different chemical structure?	11:57:51	7	Q. Have you accurately depicted the chemical	11:59:39
8	MR. MARGOLIS: Objection. Vague.	11:57:55	8	structure of EDTA in paragraph 35 of your	11:59:42
9	THE WITNESS: We've already discussed	11:57:57	9	declaration?	11:59:45
10	this. There are certain rules you can use,	11:58:01	10	A. I believe I have, yes.	11:59:46
11	but it would depend upon the structure you're	11:58:06	11	Q. Take a look, if you would, now at page 11 of	11:59:48
12	talking about. In the absence of a	11:58:12	12	your declaration.	11:59:52
13	structure, it's very hard to say.	11:58:14	13	A. Yes.	11:59:52
14	Q. Have you ever accurately predicted the	11:58:16	14	Q. And let's look at paragraph 42. In the first	11:59:53
15	physical and chemical properties of tyloxapol --	11:58:18	15	two sentences you say, "When present as a salt form,	11:59:56
16	A. Why would?	11:58:18	16	EDTA is generally referred to as an edetate salt.	12:00:00
17	Q. -- based on --	11:58:20	17	Thus, there are four different edetate salts	12:00:03
18	A. Why would I need to?	11:58:21	18	consisting of EDTA and sodium: A monosodium,	12:00:06
19	Q. Sorry. Let me just. Sorry. Let me ask my	11:58:23	19	disodium, trisodium, and tetrasodium edetate salt."	12:00:10
20	question, just so we --	11:58:26	20	Are those true statements?	12:00:15
21	A. Sorry.	11:58:26	21	A. Yes.	12:00:23
22	Q. -- have a clear record. No problem.	11:58:27	22	Q. Is EDTA a well-known chelating agent?	12:00:24
Page 171		Page 173			
1	Have you ever accurately predicted the	11:58:28	1	A. It is.	12:00:29
2	physical and chemical properties of tyloxapol based	11:58:30	2	Q. What does it mean that EDTA is a chelating	12:00:29
3	on the physical and chemical properties of a	11:58:33	3	agent?	12:00:34
4	different non-ionic surfactant with a different	11:58:35	4	A. It will grab particularly ions and interact	12:00:36
5	chemical structure?	11:58:38	5	with them. So, in theory, it could, in theory,	12:00:42
6	MR. MARGOLIS: Objection. Vague.	11:58:39	6	interact with an ion with four positive charges on	12:00:48
7	THE WITNESS: I have used tyloxapol. I	11:58:42	7	it, but it typically is -- it's very well-known to	12:00:53
8	have measured its size, its behavior. I have	11:58:44	8	interact or chelate or sequester things like calcium	12:00:56
9	never had the need to do as you suggest.	11:58:48	9	with two charges.	12:01:00
10	Q. Have you ever determined the membrane active	11:58:52	10	Q. How does EDTA act as a chelating agent?	12:01:01
11	effects of tyloxapol?	11:58:56	11	A. You've got your ion, you've got the charges,	12:01:08
12	A. Not tyloxapol, no.	11:58:58	12	and the negative head groups interact with the	12:01:10
13	Q. Are you familiar with the various equilibrium	11:59:04	13	calcium.	12:01:14
14	phases of tyloxapol in aqueous liquid preparations?	11:59:07	14	Q. In EDTA sodium salt, is it the edetate or is	12:01:15
15	A. Yes.	11:59:10	15	it the sodium that is responsible for chelation?	12:01:20
16	Q. Take a look, if you would, now back to your	11:59:12	16	A. In the what? In the salt? It's the free	12:01:23
17	declaration, page 9, paragraph 35.	11:59:16	17	acids -- it's the acids, the ionized form.	12:01:27
18	A. Yes.	11:59:19	18	Q. The edetate?	12:01:28
19	Q. And you say, "EDTA, otherwise known as edetic	11:59:19	19	A. The ionized form of the edetate, yes.	12:01:30
20	acid or ethylenediaminetetraacetic acid, has the	11:59:23	20	Q. Do both the disodium and tetrasodium salts of	12:01:33
21	following chemical structure:" And then you provide	11:59:27	21	EDTA function as chelating agents?	12:01:37
22	a chemical structure.	11:59:30	22	A. Yes.	12:01:40

Page 174	Page 176
<p>1 Q. With both the disodium and tetrasodium salts 12:01:41</p> <p>2 of EDTA, does the edetate function as a chelating 12:01:44</p> <p>3 agent by binding and sequestering certain metal ions 12:01:48</p> <p>4 in solution? 12:01:53</p> <p>5 A. That's one way it can act as a chelator. 12:01:55</p> <p>6 Q. What other ways can it act? 12:01:58</p> <p>7 A. I don't know. I'm just trying to think. It 12:01:59</p> <p>8 doesn't have to be in solution, I think. I'm just 12:02:02</p> <p>9 trying to think about that one. That's why I 12:02:06</p> <p>10 qualified that. 12:02:08</p> <p>11 Q. What results from the chelation of metal ions 12:02:09</p> <p>12 by the disodium and tetrasodium salts of EDTA? 12:02:12</p> <p>13 MR. MARGOLIS: Objection. Vague. 12:02:17</p> <p>14 THE WITNESS: Sorry? 12:02:18</p> <p>15 Q. What results from the chelation of metal ions 12:02:19</p> <p>16 by the disodium and tetrasodium salts of EDTA? 12:02:21</p> <p>17 A. That's really vague. 12:02:21</p> <p>18 MR. MARGOLIS: Objection. Vague. 12:02:25</p> <p>19 Compound. 12:02:26</p> <p>20 THE WITNESS: That's really vague. I 12:02:26</p> <p>21 don't know how to -- what results? 12:02:27</p> <p>22 Q. Okay. I'm sorry. 12:02:30</p>	<p>1 to the meaning to the term besides the words 12:04:05</p> <p>2 themselves." 12:04:07</p> <p>3 Do you see that? 12:04:08</p> <p>4 A. I do. 12:04:08</p> <p>5 Q. Is it fair to say that the plain language of 12:04:09</p> <p>6 the claims of the patents-in-suit does not limit the 12:04:12</p> <p>7 phrases sodium edetate or EDTA sodium salt to edetic 12:04:15</p> <p>8 acid, tetrasodium salt or tetrasodium edetate? 12:04:20</p> <p>9 MR. MARGOLIS: Objection. Vague. 12:04:24</p> <p>10 THE WITNESS: I believe it does because 12:04:26</p> <p>11 the plain and ordinary language is sodium 12:04:29</p> <p>12 edetate is a particular form of EDTA. It's a 12:04:34</p> <p>13 particular salt of EDTA. 12:04:36</p> <p>14 Q. Do the terms or the -- let me strike that and 12:04:38</p> <p>15 try again. 12:04:40</p> <p>16 Do the phrases edetic acid, tetrasodium salt 12:04:41</p> <p>17 or tetrasodium edetate appear anywhere in the claims 12:04:44</p> <p>18 of the patents-in-suit? 12:04:47</p> <p>19 A. Do the words -- 12:04:49</p> <p>20 Q. Do the phrases edetic acid, tetrasodium salt 12:04:52</p> <p>21 or tetrasodium edetate appear anywhere in the claims 12:04:56</p> <p>22 of the patents-in-suit? 12:04:59</p>
Page 175	Page 177
<p>1 A. Sorry. 12:02:31</p> <p>2 Q. Yeah. Yeah. I apologize. I'm -- so, let me 12:02:32</p> <p>3 try to rephrase it for you. 12:02:36</p> <p>4 What is the result of the chelation process 12:02:37</p> <p>5 by the disodium and tetrasodium salts of EDTA? 12:02:41</p> <p>6 MR. MARGOLIS: Objection. Vague. 12:02:45</p> <p>7 Compound. 12:02:46</p> <p>8 THE WITNESS: In what circumstances? 12:02:47</p> <p>9 Q. In an aqueous liquid preparation. 12:02:49</p> <p>10 MR. MARGOLIS: Same objections. 12:02:52</p> <p>11 THE WITNESS: Yeah. If there are -- if 12:02:53</p> <p>12 there's calcium there, it may bind the 12:03:02</p> <p>13 calcium. 12:03:04</p> <p>14 Q. Okay. I apologize, Doctor. Take a look, if 12:03:15</p> <p>15 you would, at page 11, paragraph 43 of your 12:03:44</p> <p>16 declaration. 12:03:47</p> <p>17 A. Okay. 12:03:48</p> <p>18 Q. And you say, "I have reviewed the 12:03:50</p> <p>19 patents-in-suit, including the specification and the 12:03:54</p> <p>20 claims, and have found the terms 'sodium edetate' 12:03:56</p> <p>21 and 'EDTA sodium salt' used, but there is no 12:03:59</p> <p>22 explanation or definition or any other indication as 12:04:02</p>	<p>1 A. I would have to re-read them again. 12:05:03</p> <p>2 Q. Take as much time as you need. 12:05:06</p> <p>3 A. I'm just -- let me get this right. I'm very 12:05:11</p> <p>4 sorry to ask you yet again. Apologies. 12:05:14</p> <p>5 Q. That's okay. 12:05:17</p> <p>6 A. You're asking do the words sodium -- 12:05:17</p> <p>7 Q. Do the phrases edetic acid, tetrasodium salt 12:05:21</p> <p>8 or tetrasodium edetate appear anywhere in the claims 12:05:26</p> <p>9 of the patents-in-suit? 12:05:29</p> <p>10 A. I already looked at the first two patents, 12:07:01</p> <p>11 and I don't believe they do, but I don't see why 12:07:04</p> <p>12 they would appear because you don't give the full 12:07:06</p> <p>13 names of other chemicals in there either. 12:07:09</p> <p>14 Q. Is it fair to say that the specification of 12:07:12</p> <p>15 the patents-in-suit does not limit the phrases 12:07:14</p> <p>16 sodium edetate or EDTA sodium salt to edetic acid, 12:07:17</p> <p>17 tetrasodium salt or tetrasodium edetate? 12:07:23</p> <p>18 MR. MARGOLIS: Objection. Vague. 12:07:26</p> <p>19 THE WITNESS: I believe it does because 12:07:27</p> <p>20 it is -- sodium edetate and edetate sodium 12:07:30</p> <p>21 salt means something specific. 12:07:35</p> <p>22 Q. Do the patents say that? 12:07:37</p>

Page 178	Page 180
<p>1 MR. MARGOLIS: Objection. Vague. 12:07:42</p> <p>2 THE WITNESS: But they don't give the 12:07:45</p> <p>3 full names of any material. 12:07:48</p> <p>4 Q. The patents-in-suit nowhere use the term 12:07:49</p> <p>5 tetrasodium, do they? 12:07:52</p> <p>6 A. Well, there's no need to use the term 12:07:53</p> <p>7 tetrasodium because I think it's very -- it's 12:07:56</p> <p>8 explicit what they are. 12:07:58</p> <p>9 Q. Is it a fact that the patents-in-suit do not 12:07:59</p> <p>10 use the term tetrasodium? 12:08:02</p> <p>11 A. But they use the term sodium edetate and EDTA 12:08:07</p> <p>12 sodium salt, which is exactly the same material. 12:08:12</p> <p>13 Q. The patents-in-suit don't use the term 12:08:14</p> <p>14 tetrasodium, do they, Doctor? 12:08:17</p> <p>15 A. There's no need to use the term, though. 12:08:19</p> <p>16 Q. Take a look, if you would, at page 11, 12:08:23</p> <p>17 paragraph 44 of your declaration. 12:08:27</p> <p>18 A. Yes. 12:08:29</p> <p>19 Q. The first two sentences say, "I have reviewed 12:08:29</p> <p>20 the prosecution histories of the patents-in-suit and 12:08:33</p> <p>21 note that during prosecution of U.S. Patent No. 12:08:36</p> <p>22 8,129,431, the Applicants stated, '[n]ote that 12:08:39</p>	<p>1 Merck Index in connection with your opinions in this 12:09:48</p> <p>2 case? 12:09:49</p> <p>3 A. Yes. 12:09:49</p> <p>4 Q. And I believe it's Exhibit 2 to your 12:09:50</p> <p>5 declaration. If you could turn there? If I refer 12:09:54</p> <p>6 to Exhibit 2 to your declaration as excerpts from 12:10:00</p> <p>7 the 2001 Merck Index, will you understand what I 12:10:03</p> <p>8 mean? 12:10:06</p> <p>9 A. Yes. 12:10:06</p> <p>10 Q. Okay. Please turn to page 620 of the 2001 12:10:07</p> <p>11 Merck Index which bears Bates number LUPIN018905. 12:10:11</p> <p>12 Do you see entry number 3544 for edetate 12:10:17</p> <p>13 sodium in the 2001 Merck Index? 12:10:24</p> <p>14 A. Yes. 12:10:27</p> <p>15 Q. Do you see the Use designation toward the 12:10:27</p> <p>16 bottom of the entry 3544 for edetate sodium in the 12:10:40</p> <p>17 2001 Merck Index? 12:10:44</p> <p>18 Do you see that? 12:10:51</p> <p>19 A. I do. 12:10:52</p> <p>20 Q. It says, "Use: Sequestering agent: One gram 12:10:53</p> <p>21 complexes 215 milligrams calcium carbonate. Usually 12:11:02</p> <p>22 added to pharmaceuticals in the form of the calcium 12:11:06</p>
Page 179	Page 181
<p>1 sodium tetraborate is also known as borax, and EDTA 12:08:44</p> <p>2 sodium salt is also known as sodium edetate.' This 12:08:47</p> <p>3 statement suggests that 'EDTA sodium salt' is 12:08:51</p> <p>4 synonymous with 'sodium edetate,' but provides no 12:08:54</p> <p>5 further clarification of the meaning of these 12:08:56</p> <p>6 terms." 12:08:59</p> <p>7 A. Um-mm. 12:08:59</p> <p>8 Q. Does the prosecution history of the '431 12:09:00</p> <p>9 patent make clear that EDTA sodium salt is 12:09:02</p> <p>10 synonymous with sodium edetate? 12:09:05</p> <p>11 A. That's what I take the meaning of that 12:09:11</p> <p>12 sentence to be. 12:09:14</p> <p>13 Q. Did you see anywhere in the prosecution 12:09:15</p> <p>14 histories of the patents-in-suit where the phrases 12:09:18</p> <p>15 sodium edetate or EDTA sodium salt were limited to 12:09:21</p> <p>16 the tetrasodium forms? 12:09:25</p> <p>17 MR. MARGOLIS: Objection. Vague. 12:09:28</p> <p>18 THE WITNESS: There was no need to 12:09:32</p> <p>19 because it was very clear what they meant. 12:09:34</p> <p>20 Q. Take a look, if you would, at page 12 of your 12:09:36</p> <p>21 declaration, paragraph 45. 12:09:40</p> <p>22 Are you relying on the 2001 Edition of the 12:09:44</p>	<p>1 disodium salt to prevent calcium-depleting action in 12:11:09</p> <p>2 the body." 12:11:13</p> <p>3 Do you see that? 12:11:14</p> <p>4 A. I do. 12:11:14</p> <p>5 Q. The edetate sodium entry in the 2001 Merck 12:11:15</p> <p>6 Index states that it is usually added to 12:11:20</p> <p>7 pharmaceuticals in the form of a calcium disodium 12:11:21</p> <p>8 salt, correct? 12:11:24</p> <p>9 MR. MARGOLIS: Objection. 12:11:25</p> <p>10 Mischaracterizes the document. 12:11:26</p> <p>11 THE WITNESS: It's talking about a 12:11:27</p> <p>12 different form. It doesn't mean it's a 12:11:29</p> <p>13 sodium edetate. It's not the same thing. 12:11:32</p> <p>14 It's talking about a different material 12:11:34</p> <p>15 altogether. 12:11:36</p> <p>16 Q. But does it say that it's talking about a 12:11:36</p> <p>17 different material? 12:11:38</p> <p>18 A. Well, I think it's quite clear that it's 12:11:38</p> <p>19 talking about different materials because of the -- 12:11:40</p> <p>20 they've got different cast numbers. They've all got 12:11:43</p> <p>21 distinctly different cast numbers. 12:11:50</p> <p>22 Q. The statement about usually added to 12:11:52</p>

Page 182		Page 184			
1	pharmaceuticals in the form of a calcium disodium	12:11:53	1	Edetate Calcium Disodium."	12:13:33
2	salt is specific to entry 3544 for sodium edetate,	12:11:57	2	Do you see that?	12:13:35
3	correct?	12:12:00	3	A. Oh, the bottom left thing, yeah.	12:13:39
4	MR. MARGOLIS: Objection. Vague.	12:12:01	4	Q. Do both the edetate sodium and the edetate	12:13:41
5	THE WITNESS: But it doesn't say -- it	12:12:03	5	disodium entries in the 2001 Merck Index refer to	12:13:44
6	doesn't say that they are synonymous.	12:12:05	6	the calcium disodium salt?	12:13:48
7	Q. But it doesn't say that they are not	12:12:08	7	A. I think you're confusing what I think is	12:13:51
8	synonymous, does it?	12:12:09	8	actually quite clear. Instead of actually	12:13:57
9	A. Well, anybody looking at this would know that	12:12:11	9	reproducing similar structures, somebody who had	12:14:00
10	it was this particular compound that they were	12:12:13	10	some basic knowledge in the area would know the	12:14:03
11	talking about rather than that compound. I'm sorry.	12:12:15	11	difference, the subtle differences between the	12:14:07
12	I'm pointing to that they would know that they were	12:12:17	12	various salt forms.	12:14:10
13	talking about the edetate calcium disodium entry	12:12:20	13	Q. My question is a little simpler than that.	12:14:11
14	3542 rather than 3544, which is the edetate sodium.	12:12:24	14	Do both the edetate sodium and the edetate disodium	12:14:14
15	Q. Let me ask it this way. Is the calcium	12:12:29	15	entries in the 2001 Merck Index refer to the calcium	12:14:17
16	disodium salt of EDTA different from the tetrasodium	12:12:32	16	disodium salt?	12:14:21
17	salt of EDTA?	12:12:36	17	MR. MARGOLIS: Objection. Vague.	12:14:23
18	A. It's the dicalcium salt -- or the calcium	12:12:38	18	THE WITNESS: That's putting words into	12:14:24
19	salt.	12:12:42	19	my mouth because lots of these things are	12:14:26
20	Q. Is the calcium disodium salt of EDTA	12:12:42	20	cross-referenced to each other. It doesn't	12:14:32
21	different from the tetrasodium salt of EDTA?	12:12:45	21	mean they're the same material. That's often	12:14:34
22	A. Yes. They're distinct different chemicals.	12:12:48	22	the case.	12:14:36
Page 183		Page 185			
1	Q. Let me direct your attention to the edetate	12:12:50	1	Q. Well, I'm not trying to put words in your	12:14:37
2	disodium entry in the 2001 Merck Index which spans	12:12:53	2	mouth, Doctor. I'm just asking what the reference	12:14:39
3	the bottom of the left-hand column and the top of	12:12:57	3	teaches.	12:14:41
4	the right-hand column on page 620. It's entry	12:13:00	4	Do both the edetate sodium and edetate	12:14:41
5	number 3543.	12:13:04	5	disodium entries in the 2001 Merck Index refer to	12:14:45
6	Do you see that?	12:13:05	6	the calcium disodium salt?	12:14:48
7	A. Yes.	12:13:06	7	A. I don't think that's a teaching.	12:14:49
8	Q. Let me direct your attention to the last	12:13:07	8	Q. What do you think it is?	12:14:51
9	sentence of the paragraph spanning those two	12:13:09	9	A. I think it's just saving space that they've	12:14:52
10	columns. It says, "For structure, see Edetate	12:13:12	10	got -- why repeat -- reproduce four very similar	12:14:56
11	Calcium Disodium."	12:13:16	11	structures?	12:15:00
12	Do you see that?	12:13:17	12	Q. Take a look back to entry number 3544 for	12:15:00
13	A. Yes. Sorry. This is spanning the two	12:13:19	13	edetate sodium. And I want you to look about	12:15:04
14	columns?	12:13:24	14	halfway down through that entry, the line that	12:15:07
15	Q. Okay. Well, so, entry 3543 spans the two	12:13:24	15	begins with "Versene."	12:15:07
16	columns. It starts at the bottom of the left-hand	12:13:28	16	Do you see that?	12:15:11
17	column --		17	A. Um-mm.	12:15:12
18	A. That's right. Yeah.		18	Q. The second entry says, "Sequestrene."	12:15:12
19	Q. -- and goes to the top of the right-hand		19	Do you see that?	12:15:15
20	column.		20	A. Yes.	12:15:15
21	A. Yeah.		21	Q. Does the 2001 Merck Index identify	12:15:15
22	Q. And then it says, "For structure: See	12:13:31	22	Sequestrene as a synonym for edetate sodium?	12:15:20



Page 186		Page 188	
1	A. Yep, 12:15:27	1	Edition of The Handbook of Pharmaceutical 12:17:37
2	Q. Does the 2001 Merck Index limit Sequestrene 12:15:27	2	Excipients? 12:17:39
3	to the tetrasodium salt? 12:15:32	3	A. I think so. I think that was one of the ones 12:17:40
4	A. I believe it does. 12:15:36	4	that I did. And it's a joint American, British 12:17:43
5	Q. Do the claims of the patents -- let me strike 12:15:39	5	publication between the American Hospital 12:17:48
6	that and try again. 12:15:42	6	Association -- or the American Association of 12:17:52
7	Do the claims of the patents-in-suit refer to 12:15:42	7	Pharmaceutical Industries and the Royal 12:17:55
8	the Merck Index? 12:15:46	8	Pharmaceutical Society. 12:17:57
9	A. No. 12:15:47	9	Q. In 2003, would a person of ordinary skill in 12:17:59
10	Q. Does the specification of the patents-in-suit 12:15:47	10	the art have looked to The Handbook of 12:18:02
11	refer to the Merck Index? 12:15:50	11	Pharmaceutical Excipients -- 12:18:04
12	A. No. This is extrinsic evidence. 12:15:52	12	A. Yes. 12:18:04
13	Q. Do the prosecution histories of the 12:15:55	13	Q. -- when formulating an aqueous liquid 12:18:05
14	patents-in-suit refer to the Merck Index? 12:15:56	14	preparation? 12:18:07
15	A. No. 12:15:59	15	A. Definitely. 12:18:07
16	Q. Take a look back at your declaration now, and 12:16:00	16	Q. In 2003, would a person of ordinary skill in 12:18:08
17	let me direct your attention to page 12 and 12:16:03	17	the art have considered The Handbook of 12:18:18
18	paragraph 47.. 12:16:09	18	Pharmaceutical Excipients an important reference for 12:18:21
19	Are you relying on the 2000 Edition of The 12:16:20	19	formulating an aqueous liquid preparation? 12:18:23
20	Handbook of Pharmaceutical Excipients in connection 12:16:23	20	MR. MARGOLIS: Objection. Vague. 12:18:27
21	with your opinions in this case? 12:16:26	21	THE WITNESS: I think most formulators 12:18:29
22	A. I am. 12:16:27	22	would have had a copy on their desk, a 12:18:31
Page 187		Page 189	
1	Q. And in the first sentence you say, "Another 12:16:27	1	standard reference copy. 12:18:35
2	reference commonly used by a person of skill in the 12:16:29	2	Q. In 2003, would a person of ordinary skill in 12:18:37
3	art to identify excipients in pharmaceutical 12:16:32	3	the art have considered The Handbook of 12:18:39
4	formulations was The Handbook of Pharmaceutical 12:16:35	4	Pharmaceutical Excipients an important reference for 12:18:42
5	Excipients ('Kibbe') by Arthur H. Kibbe, Ph.D. 12:16:38	5	formulating an aqueous liquid preparation? 12:18:43
6	('Kibbe')." 12:16:41	6	A. Yes, it would. 12:18:45
7	Do you see that? 12:16:42	7	MR. MARGOLIS: Objection, Vague. 12:18:47
8	A. I do. 12:16:43	8	Q. Take a look, if you would, now at Exhibit 3 12:18:48
9	Q. Why is it your opinion that the 2000 Edition 12:16:43	9	to your declaration. And if I refer to Exhibit 3 to 12:18:51
10	of The Handbook of Pharmaceutical Excipients was a 12:16:47	10	your declaration as excerpts from the 2000 Edition 12:18:56
11	reference commonly used by a person of ordinary 12:16:50	11	of The Handbook of Pharmaceutical Excipients, will 12:18:59
12	skill in the art to identify excipients in 12:16:52	12	you understand what I mean? 12:19:02
13	pharmaceutical formulations? 12:16:54	13	A. Yes. 12:19:03
14	A. It's a book that is -- this is the third -- I 12:16:58	14	Q. Take a look at page 191. It bears Bates 12:19:05
15	think it's the third edition that we're talking 12:17:03	15	number LUPIN010505. And let me direct your 12:19:09
16	about -- and that when you're looking at formulation 12:17:06	16	attention to part 7. 12:19:15
17	and you want to formulate, there's a few places that 12:17:09	17	A. Yes. 12:19:19
18	you will go to to ensure that those excipients are 12:17:12	18	Q. In that first paragraph the first sentence 12:19:21
19	suitable for pharmaceutical formulation, and the two 12:17:16	19	says, "Edetic acid and edetate salts are used in 12:19:25
20	most common places somebody would go to would be the 12:17:20	20	pharmaceutical formulations, cosmetics, and foods as 12:19:29
21	SGA GRAS List and the handbook, this book. 12:17:31	21	chelating agents; that is, they form stable 12:19:33
22	Q. Have you authored any monographs in the 2000 12:17:32	22	water-soluble complexes (chelates) with alkaline 12:19:36

Page 190		Page 192	
1	earth and heavy metal ions." 12:19:41	1	would. Let me direct your attention to page 14, 12:22:03
2	Does this statement apply to both the 12:19:44	2	paragraph 50. 12:22:08
3	disodium salt of EDTA and the tetrasodium salt of 12:19:46	3	Are you relying on the Burdock reference in 12:22:14
4	EDTA? 12:19:51	4	connection with your opinions in this case? 12:22:16
5	A. Yes. 12:19:52	5	A. I am. 12:22:18
6	Q. The second sentence reads, "The chelated form 12:19:53	6	Q. I believe it's Exhibit 7 in your tabs. If I 12:22:19
7	has few of the properties of the free ion, and for 12:19:56	7	refer to Exhibit 7 -- 12:22:29
8	this reason chelating agents are often described as 12:20:00	8	A. Yes. 12:22:30
9	'removing' ions from solution; this process is also 12:20:04	9	Q. -- to your declaration as the Burdock 12:22:31
10	called sequestering." 12:20:08	10	reference, will you understand what I mean? 12:22:33
11	Does this statement apply to both the 12:20:10	11	A. I will. 12:22:35
12	disodium salt of EDTA and the tetrasodium salt of 12:20:12	12	Q. Take a look, if you would, at page 916 of the 12:22:36
13	EDTA? 12:20:17	13	Burdock reference. It bears Bates number 12:22:40
14	A. Yes. 12:20:23	14	PROLENSA00006182. 12:22:44
15	Q. And then the next sentence says, "The 12:20:24	15	A. Yes. 12:22:48
16	stability of the metal-edetate complex depends on 12:20:26	16	Q. Are you relying on the EDTA disodium entry in 12:22:49
17	the metal ion involved and also on the pH." 12:20:29	17	the Burdock reference in connection with your 12:22:55
18	Does this statement apply to both disodium 12:20:33	18	opinions in this case? 12:22:57
19	edetate and tetrasodium edetate? 12:20:36	19	A. I am. 12:22:58
20	A. It applies to all the edetate salts, yes. 12:20:39	20	Q. The EDTA disodium entry in the Burdock 12:22:59
21	Q. Take a look, if you would, at page 192. It 12:20:42	21	reference lists a number of synonyms for EDTA 12:23:03
22	bears Bates number LUPIN010506. And take a look at 12:20:47	22	disodium. 12:23:06
Page 191		Page 193	
1	number 18, Related Substances. 12:20:55	1	Do you -- 12:23:06
2	A. Um-mm. 12:20:57	2	A. Yes. 12:23:06
3	Q. Does the 2000 Edition of The Handbook of 12:20:59	3	Q. -- see that? Is that a "yes"? 12:23:07
4	Pharmaceutical Excipients identify the disodium salt 12:21:03	4	A. Yes. Sorry. 12:23:10
5	of EDTA and the tetrasodium salt of EDTA as related 12:21:05	5	Q. Back to paragraph 50 now of your 12:23:11
6	substances to edetic acid and edetate salts? 12:21:11	6	declaration -- you might want to put a finger or a 12:23:16
7	A. Yes. 12:21:16	7	tab or something in there. So, paragraph 50 of your 12:23:18
8	Q. Does the 2000 Edition of The Handbook of 12:21:17	8	declaration, third sentence, it says, "The synonyms 12:23:28
9	Pharmaceutical Excipients state that the phrases 12:21:21	9	for 'EDTA, disodium' includes edetate disodium." 12:23:34
10	sodium edetate or EDTA sodium salt are defined to 12:21:22	10	In your opinion, does the Burdock reference 12:23:37
11	exclude the disodium salt of EDTA? 12:21:27	11	state that the synonyms for EDTA disodium include 12:23:39
12	MR. MARGOLIS: Objection. Vague. 12:21:31	12	edetate disodium? 12:23:43
13	THE WITNESS: I'm really very sorry 12:21:33	13	A. Ask the question again? I'm sorry. I lost 12:23:56
14	here. It is very clearly sodium edetate with 12:21:35	14	you. 12:23:58
15	a particular formula of a particular cast 12:21:39	15	Q. Sure. Okay. In your opinion, does the 12:23:58
16	number that's different than another -- than 12:21:41	16	Burdock reference state that the synonyms for EDTA 12:23:59
17	this disodium edetate. They are clearly 12:21:44	17	disodium include edetate disodium? 12:24:03
18	different compounds. If they were the same 12:21:47	18	A. Yes. 12:24:23
19	material or the same name, they would 12:21:54	19	Q. And so if you go back to the EDTA disodium 12:24:24
20	actually make that explicit in here so there 12:21:56	20	entry in the Burdock reference -- 12:24:28
21	would be no confusion. 12:22:00	21	A. Yes. 12:24:30
22	Q. Take a look back at your declaration, if you 12:22:00	22	Q. -- turn now to the next page, page 917, which 12:24:30

Page 194	<p>1 bears Bates number PROLENSA00006183. 12:24:33</p> <p>2 A. Yes. 12:24:39</p> <p>3 Q. And let me direction your attention to the 12:24:40</p> <p>4 fifth line from the top. 12:24:43</p> <p>5 A. Yes. 12:24:44</p> <p>6 Q. Do you see that? 12:24:45</p> <p>7 A. Yes. 12:24:47</p> <p>8 Q. It says "EDTA sodium"? 12:24:47</p> <p>9 A. Yes. 12:24:49</p> <p>10 Q. The Burdock reference states that EDTA sodium 12:24:49</p> <p>11 is a synonym for EDTA disodium. 12:24:52</p> <p>12 A. Yes. 12:24:52</p> <p>13 Q. Do you see that? 12:24:55</p> <p>14 A. I'm aware of that. 12:24:56</p> <p>15 Q. And then down to the fourth line from the 12:24:57</p> <p>16 bottom of the top section of page 917, the line that 12:24:58</p> <p>17 begins with "Sequestrene sodium." 12:25:02</p> <p>18 Do you see that? 12:25:05</p> <p>19 A. Yes. 12:25:05</p> <p>20 Q. And the next entry, the Burdock reference 12:25:06</p> <p>21 states that sodium ethylenediaminetetraacetate is a 12:25:08</p> <p>22 synonym for EDTA disodium. 12:25:13</p>	Page 196	<p>1 collectively as Edetates)." 12:26:27</p> <p>2 Are the salts of EDTA, including the disodium 12:26:29</p> <p>3 salt of EDTA and the tetrasodium salt of EDTA 12:26:32</p> <p>4 collectively known as edetates? 12:26:36</p> <p>5 A. Yes. That's been stated earlier. 12:26:39</p> <p>6 Q. And now take a look, if you would, at page 12:26:41</p> <p>7 96. It bears Bates number LUPIN018914. 12:26:44</p> <p>8 A. Yes. 12:26:50</p> <p>9 Q. And toward the bottom it says, "Tetrasodium 12:26:51</p> <p>10 EDTA." 12:26:57</p> <p>11 Do you see that? 12:26:58</p> <p>12 A. I do. 12:26:59</p> <p>13 Q. In connection with your opinions in this 12:27:01</p> <p>14 case, are you relying on the entry entitled 12:27:03</p> <p>15 "Tetrasodium EDTA" that spans pages 95 -- sorry -- 12:27:06</p> <p>16 96 to 97 of the Lanigan reference? 12:27:10</p> <p>17 A. I am. 12:27:13</p> <p>18 Q. At page 96, the bottom paragraph says, 12:27:14</p> <p>19 "Tetrasodium EDTA is also known as Edetate Sodium." 12:27:19</p> <p>20 And then page 97, the second line says, "EDTA 12:27:25</p> <p>21 Disodium." 12:27:32</p> <p>22 Do you see that? 12:27:32</p>
Page 195	<p>1 Do you see that? 12:25:15</p> <p>2 A. Yes. 12:25:16</p> <p>3 Q. Okay. Take a look now back at -- on your 12:25:16</p> <p>4 declaration, page 13, paragraph 48. 12:25:19</p> <p>5 Are you relying on the Lanigan reference -- 12:25:31</p> <p>6 A. I am. 12:25:34</p> <p>7 Q. -- in connection with your opinions in this 12:25:34</p> <p>8 case? 12:25:36</p> <p>9 And I apologize, Doctor, just for the court 12:25:36</p> <p>10 reporter, if we could wait until I am finished 12:25:38</p> <p>11 asking the question. So, I'll try it again. 12:25:42</p> <p>12 Are you relying on the Lanigan reference in 12:25:43</p> <p>13 connection with your opinions in this case? 12:25:45</p> <p>14 A. I am. 12:25:47</p> <p>15 Q. Okay. Thank you. If I refer to Exhibit 4 to 12:25:47</p> <p>16 your declaration as the Lanigan reference, will you 12:25:52</p> <p>17 understand what I mean? 12:25:53</p> <p>18 A. Yes. Yes. Sorry. 12:25:55</p> <p>19 Q. Take a look at page 95 of the Lanigan 12:26:03</p> <p>20 reference. It bears Bates number LUPIN018913. And 12:26:14</p> <p>21 at the top of the right-hand column, the first full 12:26:20</p> <p>22 sentence starts, "EDTA and its salts (known 12:26:23</p>	Page 197	<p>1 A. Yes. 12:27:33</p> <p>2 Q. In the entry entitled "Tetrasodium EDTA" on 12:27:33</p> <p>3 pages 96 to 97 of the Lanigan reference, does the 12:27:37</p> <p>4 Lanigan reference treat edetate sodium and EDTA 12:27:42</p> <p>5 disodium as one and the same? 12:27:46</p> <p>6 MR. MARGOLIS: Objection. Vague. 12:27:49</p> <p>7 THE WITNESS: Under the -- under the 12:27:51</p> <p>8 heading Trisodium EDTA, you're directing me 12:27:58</p> <p>9 to look at what? 12:28:06</p> <p>10 Q. No. No. I'm directing you to look at the 12:28:07</p> <p>11 second line at the top of page 97. 12:28:09</p> <p>12 Do you see that it says, "EDTA Disodium"? 12:28:13</p> <p>13 A. I do. 12:28:16</p> <p>14 Q. And that's within the entry for Tetrasodium 12:28:16</p> <p>15 EDTA? 12:28:21</p> <p>16 A. Yes. 12:28:21</p> <p>17 Q. Do you see that? 12:28:22</p> <p>18 A. I do. 12:28:22</p> <p>19 Q. Okay. In the entry entitled Tetrasodium EDTA 12:28:22</p> <p>20 on pages 96 to 97 -- 12:28:40</p> <p>21 A. Yes. 12:28:42</p> <p>22 Q. -- of the Lanigan reference, does the Lanigan 12:28:42</p>

Page 198	Page 200
1 reference treat edetate sodium and EDTA disodium as 12:28:45	1 A. Just let me -- I will have to read that. 12:31:09
2 one and the same? 12:28:50	2 Sorry. 12:31:13
3 MR. MARGOLIS: Objection. Vague. 12:28:52	3 It's really small writing. I didn't realize 12:31:34
4 THE WITNESS: I agree with you that it's 12:28:53	4 my eyes were this bad. The edetate sodium has 12:31:37
5 in there. But, quite clearly, it's a 12:28:56	5 Sequestrene NA2 after it. 12:31:41
6 typographical as it is in the other 12:28:58	6 Q. In Lanigan? 12:31:46
7 reference, because if it wasn't a 12:29:01	7 A. No. In the Merck Index. 12:31:48
8 typographical mistake, it would be really 12:29:03	8 Q. In the Merck Index the edetate sodium entry 12:31:51
9 explicit and it wouldn't just be one out of a 12:29:06	9 has Sequestrene without a number, correct? 12:31:55
10 list, in some cases of 30, it would be -- 12:29:10	10 A. In the Merck Index the sodium edetate has 12:31:57
11 there wouldn't be two separate entries. So, 12:29:13	11 Sequestrene without a number, but EDTA sodium has 12:32:00
12 I believe that is clearly a typographical 12:29:15	12 Sequestrene NA2, which is reproduced for -- in The 12:32:06
13 error. 12:29:18	13 Pharmaceutical Handbook under disodium edetate. 12:32:13
14 Q. Do you typically rely on documents that have 12:29:18	14 It's really confusing. 12:32:18
15 typographic errors? 12:29:20	15 Q. Well, let's take another look. 12:32:24
16 A. No. It's very unfortunate, and I must 12:29:22	16 Is it fair to say that this really isn't as 12:32:29
17 apologize. My two primary references were obviously 12:29:29	17 clear as you made out in your earlier testimony? 12:32:31
18 the Merck, which is an encyclopedia, and the 12:29:35	18 A. No. I think there are -- 12:32:33
19 Pharmaceutical Handbook. I could have chosen from a 12:29:39	19 MR. MARGOLIS: Objection. 12:32:33
20 whole list of references, and I, unfortunately, 12:29:43	20 Mischaracterizing testimony. 12:32:35
21 didn't spot these at the time. 12:29:46	21 THE WITNESS: -- are typographical 12:32:35
22 Q. Take a look, if you would, at the Disodium 12:29:48	22 errors, unfortunately. 12:32:37
Page 199	Page 201
1 EDTA entry. 12:29:50	1 I think it is clear. And the reason I'm 12:32:37
2 A. For Lannigan or for -- 12:29:53	2 going to say -- the reason I believe it is 12:32:41
3 Q. From Lannigan. Um-mm. I believe it is on 12:29:54	3 very clear is because if they were synonyms 12:32:42
4 page 96. 12:30:05	4 for each other, you would not be having 12:32:46
5 A. Yes. Um. Yes. 12:30:13	5 separate cast numbers, you would not be 12:32:48
6 Q. And do you see the bottom paragraph of that 12:30:13	6 having separate identifications. 12:32:50
7 entry says, "Synonyms for Disodium EDTA include"? 12:30:15	7 Q. Take a look -- 12:32:52
8 A. Yes. 12:30:21	8 A. And you can buy separate -- and when you buy 12:32:53
9 Q. And then toward the bottom of that it 12:30:22	9 the material, you buy them as separate materials as 12:32:55
10 identifies Sequestrene? 12:30:25	10 well. 12:32:58
11 A. Yes. 12:30:28	11 Q. You've got the documents side-by-side here, 12:32:58
12 Q. Does the Lanigan reference identify 12:30:28	12 correct? 12:33:00
13 Sequestrene as a synonym for disodium EDTA? 12:30:30	13 A. Well, yes. 12:33:02
14 A. I am going to say that I haven't followed 12:30:35	14 Q. And you see on page 3541 of the Merck Index 12:33:03
15 this one through, but it's been very clear when you 12:30:38	15 that entry number 3544 for edetate sodium uses the 12:33:11
16 are talking to me in certain cases some references 12:30:41	16 term Sequestrene with no number, correct? 12:33:16
17 have Sequestrene and a number afterwards, so it's 12:30:44	17 A. Correct. 12:33:18
18 not straightforward and I wouldn't like to comment. 12:30:47	18 Q. And on page 96 of the Lanigan reference, the 12:33:19
19 I'm sorry. 12:30:51	19 disodium EDTA entry also uses Sequestrene in the 12:33:24
20 Q. The Lanigan reference uses the term 12:31:00	20 same way without a number, correct? 12:33:28
21 Sequestrene in the same way that the Merck Index 12:31:02	21 A. Correct. But then if we look at both the 12:33:32
22 uses Sequestrene without a number, correct? 12:31:06	22 Merck and the Pharmaceutical Excipients Handbook, 12:33:35

Page 202		Page 204	
1	they both have Sequestrene NA2 after -- have NA2	12:33:39	1 A. No. 12:35:46
2	after the Sequestrene.	12:33:46	2 Q. Does the specification of the patents-in-suit
3	Q. On page 96 of the Lanigan reference, disodium	12:33:48	3 refer to the Lewis reference? 12:35:49
4	EDTA -- let me strike that and try again.	12:33:52	4 A. No. 12:35:51
5	On page 96 of the Lanigan reference, the	12:33:55	5 Q. Do the prosecution histories of the
6	entry for disodium EDTA identifies as a synonym	12:33:57	6 patents-in-suit refer to the Lewis reference? 12:35:53
7	Sequestrene with no number, correct?	12:34:02	7 A. No. 12:35:55
8	A. That is correct.	12:34:04	8 MR. HASFORD: Actually, I'm going to go
9	Q. Let's take a look back at --	12:34:07	9 to a new exhibit, but I don't know what time
10	A. But that is obviously a typographical error	12:34:10	10 it is. Is this a good time for a lunch break
11	in the basis of both the Merck and the Excipient	12:34:13	11 or are we still -- do we still have a ways to
12	Handbook.	12:34:17	12 go? 12:36:11
13	Q. There's a lot of typographical errors in the	12:34:17	13 MR. MARGOLIS: Well, it's probably about
14	documents on which you're relying, aren't there,	12:34:20	14 time for a break. I guess we can go off the
15	Doctor?	12:34:22	15 record. 12:36:13
16	A. Unfortunately, in the secondary exhibits,	12:34:22	16 MR. HASFORD: Yeah. Why don't we go off
17	yes. In the two main exhibits, no.	12:34:25	17 the record and discuss for just a second
18	Q. Take a look, if you would, at page 13,	12:34:27	18 because I'm going to start into another line
19	paragraph 49 of your declaration.	12:34:32	19 here. 12:36:21
20	Are you relying on the Lewis reference in	12:34:44	20 THE VIDEOGRAPHER: The time is
21	connection with your opinions in this case?	12:34:47	21 approximately 12:37 p.m., Friday, September
22	A. Yes.	12:34:48	22 4th, 2015. This is the end of tape number
Page 203		Page 205	
1	Q. If I refer to Exhibit 6 to your declaration	12:34:49	1 three of the videotaped deposition of Dr.
2	as the Lewis reference, will you understand what I	12:34:52	2 Jayne Lawrence. We are off the record.
3	mean?	12:34:55	3 (Lunch recess from 12:37 to 1:27.)
4	A. Yes.	12:34:55	4 THE VIDEOGRAPHER: Good afternoon. The
5	Q. Turn there, please, and let me direct your	12:34:56	5 time is approximately 1:27 p.m., Friday,
6	attention to page 438. It bears Bates number	12:35:02	6 September 4, 2015. This is tape number four
7	PROLENSA00006191. And at the bottom of the	12:35:06	7 of the videotaped deposition of Dr. Jayne
8	left-hand column, there's an edetate entry.	12:35:14	8 Lawrence. We are back on the record.
9	Do you see that?	12:35:18	9 BY MR. HASFORD: 13:26:12
10	A. Yes.	12:35:19	10 Q. Good afternoon, Doctor. 13:26:12
11	Q. Does the Lewis reference state that edetate	12:35:20	11 A. Good afternoon. 13:26:13
12	refers to "any salt or ester of edetic acid"?	12:35:22	12 Q. Would you please turn to page 20 of your CV
13	A. Yes.	12:35:27	13 for me? Let me direct your attention to item 5
14	Q. Does this statement apply to both the	12:35:28	14 under Articles in Academic Journals. 13:26:22
15	disodium salt of EDTA and the tetrasodium salt of	12:35:32	15 MS. HASFORD: I'm handing the court
16	EDTA?	12:35:33	16 reporter what I would ask to be marked as
17	A. Yes. And I believe that's in my -- that	12:35:34	17 Lawrence Exhibit 2. 13:26:31
18	that's in my report under point 42.	12:35:36	18 For the record, Lawrence Exhibit 2
19	Q. Do the patents -- let me strike that and try	12:35:39	19 corresponds to item number 5 under Articles
20	again.	12:35:42	20 in Academic Journals on Dr. Lawrence's
21	Do the claims of the patents-in-suit refer to	12:35:42	21 curriculum vitae. 13:26:41
22	the Lewis reference?	12:35:45	22 (Whereupon, Plaintiff's Deposition 13:26:41

Page 206			Page 208		
1	Exhibit No. Lawrence 2 was marked for	13:27:04	1	diclofenac sodium and disodium	13:29:27
2	Identification.)	13:27:05	2	ethylenediaminetetraacetate on electrical	13:29:30
3	Q. Is Lawrence Exhibit 2 publication number 5 on	13:27:05	3	parameters of the mucosal membrane and their	13:29:34
4	your curriculum vitae?	13:27:09	4	relation to the permeability enhancing	13:29:37
5	A. Yes.	13:27:12	5	effects in the rat jejunum" by Yamashita,	13:29:40
6	Q. Are you the M.J. Lawrence who co-authored	13:27:12	6	et al, in the J. Pharm. Pharmacol. 1987,	13:29:45
7	Lawrence Exhibit 2?	13:27:16	7	volume 39, pages 621 to 626.	13:29:48
8	A. Yes.	13:27:17	8	(Whereupon, Plaintiff's Deposition	13:30:13
9	Q. Please turn to page 154 of Lawrence Exhibit	13:27:17	9	Exhibit No. Lawrence 3 was marked for	13:30:13
10	2. Let me direct your attention to the first	13:27:26	10	Identification.)	13:30:14
11	sentence of the second paragraph. Would you read	13:27:30	11	Q. Is Lawrence Exhibit 3 the 1987 Yamashita	13:30:14
12	that to yourself, please, and then let me know when	13:27:36	12	article that you cite in reference 47 of Lawrence	13:30:18
13	you're ready.	13:27:37	13	Exhibit 2?	13:30:21
14	A. Okay.	13:27:51	14	A. It looks like it, yes.	13:30:22
15	Q. In Lawrence Exhibit 2 you use the term EDTA	13:27:52	15	Q. Take a look at the first sentence of the	13:30:23
16	and you cite to footnote 47.	13:27:57	16	second paragraph of the body. It starts, "In an	13:30:30
17	Do you see that?	13:27:59	17	earlier report"?	13:30:34
18	A. Yes. To reference 47, yes.	13:28:00	18	A. Yes.	13:30:41
19	Q. Turn, then, to page 167 of Lawrence Exhibit 2	13:28:03	19	Q. Does Lawrence Exhibit 3 use the broad term	13:30:42
20	and take a look at reference 47. Read that to	13:28:08	20	EDTA interchangeably with disodium	13:30:47
21	yourself, if you would, and let me know when you're	13:28:14	21	ethylenediaminetetraacetate which is the disodium	13:30:50
22	ready.	13:28:17	22	salt of EDTA?	13:30:54
Page 207			Page 209		
1	A. Yes, I'm ready.	13:28:17	1	MR. MARGOLIS: Objection. Vague.	13:30:56
2	Q. Reference 47 in Lawrence Exhibit 2 is a 1987	13:28:19	2	THE WITNESS: It's defining -- it's	13:31:03
3	journal article by Yamashita, et al, entitled	13:28:26	3	saying it's going to define disodium -- you	13:31:05
4	"Effects of diclofenac sodium and disodium	13:28:31	4	can say it better than me --	13:31:08
5	ethylenediaminetetraacetate on electrical parameters	13:28:34	5	ethylenediaminetetraacetate as EDTA.	13:31:12
6	of the mucosal membrane and their relation to the	13:28:39	6	Q. You may put this document aside.	13:31:12
7	permeability enhancing effects in the rat jejunum."	13:28:43	7	A. Okay.	13:31:15
8	Do you see that?	13:28:49	8	Q. Take a look now, if you would, back at your	13:31:15
9	A. I do.	13:28:49	9	declaration, and let me direct your attention to	13:31:18
10	Q. Is disodium ethylenediaminetetraacetate the	13:28:49	10	page 15.	13:31:23
11	disodium salt of EDTA?	13:28:54	11	A. Yes.	13:31:25
12	A. Yes.	13:28:57	12	Q. And, in particular, paragraph 58. Are you	13:31:26
13	Q. In Lawrence Exhibit 2 do you use the term	13:28:58	13	relying on the 2000 Edition of Remington's The	13:31:33
14	EDTA broadly to refer to the disodium salt of EDTA?	13:29:01	14	Science and Practice of Pharmacy in connection with	13:31:38
15	A. I think I used it incorrectly.	13:29:05	15	your opinions in this case?	13:31:40
16	Q. Okay. Take a look now -- actually, let me	13:29:07	16	A. Yes.	13:31:42
17	mark a new document.	13:29:09	17	Q. And in the second sentence in paragraph 58 of	13:31:43
18	MR. HASFORD: I'm handing the court	13:29:19	18	your declaration it starts, "For example, the 2000	13:31:47
19	reporter what I ask to be marked as Lawrence	13:29:20	19	edition of Remington's, a reference that would have	13:31:50
20	Exhibit 3.	13:29:22	20	been well-known to the person of ordinary skill in	13:31:53
21	For the record, Lawrence Exhibit 3 is a	13:29:22	21	the art, provides the following definition of	13:31:56
22	copy of the article entitled, "Effects of	13:29:24	22	stability."	13:31:59

Page 210		Page 212		
1	Does the 2000 edition of Remington's provide	13:32:00	1 administration"?	13:34:21
2	a definition of stability of a pharmaceutical	13:32:03	2 A. That's administration into the body by any	13:34:22
3	product?	13:32:06	3 other route than enteral. So it includes	13:34:25
4	A. Yes.	13:32:09	4 ophthalmic, intravenous, intramuscular, et cetera.	13:34:30
5	Q. Does the 2000 edition of Remington's provide	13:32:09	5 Q. Tum, if you would, to Exhibit 8 to your	13:34:34
6	understanding to a person of ordinary skill in the	13:32:13	6 claim construction declaration. If I refer to	13:34:39
7	art of the meaning of stability of a pharmaceutical	13:32:15	7 Exhibit 8 to your declaration as the Vadas	13:34:50
8	product?	13:32:18	8 reference, will you understand what I mean?	13:34:53
9	A. Let me just read the -- can you ask me the	13:32:18	9 A. Yes.	13:34:55
10	question again, please?	13:32:44	10 Q. Now, go back, if you would, to your	13:34:56
11	Q. Certainly.	13:32:44	11 declaration. Please look at paragraphs 53 through	13:35:00
12	A. Yes.	13:32:44	12 72 of your declaration. They span pages 14 through	13:35:04
13	Q. Does the 2000 edition of Remington's provide	13:32:44	13 21. Let me know when you're ready.	13:35:18
14	understanding to a person of ordinary skill in the	13:32:47	14 A. Okay.	13:38:42
15	art of the meaning of stability of a pharmaceutical	13:32:50	15 Q. Do paragraphs 53 through 72 of your	13:38:43
16	product?	13:32:53	16 declaration set forth your opinions in this case on	13:38:47
17	MR. MARGOLIS: Objection. Vague.	13:32:55	17 the claim term "stable" and the phrase "in an amount	13:38:50
18	THE WITNESS: It defines -- it gives a	13:32:59	18 sufficient to stabilize said first component"?	13:38:54
19	good practical definition of stability with	13:33:04	19 A. Yes.	13:38:58
20	somebody skilled in the art in my opinion.	13:33:08	20 Q. In connection with your opinions in this case	13:38:59
21	Q. Okay. And now read the rest of the sentence	13:33:10	21 on the claim term "stable" and the phrase "in an	13:39:01
22	to yourself, that sentence in paragraph 58 of your	13:33:12	22 amount sufficient to stabilize said first	13:39:04
Page 211		Page 213		
1	declaration that spans pages 15 and 16, and let me	13:33:16	1 component," do you cite any item of extrinsic	13:39:07
2	know when you're ready.	13:33:21	2 evidence other than the Vadas reference?	13:39:11
3	A. I'm ready.	13:33:31	3 A. No, I don't.	13:39:21
4	Q. You mention microbiological specifications.	13:33:32	4 Q. Take a look, if you would, back at the Vadas	13:39:25
5	Do you see that?	13:33:35	5 reference, and let me direct your attention to page	13:39:29
6	A. Yes.	13:33:35	6 987. That bears Bates number LUPIN018965. I know	13:39:32
7	Q. Do microbiological specifications deal with	13:33:36	7 the type is kind of small.	13:39:43
8	bacterial and fungal counts?	13:33:41	8 Let me direct your attention to the	13:39:51
9	A. Amongst other things, yes.	13:33:44	9 right-hand column.	13:39:53
10	Q. Does the concept of stability of an aqueous	13:33:45	10 A. Okay.	13:39:54
11	liquid preparation encompass microbiological	13:33:48	11 Q. Does the Vadas reference discuss	13:39:55
12	stability?	13:33:51	12 pharmaceutical product stability?	13:40:00
13	MR. MARGOLIS: Objection. Vague.	13:33:52	13 A. Yes.	13:40:05
14	THE WITNESS: It depends what type of	13:33:54	14 Q. Under that subheading or that title Product	13:40:05
15	liquid formulation.	13:33:56	15 Stability, could you read that first paragraph	13:40:09
16	Q. Under what circumstances does the concept of	13:33:58	16 beginning "Many factors," and let me know when	13:40:11
17	stability of an aqueous liquid preparation encompass	13:34:00	17 you're ready.	13:40:13
18	microbiological stability?	13:34:05	18 A. Okay.	13:40:27
19	A. It would be of particular importance if the	13:34:10	19 Q. Does the Vadas reference state that, "Many	13:40:28
20	formulation was intended for parenteral	13:34:14	20 factors affect the stability of a pharmaceutical	13:40:31
21	administration.	13:34:18	21 product, including the stability of the active	13:40:34
22	Q. What do you mean by "parenteral	13:34:19	22 ingredient or ingredients; the potential interaction	13:40:36

Page 214		Page 216		
1	between active and inactive ingredients; the	13:40:40	1 THE WITNESS: In theory, a researcher	13:42:40
2	manufacturing process; the dosage form; the	13:40:44	2 could decide any conditions, but to do that	13:42:45
3	container-liner-closure system; and the	13:40:48	3 they must be certain that the degradation	13:42:49
4	environmental conditions encountered during	13:40:51	4 instabilities are the same at the	13:42:54
5	shipment, storage, and handling; and length of time	13:40:54	5 temperatures they're measuring it at as the	13:42:56
6	between manufacturing and usage"?	13:40:57	6 one they predict it to be -- as the ones at	13:43:00
7	A. It does.	13:41:00	7 use -- of use.	13:43:04
8	Q. Do you agree with that?	13:41:01	8 Q. Take a look, if you would, at page 990 of the	13:43:05
9	A. They are potential factors affecting	13:41:04	9 Vadas reference, and look at the second full	13:43:10
10	stability, yes.	13:41:08	10 paragraph. The first two sentences read, "Oxidation	13:43:22
11	Q. Take a look now at the bottom of the	13:41:09	11 may be inhibited by the use of antioxidants called	13:43:25
12	right-hand column on page 987 of the Vadas	13:41:11	12 negative catalysts. They are very effective in	13:43:28
13	reference, and let me direct your attention to Table	13:41:16	13 stabilizing pharmaceutical products undergoing a	13:43:32
14	52-1 entitled Stability Protocols.	13:41:19	14 free-radical-mediated chain reaction."	13:43:35
15	A. Yes.	13:41:22	15 Do you see that?	13:43:38
16	Q. Do you see that?	13:41:22	16 A. It -- sorry. I do.	13:43:39
17	A. I do.	13:41:23	17 Q. Does the term stabilizing in this context	13:43:41
18	Q. Does the Vadas reference provide various	13:41:24	18 refer to chemical stability?	13:43:44
19	stability protocols for testing the chemical	13:41:27	19 A. It could be physical as well.	13:43:51
20	stability of a pharmaceutical product?	13:41:29	20 Q. Does the term stabilizing in that context	13:43:53
21	A. It does.	13:41:32	21 encompass chemical stability?	13:43:56
22	Q. Are the stability protocols disclosed in the	13:41:33	22 A. It does.	13:43:58
Page 215		Page 217		
1	Vadas reference the only stability protocols that	13:41:37	1 Q. Are antioxidants added to pharmaceutical	13:44:00
2	can be used for testing the chemical stability of	13:41:39	2 products to prevent chemical degradation?	13:44:03
3	the pharmaceutical product?	13:41:39	3 MR. MARGOLIS: Objection. Vague.	13:44:08
4	A. The chemical?	13:41:39	4 THE WITNESS: To some products they may	13:44:10
5	Q. I'll repeat it. Are the stability protocols	13:41:50	5 be, yes.	13:44:12
6	disclosed in the Vadas reference the only stability	13:41:50	6 Q. Take a look, if you would, at the fourth full	13:44:12
7	protocols that can be used for testing the chemical	13:41:51	7 paragraph.	13:44:17
8	stability of a pharmaceutical product?	13:41:54	8 A. Yes.	13:44:17
9	MR. MARGOLIS: Objection. Vague.	13:41:57	9 Q. And the first sentence says, "The commonly	13:44:18
10	THE WITNESS: There are standardized	13:42:00	10 used antioxidants for aqueous systems include sodium	13:44:21
11	International -- ICH -- International	13:42:07	11 sulfite, sodium metabisulfite, sodium bisulfite,	13:44:25
12	Conference and Harmonization guidelines,	13:42:09	12 sodium thiosulfate, and ascorbic acid."	13:44:30
13	which tend to be used by most -- a lot of	13:42:12	13 Do you see that?	13:44:36
14	regulators and a lot of researchers.	13:42:15	14 A. I do.	13:44:36
15	So, you are correct that there were the	13:42:18	15 Q. Do you agree with the Vadas reference that	13:44:37
16	conditions, but normally people would use the	13:42:21	16 sodium sulfite is a commonly used antioxidant for	13:44:39
17	standardized conditions.	13:42:24	17 aqueous systems?	13:44:43
18	Q. What other conditions besides those disclosed	13:42:26	18 A. That's not actually what the reference is	13:44:48
19	in Table 52-1 of the Vadas reference can be used for	13:42:30	19 saying. It's saying what the most frequent used	13:44:51
20	testing the chemical stability of a pharmaceutical	13:42:35	20 antioxidants are. It's not saying antioxidants are	13:44:53
21	product?	13:42:38	21 commonly used, in my opinion.	13:44:58
22	MR. MARGOLIS: Objection. Vague.	13:42:38	22 Q. Well, it says, "The commonly used	13:44:59



Page 218	<p>1 antioxidants for aqueous systems include sodium 13:45:01</p> <p>2 sulfite." 13:45:01</p> <p>3 Do you see that? 13:45:05</p> <p>4 A. That it is one of the more frequently used. 13:45:05</p> <p>5 What I'm saying is it doesn't tell you that lots of 13:45:08</p> <p>6 formulations have antioxidants in it. That's 13:45:11</p> <p>7 different. 13:45:14</p> <p>8 Q. When, if at all, would a person of ordinary 13:45:15</p> <p>9 skill in the art be motivated to use an antioxidant 13:45:18</p> <p>10 in an aqueous liquid preparation? 13:45:23</p> <p>11 MR. MARGOLIS: Objection. Vague. 13:45:27</p> <p>12 THE WITNESS: If they suspected their 13:45:31</p> <p>13 formulation was going to be unstable in its 13:45:34</p> <p>14 absence. 13:45:39</p> <p>15 Q. Take a look, if you would, at page 992 of the 13:45:40</p> <p>16 Vadas reference. And let me direct your attention 13:45:46</p> <p>17 to the right-hand column and, in particular, the 13:45:50</p> <p>18 last full paragraph and the first three sentences. 13:45:53</p> <p>19 It states, "According to the Arrhenius relationship, 13:45:58</p> <p>20 faster degradation occurs at the higher 13:46:01</p> <p>21 temperatures; hence, assays for the high-temperature 13:46:04</p> <p>22 data usually are run more often but for a shorter 13:46:08</p>	Page 220	<p>1 THE WITNESS: It explains that you can 13:47:24</p> <p>2 misinterpret your data by using the wrong 13:47:29</p> <p>3 analysis. That's what it's telling you. 13:47:32</p> <p>4 Q. Based on the teachings of the Vadas 13:47:35</p> <p>5 reference, would a person of ordinary skill in the 13:47:37</p> <p>6 art understand that chemical stability testing 13:47:39</p> <p>7 results are more reliable at higher temperatures or 13:47:42</p> <p>8 lower temperatures? 13:47:45</p> <p>9 MR. MARGOLIS: Objection. Lack of 13:47:48</p> <p>10 foundation. 13:47:49</p> <p>11 THE WITNESS: That's not possible to 13:47:50</p> <p>12 answer because you're basing that on clearly 13:47:54</p> <p>13 incorrect or deficient analysis of the 13:48:00</p> <p>14 Arrhenius equation. 13:48:04</p> <p>15 It goes on to say that it's better to 13:48:07</p> <p>16 have a weighted least-squares analysis so you 13:48:10</p> <p>17 avoid this effect. 13:48:13</p> <p>18 Q. I'm just asking in general. Based on the 13:48:15</p> <p>19 teachings of the Vadas reference, would a person of 13:48:17</p> <p>20 ordinary skill in the art understand that chemical 13:48:20</p> <p>21 stability testing results are more reliable at 13:48:22</p> <p>22 higher temperatures or lower temperatures? 13:48:25</p>
Page 219	<p>1 period of time. The effect of simple least-squares 13:46:11</p> <p>2 analysis of this type of data is to force the 13:46:17</p> <p>3 Arrhenius equation through the low temperature data 13:46:20</p> <p>4 and essentially ignore the high temperature 13:46:24</p> <p>5 information. Thus, much more credence is placed in 13:46:27</p> <p>6 the point estimates of the low temperature than is 13:46:30</p> <p>7 warranted." 13:46:34</p> <p>8 Do you see that? 13:46:34</p> <p>9 A. Just let me re-read this. Sorry. 13:46:38</p> <p>10 Q. Take as much time as you need to read it to 13:46:41</p> <p>11 yourself and tell me when you're ready. 13:46:44</p> <p>12 A. Okay. 13:46:57</p> <p>13 Q. Does the Vadas reference state that in 13:46:58</p> <p>14 chemical stability testing much more credence is 13:47:01</p> <p>15 placed in the point estimates of the low temperature 13:47:04</p> <p>16 than is warranted? 13:47:06</p> <p>17 A. No, it doesn't. 13:47:08</p> <p>18 Q. Does the Vadas reference teach that chemical 13:47:12</p> <p>19 stability testing results are more reliable at high 13:47:14</p> <p>20 temperatures or low temperatures? 13:47:18</p> <p>21 MR. MARGOLIS: Objection. Lack of 13:47:22</p> <p>22 foundation. 13:47:23</p>	Page 221	<p>1 A. I don't believe it teaches that. I'm sorry. 13:48:27</p> <p>2 Q. Okay. Does the Vadas reference state that 13:48:29</p> <p>3 the term stable is an indefinite term? 13:48:32</p> <p>4 MR. MARGOLIS: Objection. Vague. 13:48:36</p> <p>5 THE WITNESS: It doesn't use legal 13:48:40</p> <p>6 language to define stability, no. 13:48:41</p> <p>7 Q. Does the Vadas reference state that a 13:48:43</p> <p>8 particular threshold under -- let me strike that and 13:48:45</p> <p>9 try again. 13:48:49</p> <p>10 Does the Vadas reference state that a 13:48:50</p> <p>11 particular threshold under particular measurement 13:48:51</p> <p>12 conditions must be specified to permit distinction 13:48:54</p> <p>13 between formulations that are stable and those that 13:48:58</p> <p>14 are not? 13:49:00</p> <p>15 MR. MARGOLIS: Objection. Vague. 13:49:02</p> <p>16 THE WITNESS: Ask the question again? 13:49:22</p> <p>17 Q. Sure. Actually, before I ask that question, 13:49:23</p> <p>18 let me go back to one of your previous answers 13:49:25</p> <p>19 because you mentioned legal language. 13:49:30</p> <p>20 Do you remember that? 13:49:33</p> <p>21 A. Yes. 13:49:33</p> <p>22 Q. Does the Vadas reference state that the term 13:49:34</p>

Page 222	<p>1 stable is a scientifically indefinite term? 13:49:38</p> <p>2 MR. MARGOLIS: Objection. Vague. 13:49:45</p> <p>3 THE WITNESS: I don't understand what -- 13:49:45</p> <p>4 scientifically indefinite term is not a 13:49:48</p> <p>5 phrase I'm familiar with. 13:49:50</p> <p>6 Q. Could there be a circumstance under which a 13:49:53</p> <p>7 term has no scientifically definite meaning? 13:49:57</p> <p>8 A. There are cases where the science perhaps is 13:50:22</p> <p>9 in a debate and people might argue about the 13:50:25</p> <p>10 definition, yes. 13:50:28</p> <p>11 Q. Does the Vadas reference state that the term 13:50:29</p> <p>12 stable is an unclear or incomprehensible term? 13:50:33</p> <p>13 A. No. It does clearly state, however, that you 13:50:38</p> <p>14 have to define what you mean by stability in the 13:50:41</p> <p>15 pharmaceutical context. 13:50:44</p> <p>16 Q. And in your previous answer you talked about 13:50:47</p> <p>17 circumstances under which a term might have no 13:50:50</p> <p>18 scientifically definite meaning. 13:50:53</p> <p>19 Does the Vadas reference state that the term 13:50:55</p> <p>20 stable has no scientifically definite meaning? 13:50:57</p> <p>21 MR. MARGOLIS: Objection. Asked and 13:51:02</p> <p>22 answered. 13:51:04</p>	Page 224	<p>1 that a particular threshold under particular 13:52:12</p> <p>2 measurement conditions must be specified to permit 13:52:15</p> <p>3 distinction between formulations that are stable and 13:52:17</p> <p>4 those that are not? 13:52:20</p> <p>5 A. To remain within its physical, chemical, 13:52:20</p> <p>6 microbiologic, therapeutic and toxicological 13:52:23</p> <p>7 specifications, I believe does answer that -- does 13:52:26</p> <p>8 address it. 13:52:28</p> <p>9 Q. The Vadas reference doesn't state that 13:52:29</p> <p>10 though, does it? 13:52:31</p> <p>11 MR. MARGOLIS: Objection. Vague. 13:52:33</p> <p>12 THE WITNESS: I'm confused now by your 13:54:00</p> <p>13 question because the comments I have in -- in 13:54:04</p> <p>14 quotation marks here, which I just quoted to 13:54:10</p> <p>15 you from about remaining within physical, 13:54:14</p> <p>16 chemical, microbiologic, therapeutic and 13:54:18</p> <p>17 toxicological specifications is a direct 13:54:21</p> <p>18 quote from Vadas. 13:54:25</p> <p>19 Q. Does that quote in the Vadas reference state 13:54:29</p> <p>20 that a particular threshold under particular 13:54:32</p> <p>21 measurement conditions must be specified to permit 13:54:34</p> <p>22 distinction between formulations that are stable and 13:54:37</p>
Page 223	<p>1 THE WITNESS: In as far as it tells you 13:51:05</p> <p>2 that you have to define it yourself, your 13:51:07</p> <p>3 particular conditions required. So that 13:51:13</p> <p>4 means that stability will have a potentially 13:51:15</p> <p>5 different meaning for a different 13:51:20</p> <p>6 pharmaceutical context. 13:51:23</p> <p>7 Q. Take a look, if you would, at -- oh, sorry. 13:51:25</p> <p>8 Let me go back to another question that I asked you. 13:51:30</p> <p>9 You asked me to reask it. 13:51:33</p> <p>10 Does the Vadas reference state that a 13:51:35</p> <p>11 particular threshold under particular measurement 13:51:38</p> <p>12 conditions must be specified to permit distinction 13:51:41</p> <p>13 between formulations that are stable and those that 13:51:46</p> <p>14 are not? 13:51:48</p> <p>15 MR. MARGOLIS: Objection. Vague. 13:51:50</p> <p>16 THE WITNESS: I believe that's what that 13:51:53</p> <p>17 first definition is telling you, that you 13:51:55</p> <p>18 have to have a capability of a particular 13:51:58</p> <p>19 formulation and you define its 13:52:02</p> <p>20 stability and -- and I think that answers the 13:52:05</p> <p>21 question. 13:52:09</p> <p>22 Q. Does the Vadas reference explicitly state 13:52:09</p>	Page 225	<p>1 those that are not? 13:54:40</p> <p>2 A. Why would you have -- otherwise, why would 13:54:43</p> <p>3 you have specifications? You're defining your 13:54:46</p> <p>4 stability and specifying it. And it goes on to give 13:54:52</p> <p>5 other examples of this. 13:54:57</p> <p>6 Q. Take a look back at your declaration, if you 13:55:01</p> <p>7 would, page 16, paragraph 59. And let me direct 13:55:04</p> <p>8 your attention to the second sentence. Read that to 13:55:10</p> <p>9 yourself, if you would, and let me know when you're 13:55:15</p> <p>10 ready. 13:55:18</p> <p>11 A. Okay. 13:55:30</p> <p>12 Q. Are chemical stability and physical stability 13:55:30</p> <p>13 the same or different types of stability? 13:55:33</p> <p>14 A. They're generally considered as different 13:55:40</p> <p>15 types of stability. 13:55:44</p> <p>16 Q. Does the concept of chemical stability deal 13:55:44</p> <p>17 with the propensity toward chemical degradation? 13:55:46</p> <p>18 A. Yes, but it may influence the physical 13:55:55</p> <p>19 stability as a result. I was going to give the 13:56:00</p> <p>20 example of liposomes when they're oxidized they may 13:56:03</p> <p>21 become unstable. So, it's very hard to totally or 13:56:07</p> <p>22 to totally divorce them. 13:56:12</p>

Page 226		Page 228	
1	Q. Generally, does the concept of chemical stability deal with the propensity toward degradation?	13:56:12	13:56:15
2			
3	A. It does.	13:56:17	13:56:18
4			
5	Q. Generally, does the concept of physical stability deal with the propensity toward changes in appearance or other physical properties?	13:56:19	13:56:21
6			
7	A. It does.	13:56:25	13:56:27
8			
9	Q. Take a look, if you would, at page 17 of your declaration, paragraph 61.	13:56:28	13:56:32
10			
11	A. Yes.	13:56:36	13:56:37
12			
13	Q. The first sentence states, "The specification does state that an object of the invention is to provide a formulation that is 'stable within a pH range giving no irritation to the eyes' and that the preservative effect 'does not substantially deteriorate.'"	13:56:40	13:56:45
14			
15	You're referring to the specification of the patents-in-suit, correct?	13:56:49	13:56:52
16			
17	A. Yes.	13:56:54	13:56:57
18			
19	Q. Is that a true statement?	13:56:58	13:57:00
20			
21	A. From -- from the patents? Yes.	13:57:03	13:57:03
22			
Page 227		Page 229	
1	Q. Okay. Take a look now at paragraph 62 in your declaration. And the first sentence states, "Experimental Examples 1 and 2, entitled 'Stability Test of Sodium 2-amino-3-(4-bromobenzoyl) phenylacetate,' disclose specific conditions under which stability may be measured."	13:57:06	13:57:12
2			
3	Is that a true statement?	13:57:15	13:57:19
4			
5	A. Yes.	13:57:26	13:57:28
6			
7	Q. Take a look now at paragraph 63 of your declaration on page 18. You state, "Experimental Example 1 tested four formulations with identical compositions except for variations in the type and amount of surfactant. Comparison Example 1 used 0.15 grams of polysorbate 80, sample A-02 used 0.15 grams of polyoxyl 40 stearate, sample A-02 used 0.15 grams of tyloxapol, and sample A-03 used 0.02 grams of tyloxapol."	13:57:30	13:57:33
8			
9	Is that a true statement?	13:57:34	13:57:38
10			
11	A. It is.	13:57:47	13:57:49
12			
13	Q. And then in the next sentence you say, "Experimental Example 1 also states that the composition containing 0.02 percent weight per volume tyloxapol is 'more stable' than a composition containing 0.15 percent weight per volume tyloxapol."	13:57:53	13:57:58
14			
15	Is that a true statement?	13:58:03	13:58:10
16			
17	A. Yes.	13:58:14	13:58:16
18			
19	Q. Does Experimental Example 1 test against the closest prior art for comparison purposes?	13:58:20	13:58:23
20			
21	MR. MARGOLIS: Objection. Vague. Calls	13:58:26	13:58:26
22			
1	for a legal conclusion,	13:58:29	13:58:33
2	THE WITNESS: What do you consider the closest prior art?	13:58:35	13:58:37
3			
4	Q. What do you consider the closest prior art?	13:58:37	13:58:40
5			
6	MR. MARGOLIS: Objection. Vague.	13:58:40	13:58:44
7			
8	THE WITNESS: I don't have all that information to hand, so I cannot answer.	13:58:44	13:58:46
9			
10	Q. Do you know whether Experimental Example 1 tests against the closest prior art for comparison purposes?	13:58:48	13:58:51
11			
12	MR. MARGOLIS: Objection, Vague. Calls for a legal conclusion. Asked and answered.	13:58:55	13:58:56
13			
14	THE WITNESS: I don't have that information to hand to make that comparison.	13:59:00	13:59:01
15			
16	Q. Take a look, if you would, at page 18 of your declaration, paragraph 64. And the first sentence says that, "The discussion after Experimental Example 1 states that the bromfenac 'in each eye drop was stable in the order of tyloxapol-containing preparation greater than polyoxyl 40 stearate-containing preparation greater than polysorbate 80-containing preparation.'"	13:59:04	13:59:09
17			
18			
19			
20			
21			
22			

Page 230	<p>1 sample A-08 used 0.05 grams of polyoxyl 40 14:00:59</p> <p>2 stearate." 14:01:05</p> <p>3 Is that a true statement? 14:01:05</p> <p>4 A. Yes. 14:01:07</p> <p>5 Q. Take a look now at paragraph 19 -- I'm 14:01:08</p> <p>6 sorry -- page 19, paragraph 66. The first sentence 14:01:12</p> <p>7 states, "Experimental Example 2 states that, with 14:01:16</p> <p>8 certain formulations, the amount of bromfenac in the 14:01:20</p> <p>9 formulation is not less than 90 percent after 14:01:24</p> <p>10 storage at 60 degrees Celsius for four weeks, which 14:01:28</p> <p>11 'indicates that [the tested] compositions have 14:01:33</p> <p>12 sufficient stability for eye drops.'" 14:01:35</p> <p>13 Is that a true statement? 14:01:38</p> <p>14 A. It's a reproduction from the -- yes. 14:01:42</p> <p>15 Q. Take a look, if you would, at page 20 of your 14:01:46</p> <p>16 declaration, paragraph 67. In the first sentence 14:01:50</p> <p>17 you write, "That preparations having a less than 90 14:01:54</p> <p>18 percent remaining rate may also qualify as 'stable' 14:01:57</p> <p>19 is confirmed by the results of Experimental Example 14:02:01</p> <p>20 1, discussed above." 14:02:04</p> <p>21 Is that a true statement? 14:02:06</p> <p>22 A. That's the implications of what's said, yes. 14:02:12</p>
Page 232	<p>1 Q. Correct. 14:05:05</p> <p>2 A. No. 14:05:07</p> <p>3 Q. Did you ever ask anyone whether Lupin has any 14:05:08</p> <p>4 patents using the claim term stable like the 14:05:12</p> <p>5 patents-in-suit? 14:05:14</p> <p>6 A. No. Because, I didn't feel it was relevant 14:05:18</p> <p>7 because I was considering only these patents. 14:05:21</p> <p>8 MR. HASFORD: I'm handing the court 14:05:24</p> <p>9 reporter what I would ask to be marked as 14:05:26</p> <p>10 Lawrence Exhibit 4. 14:05:29</p> <p>11 For the record, Lawrence Exhibit 4 is a 14:05:31</p> <p>12 copy of United States Patent No. 8,192,755. 14:05:33</p> <p>13 (Whereupon, Plaintiff's Deposition 14:05:59</p> <p>14 Exhibit No. Lawrence 4 was marked for 14:05:59</p> <p>15 Identification.) 14:06:01</p> <p>16 Q. If I refer to U.S. Patent No. 8,192,755 as 14:06:01</p> <p>17 the '755 patent, will you understand what I mean? 14:06:08</p> <p>18 A. Yes. 14:06:11</p> <p>19 Q. On the front page of the '755 patent do you 14:06:12</p> <p>20 see that the '755 patent is assigned to Lupin 14:06:15</p> <p>21 Limited? 14:06:19</p> <p>22 A. Yes. 14:06:20</p>
Page 231	<p>1 Q. In the next sentence you say, "All of the 14:02:14</p> <p>2 results of Experimental Example 1 were less than 90 14:02:17</p> <p>3 percent, and the applicants pointed to this example 14:02:20</p> <p>4 to support their claims to 'stable' preparations 14:02:23</p> <p>5 during prosecution." 14:02:26</p> <p>6 Is that a true statement? 14:02:27</p> <p>7 A. Yes. 14:02:29</p> <p>8 Q. Now, look at paragraph 69 on page 20. And I 14:02:30</p> <p>9 want you to read to yourself paragraphs 69, 70 and 14:02:36</p> <p>10 71 spanning over to page 21. 14:02:41</p> <p>11 A. Okay. 14:02:44</p> <p>12 Q. Let me know when you're ready. 14:02:45</p> <p>13 A. Okay. 14:04:33</p> <p>14 Q. In paragraph 69 through 71 of your 14:04:34</p> <p>15 declaration, do you set forth and respond to 14:04:38</p> <p>16 plaintiffs' proposed constructions of the term 14:04:41</p> <p>17 "stable" and the phrase "in an amount sufficient to 14:04:45</p> <p>18 stabilize said first component"?" 14:04:48</p> <p>19 A. I do. 14:04:51</p> <p>20 Q. In paragraph 69 through 71 of your 14:04:51</p> <p>21 declaration, do you cite any document? 14:04:54</p> <p>22 A. If I cite a document to support my claim? 14:04:58</p>
Page 233	<p>1 Q. Are you providing opinions in this case on 14:06:20</p> <p>2 behalf of Lupin Limited? 14:06:23</p> <p>3 A. I am. 14:06:24</p> <p>4 Q. Turn to column 21 of Lupin's '755 patent. 14:06:25</p> <p>5 Let me direct your attention to claim 16. Claim 16 14:06:31</p> <p>6 reads, "A stable improved pharmaceutical composition 14:06:39</p> <p>7 for controlled release of Beta-lactam antibiotic or 14:06:42</p> <p>8 its pharmaceutically acceptable salts, the 14:06:47</p> <p>9 composition comprising a hydrophilic matrix and an 14:06:51</p> <p>10 adjuvant, the adjuvant comprising probenecid, 14:06:56</p> <p>11 wherein the hydrophilic matrix and the adjuvant are 14:07:02</p> <p>12 compressed together into a tablet dosage form or 14:07:07</p> <p>13 compressed separately into tablets and packed in a 14:07:10</p> <p>14 way to be administered simultaneously." 14:07:15</p> <p>15 Do you see that? 14:07:17</p> <p>16 A. I do. 14:07:18</p> <p>17 Q. Claim 16 of Lupin's '755 patent is directed 14:07:18</p> <p>18 to a stable improved pharmaceutical composition. 14:07:22</p> <p>19 Do you see that? 14:07:25</p> <p>20 A. Claim 16, you said? Yes. 14:07:26</p> <p>21 Q. Correct. 14:07:29</p> <p>22 A. Yes. 14:07:30</p>

Page 234		Page 236			
1	Q. Does Lupin's use of the term stable in claim	14:07:30	1	information in there.	14:15:53
2	16 of the '755 patent make that claim invalid for	14:07:33	2	Q. Take a look again at claim 16. Does Lupin's	14:15:54
3	indefiniteness?	14:07:37	3	'755 patent provide a definition of stable as that	14:15:59
4	MR. MARGOLIS: Objection. Lack of	14:07:38	4	claim term is used in claim 16?	14:16:03
5	foundation. Calls for a legal conclusion.	14:07:40	5	MR. MARGOLIS: Objection. Lack of	14:16:07
6	THE WITNESS: Unless I read the whole	14:07:42	6	foundation. Asked and answered.	14:16:08
7	patent and all the claims, I really can't	14:07:44	7	THE WITNESS: Could you repeat the	14:16:11
8	comment on just one claim taken from the	14:07:47	8	question, please?	14:16:13
9	patent. Obviously, that would have to be	14:07:52	9	Q. Sure. Does Lupin's '755 patent provide a	14:16:14
10	examined, but I can't comment definitively	14:07:55	10	definition of the term stable as that term is used	14:16:18
11	one way or another because I have not seen it	14:07:57	11	in claim 16?	14:16:21
12	before.	14:08:00	12	MR. MARGOLIS: Objection. Asked and	14:16:23
13	Q. Well, take as much time as you need to read	14:08:00	13	answered. Calls for a legal conclusion.	14:16:24
14	it.	14:08:02	14	THE WITNESS: I think to make any more	14:16:50
15	A. Okay. Okay.	14:08:03	15	conclusions, I would need to take some legal	14:16:53
16	Q. Does Lupin's use of the term stable in claim	14:13:48	16	advice as to what takes precedence over what.	14:17:00
17	16 of the '755 patent make that claim invalid for	14:13:53	17	So, I don't feel qualified at the present	14:17:03
18	indefiniteness?	14:13:58	18	time having read this so quickly to make a	14:17:06
19	MR. MARGOLIS: Objection. Lack of	14:13:59	19	definitive comment.	14:17:09
20	foundation. Calls for a legal conclusion.	14:14:01	20	Q. And I'm not asking you for a legal	14:17:11
21	Q. You may answer.	14:14:05	21	conclusion.	14:17:13
22	A. Well, I've got a couple of general comments	14:14:08	22	A. No. No.	14:17:13
Page 235		Page 237			
1	from my quick reading of the patent. It normally	14:14:13	1	Q. I'm just asking whether Lupin's '755 patent	14:17:14
2	takes me a lot longer to read the patents.	14:14:18	2	provides a definition of the term stable as that	14:17:18
3	First of all, I don't believe it's a main	14:14:21	3	term is used in claim 16?	14:17:20
4	claim, is it? The main claim of the patent. But	14:14:27	4	MR. MARGOLIS: Objection. Vague. Asked	14:17:23
5	they do specifically define ICH storage conditions.	14:14:31	5	and answered.	14:17:30
6	They do compare before and after.	14:14:39	6	THE WITNESS: I believe there is some an	14:17:31
7	So, while I agree it's not a perfect patent,	14:14:42	7	attempt at a definition.	14:17:35
8	it does have a lot more information than the ones	14:14:46	8	Q. You can put that document aside.	14:17:37
9	we're considering today.	14:14:51	9	A. Okay.	14:17:39
10	Q. Did you see any definition of stable in the	14:14:53	10	Q. Did you ever ask anyone whether Innopharma	14:17:40
11	patent?	14:14:56	11	has any patents or patent applications using the	14:17:43
12	MR. MARGOLIS: Objection. Vague.	14:14:57	12	claim term stabilize of the patents-in-suit?	14:17:46
13	THE WITNESS: "The pharmaceutical	14:15:08	13	A. I did not.	14:17:49
14	composition of claim 1, further comprising a	14:15:12	14	MR. HASFORD: I'm handing the court	14:18:04
15	matrix stabilizing agent; wherein the	14:15:15	15	reporter what I ask to be marked as Lawrence	14:18:05
16	in vitro dissolution characteristics of the	14:15:19	16	Exhibit 5.	14:18:07
17	composition are essentially maintained upon	14:15:29	17	For the record, Lawrence Exhibit 5 is a	14:18:08
18	storage for one month under accelerated	14:15:34	18	copy of U.S. Patent Application Publication	14:18:10
19	stability conditions of 40 degrees and 75	14:15:38	19	No. 2013/0210878.	14:18:14
20	percent relative humidity."	14:15:43	20	(Whereupon, Plaintiff's Deposition	14:18:45
21	I agree it's not the most obvious	14:15:46	21	Exhibit No. Lawrence 5 was marked for	14:18:46
22	definition of stability, but there is some	14:15:51	22	Identification.)	14:18:47

Page 238		Page 240			
1	Q. If I refer to U.S. Patent Application	14:18:47	1	reporter what I would ask to be marked as	14:21:52
2	Publication No. 2013/0210878 as the '878	14:18:52	2	Lawrence Exhibit 6.	14:21:55
3	application, will you understand what I mean?	14:19:00	3	For the record, Lawrence Exhibit 6	14:21:56
4	A. I will.	14:19:02	4	corresponds to item number 6 in the Book	14:21:57
5	Q. On the front page of the '878 application, do	14:19:03	5	Chapters identified in Dr. Lawrence's	14:22:01
6	you see that it is assigned to Innopharma, Inc.?	14:19:07	6	curriculum vitae.	14:22:03
7	A. I do.	14:19:10	7	(Whereupon, Plaintiff's Deposition	14:22:16
8	Q. Are you providing opinions in this case on	14:19:10	8	Exhibit No. Lawrence 6 was marked for	14:22:17
9	behalf of Innopharma?	14:19:13	9	Identification.)	14:22:44
10	A. I am.	14:19:14	10	Q. Does Lawrence Exhibit 6 correspond to item	14:22:44
11	Q. Turn to page 6, claim 10. Read that to	14:19:16	11	number 6 in the Chapters in Books listed on page 19	14:22:47
12	yourself and let me know when you're ready.	14:19:32	12	of your curriculum vitae?	14:22:52
13	A. Claim 6?	14:19:51	13	A. It does.	14:22:54
14	Q. Claim 10.	14:19:51	14	Q. Take a look at page 74 of Lawrence Exhibit 6.	14:22:55
15	A. Page 6. Sorry. Okay.	14:19:53	15	Read that page and let me know when you're ready.	14:23:16
16	Q. Claim 10 of Innopharma's '878 application	14:20:21	16	A. Yes.	14:24:15
17	states that, "The precipitating amount of chloride	14:20:26	17	Q. Let me direct your attention to the first	14:24:16
18	is effective to stabilize Bendamustine in the	14:20:29	18	sentence under Table 3.	14:24:19
19	mixture."	14:20:32	19	A. Yep.	14:24:20
20	Do you see that?	14:20:33	20	Q. You write, "The vesicles have been shown to	14:24:21
21	A. I do.	14:20:34	21	be very stable with respect to time over periods of	14:24:25
22	Q. Does Innopharma's use of the term stabilize	14:20:34	22	several months (Table 3)."	14:24:29
Page 239		Page 241			
1	in claim 10 of the '878 application make that claim	14:20:38	1	Do you see that?	14:24:31
2	invalid for indefiniteness?	14:20:41	2	A. I do.	14:24:32
3	MR. MARGOLIS: Objection. Lack of	14:20:44	3	Q. And then the title of Table 3 is "Stability	14:24:32
4	foundation. Calls for a legal conclusion.	14:20:45	4	of vesicle preparations with respect to size."	14:24:37
5	THE WITNESS: I don't even know what the	14:20:48	5	Do you see that?	14:24:40
6	formulation is. I don't really, if I'm	14:20:50	6	A. I do.	14:24:41
7	honest, even understand that claim.	14:20:54	7	Q. In Lawrence Exhibit 6, do you define a	14:24:41
8	Q. You can put that document aside.	14:20:55	8	particular numerical value at which the vesicles are	14:24:45
9	A. Good.	14:20:57	9	no longer stable?	14:24:49
10	Q. Did you ever tell Lupin's or Innopharma's	14:21:02	10	A. No. This is interesting because the	14:24:51
11	counsel in this case that you have used the term	14:21:05	11	technique it's measured -- this is a paper that is	14:24:54
12	stable in your peer-reviewed publications?	14:21:08	12	actually -- I'll start again. Sorry.	14:24:58
13	MR. MARGOLIS: Hold on one second. I	14:21:12	13	These sizes are determined using PCS, but I	14:25:14
14	just want to caution the witness not to	14:21:14	14	don't know whether I can find that -- people who use	14:25:20
15	reveal communications between yourself	14:21:16	15	PCS would know automatically what this meant, but I	14:25:24
16	and counsel --	14:21:18	16	can't see any methodology. I'm assuming you do know	14:25:30
17	MR. HASFORD: I'm just asking for yes or	14:21:18	17	that these are not peer-reviewed book chapters.	14:25:39
18	no.	14:21:20	18	That's why they are not rated as well in the -- as	14:25:43
19	MR. MARGOLIS: Okay. Just take it	14:21:20	19	a --	14:25:48
20	carefully. You can answer it yes or no.	14:21:21	20	Q. You authored Lawrence Exhibit 6, correct?	14:25:48
21	THE WITNESS: I believe I have.	14:21:26	21	A. I did.	14:25:54
22	MR. HASFORD: I'm handing the court	14:21:49	22	Q. You can put it aside now.	14:25:55

Page 242			Page 244		
1	Let me go to page 22 of your declaration.	14:25:57	1	Q. Do claims 26 through 30 of the '290 patent	14:28:50
2	A. Yes.	14:26:01	2	refer to the preservative efficacy standard of EP	14:28:53
3	Q. And paragraph 74, it says, "The phrase	14:26:01	3	criteria B of the European Pharmacopeia?	14:28:57
4	'satisfied the preservative efficacy standard...'	14:26:10	4	A. They do.	14:29:01
5	appears in claims 25 to 29 of the '131 patent.	14:26:13	5	Q. Why do you believe that claims 29 through 36	14:29:01
6	Claim 25 is copied below." And then you copy claim	14:26:17	6	of the '290 patent refer to the preservative	14:29:05
7	25.	14:26:21	7	efficacy standard of EP criteria B of the European	14:29:08
8	Do you see that?	14:26:22	8	Pharmacopeia?	14:29:12
9	A. I do.	14:26:23	9	MR. MARGOLIS: Objection. Vague. Calls	14:29:14
10	Q. And then in the first sentence of paragraph	14:26:24	10	for speculation.	14:29:16
11	75 you write, "While the claim states that the	14:26:27	11	Q. You may answer.	14:29:17
12	preparation must satisfy the U.S. Pharmacopeia	14:26:29	12	A. Because I checked them.	14:29:22
13	standards ("USP") as follows,' the standards that	14:26:33	13	Q. How did you check them?	14:29:29
14	follow actually appear to reflect the European	14:26:36	14	A. By going and getting the Pharmacopeia	14:29:31
15	Pharmacopeia ('EP') criteria-B standards."	14:26:39	15	standards.	14:29:34
16	Do you see that?	14:26:43	16	Q. Does the plain language of claims 26 through	14:29:35
17	A. I do.	14:26:44	17	30 of the '290 patent refer to the preservative	14:29:39
18	Q. Earlier today you talked about typographical	14:26:45	18	efficacy standard of EP criteria B of the European	14:29:42
19	errors.	14:26:47	19	Pharmacopeia?	14:29:48
20	Do you remember that?	14:26:48	20	A. Could you repeat the question, please?	14:29:51
21	A. I did.	14:26:49	21	Q. Sure. Does the plain language of claims 26	14:29:52
22	Q. And you relied on certain documents that had	14:26:49	22	through 30 of the '290 patent refer to the	14:29:57
Page 243			Page 245		
1	typographical errors in them.	14:26:52	1	preservative efficacy standard of EP criteria B of	14:30:00
2	Do you remember that?	14:26:54	2	the European Pharmacopeia?	14:30:04
3	A. I did.	14:26:55	3	A. In terms of what it says, yes.	14:30:08
4	Q. Would this suggest to a person of ordinary	14:26:55	4	Q. Is the language of claims 26 through 30 of	14:30:11
5	skill in the art that the words U.S. Pharmacopeia in	14:26:58	5	the '290 patent that refers to the preservative	14:30:14
6	claims 25 to 29 of the '131 patent are typographical	14:27:01	6	efficacy standard of EP criteria B of the European	14:30:18
7	errors that should read EP criteria B of the	14:27:05	7	Pharmacopeia consistent with the specification of	14:30:22
8	European Pharmacopeia?	14:27:10	8	the '290 patent?	14:30:24
9	MR. MARGOLIS: Objection. Vague.	14:27:13	9	MR. MARGOLIS: Objection. Vague.	14:30:27
10	THE WITNESS: One moment. It was made	14:27:22	10	THE WITNESS: I'm very sorry. I'm not	14:30:30
11	six consecutive times, though.	14:28:03	11	too certain what you're asking me.	14:30:37
12	Q. You relied on multiple typographic errors in	14:28:05	12	Q. Take a look at Experimental Example 3. You	14:30:39
13	documents that you reviewed today.	14:28:09	13	reviewed Experimental Example 3 in connection with	14:30:43
14	Do you remember that?	14:28:11	14	your opinions in this case, correct?	14:30:46
15	A. A slight difference. It wasn't a consistent	14:28:11	15	A. Yes.	14:30:48
16	error. They were spasmodic.	14:28:14	16	Q. Take a look at it and tell me when you're	14:30:49
17	Q. Let's go to the '290 patent, shall we? It's	14:28:17	17	ready.	14:30:53
18	going to be Exhibit 13, I believe, to your	14:28:21	18	A. I'm ready.	14:30:56
19	declaration. You reviewed claims 26 through 30 of	14:28:24	19	Q. Is the language of claims 26 through 30 of	14:30:57
20	the '290 patent in connection with your opinions in	14:28:38	20	the '290 patent that refers to the preservative	14:31:01
21	this case, correct?	14:28:41	21	efficacy standard of EP criteria B of the European	14:31:03
22	A. Yes.	14:28:49	22	Pharmacopeia consistent with the specification of	14:31:08

Page 246	Page 248
<p>1 the '290 patent? 14:31:11</p> <p>2 MR. MARGOLIS: Objection. Vague. 14:31:13</p> <p>3 THE WITNESS: Why did you ask me to read 14:31:27</p> <p>4 Example 3? I'm sorry. I'm confused. 14:31:31</p> <p>5 MR. MARGOLIS: I think she's looking at 14:31:39</p> <p>6 Example 3 instead of Experimental Example 3. 14:31:41</p> <p>7 Q. You need to look at Experimental Example 3 14:31:44</p> <p>8 which spans column 8 through 10. 14:31:47</p> <p>9 A. Sorry. 14:31:50</p> <p>10 Q. No problem. 14:31:51</p> <p>11 A. Now ask the question? 14:31:51</p> <p>12 Q. Certainly. Certainly. Is the language of 14:31:53</p> <p>13 claims 26 through 30 of the '290 patent that refers 14:31:56</p> <p>14 to the preservative efficacy standard of EP criteria 14:32:00</p> <p>15 B of the European Pharmacopeia consistent with the 14:32:04</p> <p>16 specification of the '290 patent? 14:32:08</p> <p>17 MR. MARGOLIS: Objection. Vague. 14:32:11</p> <p>18 Q. You may answer. 14:32:13</p> <p>19 A. Yes. 14:32:17</p> <p>20 Q. Does the specification of the '290 patent 14:32:18</p> <p>21 inform a person of ordinary skill in the art that 14:32:20</p> <p>22 claims 26 through 30 of the '290 patent that refer 14:32:24</p>	<p>1 Q. Well, my question is a little different. 14:33:39</p> <p>2 Would a person of ordinary skill in the art consider 14:33:41</p> <p>3 the specification of the patents-in-suit when 14:33:43</p> <p>4 interpreting the claims? 14:33:46</p> <p>5 A. They would consult, did you say? 14:33:56</p> <p>6 Q. Consider. 14:33:59</p> <p>7 A. I guess so, yes. Yeah. 14:34:08</p> <p>8 Q. When you reached your conclusion that the 14:34:10</p> <p>9 preservative efficacy claims of the '131 patent were 14:34:12</p> <p>10 indefinite, you did not indicate that you had looked 14:34:16</p> <p>11 at the specification, correct? 14:34:19</p> <p>12 MR. MARGOLIS: Objection. 14:34:20</p> <p>13 Mischaracterizes her declaration. 14:34:21</p> <p>14 THE WITNESS: The specification would 14:34:29</p> <p>15 not have made it any clearer. 14:34:34</p> <p>16 Q. So, when you reached your conclusion that the 14:34:39</p> <p>17 preservative efficacy claims of the '131 patent were 14:34:41</p> <p>18 indefinite, you did not look at the specification, 14:34:45</p> <p>19 correct? 14:34:48</p> <p>20 MR. MARGOLIS: Objection. 14:34:48</p> <p>21 Mischaracterizes her testimony. 14:34:49</p> <p>22 THE WITNESS: I didn't say that, no. 14:34:53</p>
Page 247	Page 249
<p>1 to the preservative efficacy -- sorry. Let me 14:32:28</p> <p>2 strike that and try again. 14:32:32</p> <p>3 Does the specification of the '290 patent 14:32:32</p> <p>4 inform a person of ordinary skill in the art that 14:32:37</p> <p>5 claims 26 through 30 of the '290 patent refer to the 14:32:41</p> <p>6 preservative efficacy standard of EP criteria B of 14:32:44</p> <p>7 the European Pharmacopeia? 14:32:49</p> <p>8 MR. MARGOLIS: Objection. Vague. 14:32:54</p> <p>9 THE WITNESS: Yes. On the condition 14:32:57</p> <p>10 that they got it correct in the 14:32:59</p> <p>11 specifications, obviously. 14:33:03</p> <p>12 Q. And earlier today you confirmed that the 14:33:04</p> <p>13 specification of the '290 patent is essentially the 14:33:07</p> <p>14 same as that of the other patents-in-suit, including 14:33:10</p> <p>15 that of the '131 patent, correct? 14:33:13</p> <p>16 A. It is essentially the same, yes. 14:33:16</p> <p>17 Q. Would a person of ordinary skill in the art 14:33:18</p> <p>18 consider the specification of the patents-in-suit 14:33:20</p> <p>19 with interpreting the claims? 14:33:23</p> <p>20 A. Yes, but the confusion would mean that I have 14:33:27</p> <p>21 to search the primary sources to try and understand 14:33:33</p> <p>22 definitively what's the situation. 14:33:37</p>	<p>1 Q. Your conclusions regarding the preservative 14:34:56</p> <p>2 efficacy claims of the '131 patent are based on less 14:34:59</p> <p>3 than all of the intrinsic evidence, correct? 14:35:03</p> <p>4 MR. MARGOLIS: Objection. 14:35:06</p> <p>5 Mischaracterizes the document. 14:35:07</p> <p>6 THE WITNESS: No, not correct. 14:35:08</p> <p>7 Q. You just testified that the specification of 14:35:09</p> <p>8 this patent informs a skilled artisan that the 14:35:14</p> <p>9 claims refer to the preservative efficacy standard 14:35:18</p> <p>10 of EP criteria B of the European Pharmacopeia. 14:35:21</p> <p>11 Do you remember that? 14:35:24</p> <p>12 MR. MARGOLIS: Objection. 14:35:25</p> <p>13 Mischaracterizes the testimony. 14:35:26</p> <p>14 THE WITNESS: Anybody who is skilled in 14:35:28</p> <p>15 the art would be irresponsible not to go and 14:35:29</p> <p>16 check out with the Pharmacopeia which ones 14:35:35</p> <p>17 were correct. I wouldn't rely on the -- just 14:35:39</p> <p>18 on the patent. 14:35:53</p> <p>19 Q. Take a look again at claims -- at the claims 14:35:56</p> <p>20 of the '131 patent, claims 25 through 29. The test 14:35:59</p> <p>21 conditions set forth in claims 29 through 29 -- let 14:36:24</p> <p>22 me try again. 14:36:24</p>



Page 250		Page 252			
1	The test conditions set forth in claims 25	14:36:31	1	MR. MARGOLIS: Objection. Vague.	14:38:40
2	through 29 of the '131 patent correspond to the	14:36:35	2	THE WITNESS: I read the prosecution	14:38:49
3	preservative efficacy standard of EP criteria B of	14:36:42	3	histories, but I didn't discuss that	14:38:52
4	the European Pharmacopeia, correct?	14:36:46	4	obviously in my report.	14:38:56
5	MR. MARGOLIS: Objection. Vague.	14:36:49	5	Q. Take a look, if you would, at Exhibit 5 to	14:38:57
6	THE WITNESS: Well, I checked them out.	14:36:53	6	your declaration. If I refer to Exhibit 5 to your	14:39:06
7	Yes, that was correct.	14:36:55	7	declaration as the Moser reference, will you	14:39:39
8	Q. Take a look now, if you would, at page 23 of	14:36:56	8	understand what I mean?	14:39:42
9	your declaration, paragraph 76. In the first	14:37:01	9	A. Yes.	14:39:43
10	sentence you write, "While similar, the USP	14:37:16	10	Q. Are you relying on the Moser reference in	14:39:43
11	standards differ in some respects from the EP	14:37:19	11	connection with your opinions in this case?	14:39:46
12	standards."	14:37:21	12	A. I am.	14:39:47
13	Is that a true statement?	14:37:21	13	Q. Does the Moser reference prior art to the	14:39:48
14	A. Yes.	14:37:22	14	patents-in-suit?	14:39:50
15	Q. In the second sentence you write, "The USP	14:37:23	15	MR. MARGOLIS: Objection. Calls for a	14:39:54
16	standards likewise differ from the standards recited	14:37:25	16	legal conclusion.	14:39:56
17	in these claims in several ways, including the	14:37:28	17	THE WITNESS: No, it's not.	14:39:58
18	organisms tested, the times at which data are	14:37:32	18	Q. Take a look at page 226 of the Moser	14:39:59
19	collected, and the permissible limits."	14:37:35	19	reference. It bears Bates number LUPIN018800.	14:40:05
20	Is that a true statement?	14:37:37	20	A. Yes.	14:40:11
21	A. It is.	14:37:38	21	Q. And take a look at the Conclusion and read	14:40:13
22	Q. In the next sentence you write, "For example,	14:37:38	22	the first sentence of the Conclusion to yourself and	14:40:17
Page 251		Page 253			
1	the claim-recited standards require that the	14:37:40	1	let me know when you're ready.	14:40:20
2	bacteria count decrease to 1/1000 at day 7, while	14:37:43	2	A. Yes.	14:40:55
3	the USP standard requires only a 1/10 reduction by	14:37:48	3	Q. Does the Moser reference teach that	14:40:56
4	day 7."	14:37:52	4	preservative efficacy testing for pharmaceutical	14:40:59
5	Is that a true statement?	14:37:53	5	products measures antimicrobial effectiveness?	14:41:02
6	A. It is.	14:37:54	6	A. Well, preservative effectiveness, yes.	14:41:07
7	Q. In the next sentence you write, "As another	14:37:55	7	Q. Does the Moser reference state that the	14:41:10
8	example, the USP requires that E. coli be among the	14:37:57	8	antimicrobial effectiveness or preservative efficacy	14:41:12
9	bacteria tested, while the claim-recited standards	14:38:01	9	test is described in the U.S. Pharmacopeia, the	14:41:16
10	do not."	14:38:04	10	European Pharmacopeia, and the Japanese	14:41:20
11	Is that a true statement?	14:38:05	11	Pharmacopeia?	14:41:23
12	A. It is.	14:38:06	12	A. It does.	14:41:24
13	Q. In the next sentence you write, "Yet	14:38:07	13	Q. Are the U.S. Pharmacopeia, the European	14:41:24
14	another -- the USP requires no increase in fungi	14:38:09	14	Pharmacopeia, and the Japanese Pharmacopeia the	14:41:27
15	counts at days 7, 14 and 28, while the	14:38:13	15	three compendia identified in the Moser reference?	14:41:31
16	claims-recited standards require a 1/10 reduction in	14:38:18	16	A. They are.	14:41:36
17	fungi counts at day 14, but do not require any	14:38:21	17	Q. Take a look at the last sentence of the	14:41:36
18	earlier testing."	14:38:25	18	Conclusion and let me know when you're ready.	14:41:39
19	Is that a true statement?	14:38:26	19	A. Yes.	14:41:44
20	A. It is.	14:38:27	20	Q. In the last sentence of the Conclusion, the	14:41:45
21	Q. Did you consider how claims 25 through 29 of	14:38:30	21	Moser reference states that one preservative	14:41:47
22	the '131 patent were added during prosecution?	14:38:34	22	efficacy test can be performed that satisfies all of	14:41:50

Page 254	Page 256
1 the compendia and their acceptance criteria. 14:41:54	1 enhancement, sometimes by up to tenfold, over that 15:00:37
2 Do you see that? 14:41:57	2 achieved using the more conventional polyethylene 15:00:42
3 A. I do. 14:41:57	3 oxide surfactants." 15:00:45
4 Q. Take a look now, if you would, at the '131 14:41:58	4 Does the art teach that amine-N-oxide 15:00:49
5 patent -- actually, I apologize. Take a look, if 14:42:03	5 surfactants are preferable to polyethylene oxide 15:00:52
6 you would, at page 24 of your declaration, paragraph 14:42:12	6 surfactants for drug solubilization? 15:00:55
7 78. 14:42:24	7 MR. MARGOLIS: Objection. Vague. 15:00:59
8 In paragraph 78 of your declaration, do you 14:42:30	8 THE WITNESS: On the basis of that 15:01:03
9 set forth and respond to plaintiffs' position 14:42:33	9 statement, it's not possible to say. You 15:01:06
10 regarding claims 25 through 29 of the '131 patent? 14:42:36	10 would want more information. I would like to 15:01:09
11 A. I do. 14:42:40	11 explain why. 15:01:12
12 Q. In paragraph 78 of your declaration do you 14:42:41	12 Q. What more information would you want? 15:01:12
13 cite any document? 14:42:43	13 A. For example, are they sensitive to 15:01:15
14 A. No. 14:42:52	14 electrolytes? What is their CMC? So, there is 15:01:19
15 MS. HASFORD: Let's go off the record. 14:42:53	15 other extraneous information there -- there's other 15:01:24
16 We need to do a tape change. And I think 14:42:54	16 extraneous information required to make that 15:01:28
17 we're fairly close to being wrapped up. 14:42:57	17 judgment. 15:01:31
18 THE VIDEOGRAPHER: The time is 14:43:00	18 Q. Is there any other information you would 15:01:32
19 approximately 2:44 p.m., Friday, September 4, 14:43:02	19 want? 15:01:35
20 2015. This is the end of tape number four of 14:43:11	20 A. Effect of temperature on these systems. 15:01:38
21 the videotaped deposition of Dr. Jayne 14:43:15	21 Q. How about pH? 15:01:42
22 Lawrence. We are off the record. 14:43:18	22 A. Yes, pH as well. 15:01:45
Page 255	Page 257
1 (Recess from 2:44 to 3:00.) 14:43:20	1 Q. Anything else? 15:01:48
2 THE VIDEOGRAPHER: The time is 14:58:44	2 A. pH, temperature, dilutability would be 15:01:50
3 approximately 3:00 p.m., Friday, September 4, 14:59:22	3 related to the CMC, electrolyte -- have I said that, 15:01:57
4 2015. This is tape number five of the 14:59:28	4 the presence of electrolyte? That may affect -- 15:02:04
5 videotaped deposition of Dr. Jayne Lawrence. 14:59:32	5 they would be the main information. 15:02:07
6 We are back on the record. 14:59:35	6 Q. You can put that document aside. 15:02:10
7 BY MR. HASFORD: 14:59:36	7 MR. HASFORD: I'm handing the court 15:02:21
8 Q. I want to direct your attention back to 14:59:36	8 reporter what I would ask to be marked as 15:02:23
9 Lawrence Exhibit 6, which was item number 6 in the 14:59:39	9 Lawrence Exhibit 7. 15:02:24
10 Book Chapters on your CV. Turn, if you would, to 14:59:43	10 For the record, Lawrence Exhibit 7 15:02:26
11 page 66 and let me direct your attention to the 14:59:47	11 corresponds to item number 7 in Chapters in 15:02:28
12 second paragraph under heading 2.1 Previous Work. 14:59:50	12 Books on Dr. Lawrence's CV. 15:02:31
13 A. Yes. 14:59:58	13 (Whereupon, Plaintiff's Deposition 15:02:51
14 Q. Okay. It says, "At about the same time as 14:59:59	14 Exhibit No. Lawrence 7 was marked for 15:02:52
15 the studies performed by Elworthy and co-workers, 15:00:02	15 Identification.) 15:02:53
16 other researchers were investigating an alternative 15:00:06	16 Q. Are you the M.J. Lawrence who co-authored 15:02:53
17 approach to increasing micellar solubilization, 15:00:09	17 Lawrence Exhibit 7? 15:03:00
18 which involved replacement of the usual 15:00:13	18 A. I am. 15:03:01
19 polyoxyethylene hydrophile present in most non-ionic 15:00:16	19 Q. Does Lawrence Exhibit 7 correspond to item 15:03:02
20 surfactants with a heterocyclic amine-N-oxide group. 15:00:22	20 number 7 in the Chapters in Books on your curriculum 15:03:04
21 Drug solubilization in the micelles produced by 15:00:28	21 vitae? 15:03:09
22 these amine-N-oxide surfactants showed a significant 15:00:32	22 A. It does. 15:03:09

Page 258		Page 260	
1	Q. Turn, if you would, to page 325 in Lawrence	15:03:10	1 curriculum vitae? 15:05:42
2	Exhibit 7. Let me direct your attention to Section	15:03:13	2 A. It does. 15:05:43
3	11.1. And in the second paragraph it begins,	15:03:18	3 Q. Did Lawrence Exhibit 8 publish in 2000? 15:05:44
4	"Pharmaceutics is an extremely broadly based	15:03:26	4 A. Yes. 15:05:48
5	discipline which takes input from areas as diverse	15:03:30	5 Q. Take a look, if you would, at page 10 of 15:05:49
6	as molecular biology, thermodynamics, and materials	15:03:34	6 Lawrence Exhibit 8. Let me direct your attention to 15:05:53
7	engineering, in order to convert pharmacologically	15:03:39	7 the first full paragraph. And the first sentence 15:05:58
8	active chemicals to medicines. Increasingly, these	15:03:43	8 says, "Sadly, our understanding is not yet 15:06:01
9	medicines are not simple tablets or syrups, but	15:03:46	9 sufficiently advanced that we are able simply to 15:06:04
10	consist of highly sophisticated systems designed to	15:03:49	10 take the covalent structure of a surfactant and from 15:06:07
11	deliver drugs to specific sites and to regulate the	15:03:53	11 this then to predict the 3D structure and properties 15:06:11
12	dose of drug to the patient."	15:03:57	12 of the vesicles it will form." 15:06:15
13	Are ophthalmic formulations highly	15:04:00	13 In 2000, was the state of the art not 15:06:17
14	sophisticated systems designed to deliver drugs to	15:04:03	14 sufficiently advanced to simply take the chemical 15:06:19
15	specific sites and to regulate the dose of drug to	15:04:07	15 structure of a surfactant and from this then predict 15:06:22
16	the patient?	15:04:10	16 the three-dimensional structure and properties of a 15:06:26
17	MR. MARGOLIS: Objection. Vague.	15:04:11	17 surfactant? 15:06:28
18	THE WITNESS: If we're talking about the	15:04:13	18 MR. MARGOLIS: Objection. 15:06:29
19	ophthalmic preparations we're discussing	15:04:15	19 Mischaracterizes the document. 15:06:30
20	today, they're not highly sophisticated.	15:04:19	20 THE WITNESS: I think it was trivial at 15:06:32
21	Q. And I'm asking you generally, are ophthalmic	15:04:22	21 that time to predict it would form vesicles. 15:06:35
22	formulations highly sophisticated systems designed	15:04:26	22 That was fairly routine. What this is 15:06:40
Page 259		Page 261	
1	to deliver drugs to specific sites and to regulate	15:04:29	1 specifically talking about is the 3-D 15:06:44
2	the dose of drug to the patient?	15:04:32	2 structure and resulting properties. That was 15:06:47
3	MR. MARGOLIS: Objection. Vague.	15:04:34	3 harder. And it's particularly dealing with a 15:06:49
4	THE WITNESS: It's really not possible	15:04:36	4 particular system that demonstrated some 15:06:53
5	to answer that. There are some sophisticated	15:04:38	5 quite unusual properties. 15:06:57
6	formulations. There are some very pedestrian	15:04:42	6 Q. When, if ever, did the state of the art 15:06:58
7	type formulations.	15:04:46	7 become sufficiently advanced to simply take the 15:07:01
8	Q. You can put that document aside,	15:04:48	8 chemical structure of a surfactant and from this 15:07:04
9	MR. HASFORD: I'm handing the court	15:05:01	9 then predict the three-dimensional structure of the 15:07:07
10	reporter what I would ask to be marked as	15:05:02	10 properties of the surfactant? 15:07:11
11	Lawrence 8.	15:05:03	11 MR. MARGOLIS: Objection. Vague. And 15:07:13
12	For the record, Lawrence Exhibit 8	15:05:04	12 mischaracterizes her testimony. 15:07:25
13	corresponds to item number 8 in Chapters in	15:05:06	13 Q. You may answer. 15:07:27
14	Books on Dr. Lawrence's curriculum vitae.	15:05:09	14 A. I think great leaps forward have been made 15:07:30
15	(Whereupon, Plaintiff's Deposition	15:05:31	15 with the combination of experimental work coupled 15:07:35
16	Exhibit No. Lawrence 8 was marked for	15:05:32	16 with molecular dynamic simulations, which have 15:07:40
17	Identification.)	15:05:32	17 probably been increasingly available from I guess 15:07:45
18	Q. Are you the M.J. Lawrence who co-authored	15:05:32	18 around the time of this abstract -- this report. 15:07:53
19	Lawrence Exhibit 8?	15:05:35	19 Q. When did the great leaps forward take place? 15:07:58
20	A. I am.	15:05:36	20 A. When computing power got sufficiently 15:08:04
21	Q. Does Lawrence Exhibit 8 correspond to item	15:05:36	21 advanced to be able to perform the difficult 15:08:08
22	number 8 in the Chapters in Books section of your	15:05:39	22 calculations that are required, difficult and 15:08:10

Page 262	Page 264
1 time-consuming calculations required to do the 3-D 15:08:15	1 foundation. 15:10:52
2 modeling. 15:08:19	2 THE WITNESS: Yeah, taking all 15:10:53
3 Q. Do you remember what year that was? 15:08:19	3 formulations, including intravenous 15:10:55
4 A. No. And to be honest with you, it probably 15:08:23	4 formulations for which these surfactants are 15:10:59
5 varied depending whether somebody had access to a 15:08:28	5 particularly suitable, I believe that to be 15:11:02
6 Super Computer and was doing the calculations on 15:08:31	6 true. 15:11:05
7 that or doing them on a little lap-based computer. 15:08:33	7 Q. You can put that document aside. 15:11:05
8 Q. You can put that aside. 15:08:36	8 MR. HASFORD: I'm handing the court 15:11:31
9 MR. HASFORD: I'm handing the court 15:09:00	9 reporter what I would ask to be marked as 15:11:33
10 reporter what I would ask to be marked as 15:09:01	10 Lawrence Exhibit 10. 15:11:34
11 Lawrence Exhibit 9. 15:09:02	11 THE WITNESS: I'm impressed you got 15:11:36
12 For the record, Lawrence Exhibit 9 15:09:03	12 that. 15:11:39
13 corresponds to item number 14 in Chapters in 15:09:05	13 Q. I'm glad you are. 15:11:39
14 Books on Dr. Lawrence's curriculum vitae. 15:09:09	14 MR. HASFORD: For the record, Lawrence 15:11:40
15 15:09:32	15 Exhibit 10 corresponds to item number 15 in 15:11:42
16 (Whereupon, Plaintiff's Deposition 15:09:32	16 Chapters in Books on Dr. Lawrence's CV. 15:11:48
17 Exhibit No. Lawrence 9 was marked for 15:09:33	17 A. No, it doesn't. 15:11:51
18 Identification.) 15:09:34	18 Q. Oh, sorry. Did I get that wrong? 15:11:52
19 Q. Are you the M. Jayne Lawrence who co-authored 15:09:34	19 A. Yes, you did. It's not 15 at all. 15:11:54
20 Lawrence Exhibit 9? 15:09:37	20 Q. Oops. Which one is it? Well, let me -- let 15:11:57
21 A. I am. 15:09:38	21 me mark it and then -- 15:12:00
22 Q. Does Lawrence Exhibit 9 correspond to item 15:09:39	22 A. Okay. 15:12:02
Page 263	Page 265
1 number 14 in the Chapters in Books section of your 15:09:41	1 Q. Oh, I apologize. So, we're on -- we're on 15:12:02
2 curriculum vitae? 15:09:45	2 item -- we're on Lawrence 10. Okay. I know what I 15:12:12
3 A. It does. 15:09:46	3 did, I skipped one. I pulled the wrong thing out 15:12:17
4 Q. Did Lawrence Exhibit 9 publish in 2006? 15:09:47	4 of my folder. 15:12:27
5 A. It did. 15:09:50	5 MR. MARGOLIS: It happens. 15:12:28
6 Q. Take a look, if you would, at page 137. Let 15:09:52	6 MR. HASFORD: I'm handing the court 15:12:30
7 me direct your attention to the third full 15:09:59	7 reporter what I'd ask to be marked as 15:12:31
8 paragraph. It states, "Perhaps the most widely used 15:10:05	8 Lawrence Exhibit 10. 15:12:33
9 non-ionic surfactants in pharmaceutical formulations 15:10:08	9 (Whereupon, Plaintiff's Deposition 15:12:33
10 are the polyoxyethylene sorbitan n-acyl esters, 15:10:12	10 Exhibit No. Lawrence 10 was marked for 15:12:42
11 i.e., the Tweens and in particular, Tween 20 and 15:10:18	11 Identification.) 15:12:42
12 Tween 80, both of which are used parenterally and 15:10:23	12 Q. Does Lawrence Exhibit 10 correspond to item 15:12:42
13 orally." 15:10:28	13 number 15 in Chapters in Books on your curriculum 15:12:45
14 Was that a true statement as of 2006? 15:10:29	14 vitae? 15:12:49
15 A. I believe so, yes. 15:10:34	15 A. It does. 15:12:49
16 Q. As of 2003, was it also true that the most 15:10:35	16 Q. And you are -- you are the M. Jayne Lawrence 15:12:50
17 widely used non-ionic surfactants in pharmaceutical 15:10:38	17 who co-authored Lawrence Exhibit 10, correct? 15:13:00
18 formulations were the polyoxyethylene sorbitan 15:10:43	18 A. I am. 15:13:02
19 n-acyl esters, i.e., the Tweens, and in particular 15:10:47	19 Q. Turn, if you would, to page 1054, and look, 15:13:05
20 Tween 20 and Tween 80? 15:10:50	20 if you would, at the section entitled 15:13:18
21 A. Taking -- 15:10:51	21 Surfactant/Water Mixtures. 15:13:23
22 MR. MARGOLIS: Objection. Lack of 15:10:51	22 In the first sentence you write, "Surfactants 15:13:28

Page 266	<p>1 are amphiphilic molecules which, when dispersed in a 15:13:30</p> <p>2 solvent, spontaneously self-assemble to form a wide 15:13:34</p> <p>3 variety of structures, including spherical and 15:13:38</p> <p>4 asymmetric micelles, hexagonal, lamellar, and a 15:13:41</p> <p>5 plethora of cubic phases." 15:13:46</p> <p>6 Is that a true statement? 15:13:48</p> <p>7 A. Yes, in the absence of additives. As I 15:13:51</p> <p>8 demonstrate, that will change things. 15:13:54</p> <p>9 Q. In the next sentence you write, "With the 15:13:56</p> <p>10 exception of the lamellar phase, each of these phase 15:13:58</p> <p>11 structures can exist in both normal and reverse 15:14:02</p> <p>12 orientations with the hydrophobic chains on the 15:14:05</p> <p>13 exterior of the aggregate, in contact with solvent 15:14:08</p> <p>14 or vice versa orientation." 15:14:13</p> <p>15 Is that a true statement? 15:14:15</p> <p>16 A. Yes. 15:14:16</p> <p>17 Q. In the next sentence you write, "The range of 15:14:17</p> <p>18 structures a particular surfactant forms and the 15:14:19</p> <p>19 concentration range over which they form, depends 15:14:21</p> <p>20 upon the molecular architecture of the surfactant, 15:14:25</p> <p>21 its concentration, and the solvent in which it is 15:14:28</p> <p>22 dispersed." 15:14:31</p>	Page 268	<p>1 paragraph you write, "Taking a drug molecule from 15:15:38</p> <p>2 concept through formulation, clinical trials, 15:15:43</p> <p>3 manufacture and the strict regulatory process to its 15:15:47</p> <p>4 ultimate use as a medicine by the patient is an 15:15:50</p> <p>5 expensive, complex and lengthy process with a great 15:15:54</p> <p>6 many hurdles at which a potential drug may fall." 15:15:58</p> <p>7 Is that a true statement? 15:16:01</p> <p>8 MR. MARGOLIS: Objection. Vague. 15:16:03</p> <p>9 Q. You may answer. 15:16:04</p> <p>10 A. I believe so. 15:16:05</p> <p>11 Q. Tum, please, to page 14, and let me direct 15:16:06</p> <p>12 your attention to Selection of Drug Molecules. In 15:16:12</p> <p>13 the first sentence you state, "The range of 15:16:15</p> <p>14 potential drug molecules is enormous." 15:16:18</p> <p>15 Is that a true statement? 15:16:20</p> <p>16 A. Yes. 15:16:22</p> <p>17 Q. And then let me direct your attention to the 15:16:23</p> <p>18 section entitled Medicines Development and 15:16:26</p> <p>19 Preclinical Testing. You state, "Once a lead 15:16:28</p> <p>20 compound has been identified, a decision has to be 15:16:33</p> <p>21 made as to whether it is possible to develop the 15:16:36</p> <p>22 molecule into a safe, effective medicine." 15:16:38</p>
Page 267	<p>1 Is that a true statement? 15:14:32</p> <p>2 A. Yes. 15:14:32</p> <p>3 Q. You may put this document aside. 15:14:33</p> <p>4 MR. HASFORD: Now, I'm handing the court 15:14:41</p> <p>5 reporter what I ask to be marked as Lawrence 15:14:43</p> <p>6 Exhibit 11. 15:14:45</p> <p>7 For the record, Lawrence Exhibit 11 15:14:46</p> <p>8 corresponds to item number 12 in Other 15:14:48</p> <p>9 Outputs on Dr. Lawrence's CV. 15:14:51</p> <p>10 (Whereupon, Plaintiff's Deposition 15:15:08</p> <p>11 Exhibit No. Lawrence 11 was marked for 15:15:09</p> <p>12 Identification.) 15:15:10</p> <p>13 Q. Did I get it right this time, Doctor? 15:15:10</p> <p>14 A. That's correct. 15:15:10</p> <p>15 Q. Does this correspond to item number 12 in 15:15:12</p> <p>16 your Outputs? 15:15:13</p> <p>17 A. Yes, it does. 15:15:14</p> <p>18 Q. Very good. Thank you. And you are the Jayne 15:15:15</p> <p>19 Lawrence who authored Lawrence Exhibit 11, correct? 15:15:17</p> <p>20 A. Well, I was one of the team. 15:15:20</p> <p>21 Q. Okay. Let me direct your attention to page 15:15:23</p> <p>22 13, and in particular section 1.2. In the second 15:15:28</p>	Page 269	<p>1 Is that a true statement? 15:16:41</p> <p>2 MR. MARGOLIS: Objection. Vague. 15:16:44</p> <p>3 Q. You may answer. 15:16:45</p> <p>4 A. I believe so. 15:16:47</p> <p>5 Q. In the next sentence you state, "To do this 15:16:48</p> <p>6 the compounds physiochemical properties as well as 15:16:50</p> <p>7 its fate and behaviour in the body all have to be 15:16:55</p> <p>8 assessed." 15:16:58</p> <p>9 Is that a true statement? 15:16:58</p> <p>10 A. Yes. 15:16:59</p> <p>11 Q. In the next sentence you state, "Particular 15:17:00</p> <p>12 attention is given to the efficacy and toxicity of 15:17:02</p> <p>13 the lead compound as these are the main reasons for 15:17:05</p> <p>14 failure of a compound to progress beyond this 15:17:09</p> <p>15 stage." 15:17:12</p> <p>16 Is that a true statement? 15:17:12</p> <p>17 A. Yes. 15:17:14</p> <p>18 MR. MARGOLIS: Objection. Vague. 15:17:14</p> <p>19 Q. If a compound were demonstrated to have liver 15:17:15</p> <p>20 toxicity, would that compound be an attractive 15:17:18</p> <p>21 candidate for use in a new ophthalmic formulation or 15:17:21</p> <p>22 would it be better to select a different compound? 15:17:24</p>

Page 270	<p>1 MR. MARGOLIS: Objection. Vague. Calls 15:17:27                  2 for speculation. 15:17:28                  3 Q. You may answer. 15:17:30                  4 A. You'd need a lot more information to decide 15:17:32                  5 than just that statement. 15:17:36                  6 Q. What more information would you need? 15:17:37                  7 A. A variety of information. For example, it 15:17:39                  8 might be a particularly nasty eye condition that 15:17:45                  9 there are no drugs for, and it might be worth the 15:17:49                  10 risk of some liver toxicity if you were going to 15:17:54                  11 perhaps save somebody's sight or something. So it 15:17:58                  12 really isn't a comment I can answer. 15:18:01                  13 Q. What other information would you need? 15:18:03                  14 A. The frequency of use, the dose of use, how 15:18:07                  15 much is going to be absorbed into the body, how long 15:18:14                  16 it's going to be used, if I have not said that, if 15:18:21                  17 there are any other ways in negating the toxicity. 15:18:26                  18 Q. Are there any other -- 15:18:31                  19 A. Probably, but -- 15:18:33                  20 Q. -- items of information you would need? 15:18:33                  21 A. Probably, but -- 15:18:35                  22 Q. Sitting here today -- 15:18:38</p>	Page 272	<p>1 are affected by the likely excipients that 15:19:44                  2 you're going to add to the formulation, the 15:19:48                  3 effect of temperature on that formulation. I 15:19:50                  4 think pH is obviously included in there as 15:19:53                  5 well because that may be -- may affect the 15:19:58                  6 stability of the drug, how it's likely to be 15:20:02                  7 degraded, what's the best formulation, what's 15:20:04                  8 the best solvent you're going to add. 15:20:07                  9 Q. Anything else? 15:20:10                  10 A. I think I've given a reasonable start. 15:20:12                  11 Q. Take a look, if you would, at page 31 of 15:20:15                  12 Lawrence Exhibit 11. And let me direct your 15:20:18                  13 attention to the section entitled Physicochemical 15:20:27                  14 Properties and their Influence on Formulation. 15:20:30                  15 In the first sentence you write, "In order to 15:20:34                  16 determine whether it is possible to successfully 15:20:36                  17 formulate a drug as a medicine, it is essential to 15:20:38                  18 determine the drug's basic physicochemical 15:20:41                  19 properties, including its water solubility, its 15:20:46                  20 partitioning between oil and water and its behaviour 15:20:48                  21 in different pH environments." 15:20:51                  22 Is this a true statement? 15:20:53</p>
Page 271	<p>1 A. I summarized a reasonable amount. 15:18:38                  2 Q. Take a look at the section on page 14 15:18:41                  3 entitled Formulation Challenges. In the first 15:18:44                  4 sentence you state, "There can be considerable 15:18:48                  5 challenges encountered in the preparation of an 15:18:49                  6 appropriate formulation or delivery form of a drug, 15:18:52                  7 with the formulation being used for pre-clinical 15:18:55                  8 studies unlikely to be the formulation used in man." 15:18:58                  9 What are some of the considerable challenges 15:19:02                  10 encountered in the preparation of an appropriate 15:19:05                  11 ophthalmic formulation? 15:19:08                  12 MR. MARGOLIS: Objection. Vague. Lack 15:19:10                  13 of foundation. 15:19:12                  14 Q. You may answer. 15:19:14                  15 A. I believe I've already answered this question 15:19:15                  16 earlier. 15:19:17                  17 Q. Could you summarize them, please? 15:19:18                  18 MR. MARGOLIS: Same objections. 15:19:22                  19 THE WITNESS: There would be -- what you 15:19:27                  20 would need to understand what the dose was, 15:19:31                  21 the dosing frequency, physicochemical 15:19:32                  22 properties of the drug, how those properties 15:19:41</p>	Page 273	<p>1 MR. MARGOLIS: Objection. Vague. 15:20:55                  2 Mischaracterizes the document. 15:20:57                  3 Q. You may answer. 15:20:59                  4 A. I believe I've told you this information is 15:21:02                  5 important in formulating a drug. 15:21:09                  6 Q. Take a look, if you would, at page 32, and 15:21:15                  7 let me direct your attention to the third sentence. 15:21:22                  8 It starts, "A successful drug." 15:21:24                  9 Do you see that? 15:21:26                  10 A. Yes. 15:21:30                  11 Q. It says, "A successful drug requires a 15:21:31                  12 balance to be struck between potency/selectivity and 15:21:33                  13 its pharmacokinetic properties." 15:21:37                  14 Is that a true statement? 15:21:40                  15 A. It is. 15:21:41                  16 Q. Take a look now at the fifth sentence. It 15:21:42                  17 says, "To achieve successful delivery and therefore 15:21:45                  18 optimal exposure of the drug to the body, however, 15:21:49                  19 requires an appropriate balance of oil and water 15:21:52                  20 solubility." 15:21:55                  21 Is that a true statement? 15:21:56                  22 MR. MARGOLIS: Objection. Vague. 15:21:58</p>

Page 274		Page 276			
1	THE WITNESS: That is taken out of	15:22:00	1	solubility and therefore permeability of the	15:23:52
2	context. It needs to be read with the	15:22:03	2	drug across the membrane, and unless it's	15:23:55
3	previous sentence.	15:22:04	3	being -- that's been the case for a while and	15:23:59
4	Q. Is it a true statement?	15:22:05	4	will continue to be the case.	15:24:02
5	MR. MARGOLIS: Objection. Vague.	15:22:07	5	Q. Was that true as of 2003?	15:24:03
6	THE WITNESS: In the context of the	15:22:08	6	MR. MARGOLIS: Objection. Vague.	15:24:07
7	previous statement, yes.	15:22:10	7	THE WITNESS: My focus of research since	15:24:09
8	Q. And the previous statement says, "In	15:22:15	8	I started as an academic was looking at ways	15:24:13
9	particular, there is often a lack of appreciation	15:22:20	9	of increasing the solubility of poorly	15:24:16
10	that a molecule will not become a successful	15:22:22	10	water-soluble drugs to improve their	15:24:29
11	medicine if it is not adequately distributed within	15:22:25	11	delivery. So, this is something that's been	15:24:32
12	the body."	15:22:28	12	a problem for a long time.	15:24:40
13	Is that a true statement?	15:22:29	13	Q. In your opinion as of 2003 --	15:24:41
14	A. I'm confused. You asked me, "To achieve	15:22:30	14	A. Yes.	15:24:44
15	successful delivery and therefore optimal exposure	15:22:33	15	Q. -- was the --	15:24:44
16	of the drug to the body." The previous statement	15:22:37	16	A. Sorry.	15:24:44
17	is --	15:22:39	17	Q. -- search still ongoing?	15:24:45
18	Q. I apologize. Go ahead. You can read it.	15:22:39	18	MR. MARGOLIS: Objection.	15:24:47
19	A. Okay. "The focus of the hit-to-lead	15:22:41	19	THE WITNESS: The search was in	15:24:47
20	optimization programmes is to drive for potency at	15:22:44	20	progress, yes.	15:24:48
21	the in vitro level, which often translates to	15:22:48	21	Q. Okay. Take a look, if you would, at the top	15:24:49
22	increased lipophilicity."	15:22:52	22	of the right-hand column on page 32. And I direct	15:24:53
Page 275		Page 277			
1	So, this is all talking about a story. I	15:22:54	1	your attention to the last sentence in the first	15:25:00
2	don't think it can be taken -- some statements are	15:22:57	2	paragraph. It says, "For example, if a drug is	15:25:04
3	obviously independently correct, but other	15:23:00	3	intended for the treatment of a simple headache,	15:25:09
4	statements relate to the previous sentence, so you	15:23:04	4	then the expense associated with the preparation of	15:25:11
5	have to be very careful how you read it.	15:23:06	5	an injection would not be justified." I apologize.	15:25:14
6	Q. Certainly. Let me direct your attention to	15:23:08	6	That was the second to last sentence.	15:25:17
7	the very bottom sentence of the left-hand column.	15:23:11	7	The last sentence is, "In order to formulate	15:25:18
8	It says, "The search therefore goes on for	15:23:14	8	a drug for delivery, other than by the oral route,	15:25:20
9	technologies to overcome the solubility/permeability	15:23:17	9	significant advantage needs to be demonstrated over	15:25:24
10	problems encountered with the formulation of drugs	15:23:21	10	the oral route of administration or else the drug	15:25:26
11	as medicines."	15:23:23	11	needs to be the first in its class."	15:25:29
12	Is that a true statement?	15:23:24	12	Is that a true statement?	15:25:32
13	A. Yes.	15:23:25	13	A. I believe it to be, yes.	15:25:35
14	Q. Was it true as of 2003 that the search was	15:23:25	14	Q. Take a look, if you would, at page 35. The	15:25:36
15	still ongoing for technologies to overcome the	15:23:29	15	first statement says, "The pharmaceutical scientist	15:25:51
16	solubility and permeability problems encountered	15:23:32	16	is always searching for new and safe materials that	15:25:53
17	with the formulation of drugs as medicines?	15:23:36	17	can be used to improve the formulation of a	15:25:56
18	MR. MARGOLIS: Objection. Vague.	15:23:39	18	medicine. These are known as excipients."	15:25:59
19	Q. You may answer.	15:23:40	19	Are those true statements?	15:26:02
20	MR. MARGOLIS: Lack of foundation.	15:23:41	20	A. Yes.	15:26:04
21	THE WITNESS: One of the limitations of	15:23:44	21	Q. Take a look, if you would, at page 39. I	15:26:04
22	drug delivery is getting the optimal	15:23:47	22	direct your attention to Section 2.4	15:26:10

Page 278	Page 280
1 Pharmacokinetics and Pharmacodynamics. It says, 15:26:13	1 A. I am. 15:28:20
2 "Once a potential drug candidate has been 15:26:17	2 Q. Does Lawrence Exhibit 12 correspond to item 15:28:20
3 identified, its fate and behaviour in the body have 15:26:19	3 number 1 in Articles in Academic Journals on your 15:28:22
4 to be assessed before a decision can be made whether 15:26:22	4 curriculum vitae? 15:28:26
5 it is possible to develop the molecule into a safe, 15:26:25	5 A. It does. 15:28:27
6 effective medicine." 15:26:28	6 Q. Take a look at page 1903. The first sentence 15:28:28
7 Is that a true statement? 15:26:30	7 of the body of the document states, "Previous 15:28:32
8 MR. MARGOLIS: Objection. Vague. 15:26:31	8 studies of the effects of structural variation of 15:28:35
9 THE WITNESS: I believe it is. 15:26:35	9 non-ionic surfactants on micellar properties and 15:28:38
10 Q. In the next sentence you write, "In 15:26:36	10 solubilization have emphasized the importance of the 15:28:42
11 particular, the drug's physicochemical, 15:26:38	11 liquid nature of the micellar core in determining 15:28:46
12 pharmacokinetic, pharmacodynamic and toxicological 15:26:41	12 solubilizing capacity." 15:28:49
13 properties all have to be established." 15:26:46	13 Is that a true statement 15:28:51
14 Is that a true statement? 15:26:47	14 A. I believe it is. 15:28:52
15 MR. MARGOLIS: Objection. 15:26:49	15 Q. You can put that document aside. 15:28:53
16 THE WITNESS: Can I just -- sorry. 15:26:49	16 MR. HASFORD: I'm handing the court 15:29:05
17 Sorry. Can I just clarify? This document 15:26:52	17 reporter what I would ask to be marked as 15:29:07
18 was written as a team, and the various 15:26:54	18 Lawrence Exhibit 13. 15:29:09
19 sections of these documents were written by 15:26:58	19 For the record, Lawrence Exhibit 13 15:29:09
20 experts in their particular fields. Just to 15:27:01	20 corresponds to item number 2 in Articles in 15:29:11
21 clarify. 15:27:04	21 Academic Journals on Dr. Lawrence's 15:29:14
22 Q. And this document went out under your name, 15:27:05	22 curriculum vitae. 15:29:16
Page 279	Page 281
1 correct? 15:27:08	1 (Whereupon, Plaintiff's Deposition 15:29:35
2 A. No. It went out under the name of the 15:27:08	2 Exhibit No. Lawrence 13 was marked for 15:29:35
3 pharmaceutical sciences advisory panel, of which I 15:27:14	3 Identification.) 15:29:36
4 was part of the team. 15:27:16	4 Q. Are you the M.J. Lawrence who co-authored 15:29:36
5 Q. You're identified as a co-author on this 15:27:17	5 Lawrence Exhibit 13? 15:29:39
6 document, correct? 15:27:19	6 A. I am. 15:29:40
7 A. I am, yes. 15:27:19	7 Q. Does Lawrence Exhibit 13 correspond to item 15:29:40
8 Q. You can put this document aside. 15:27:20	8 number 2 in Articles in Academic Journals on your 15:29:42
9 MR. HASFORD: I'm handing the court 15:27:46	9 curriculum vitae? 15:29:46
10 reporter what I would ask to be marked as 15:27:47	10 A. It does. 15:29:47
11 Lawrence Exhibit 12. 15:27:49	11 Q. Take a look at the first page and the first 15:29:48
12 For the record, Lawrence Exhibit 12 15:27:51	12 sentence. It says, "Previous studies" -- and then 15:29:51
13 corresponds to item number 1 in Articles in 15:27:55	13 there's a citation -- "have reported that the 15:29:53
14 Academic Journals on Dr. Lawrence's 15:27:59	14 lengthening" -- I apologize -- "that lengthening the 15:29:59
15 curriculum vitae. 15:28:01	15 alkyl chain of a series of n-alkylpolyoxyethylene 15:30:00
16 15:28:14	16 glycol mono ether surfactants [general formula 15:30:06
17 (Whereupon, Plaintiff's Deposition 15:28:14	17 CmE1-25m] above m equals 16, although causing an 15:30:13
18 Exhibit No. Lawrence 12 was marked for 15:28:15	18 increase in micellar size did not result in the 15:30:17
19 Identification.) 15:28:15	19 enhanced solubilization of a range of drugs." 15:30:20
20 BY MR. HASFORD: 15:28:16	20 Do you see that? 15:30:23
21 Q. Are you the M. Jayne Lawrence who co-authored 15:28:16	21 A. I do. 15:30:24
22 Lawrence Exhibit 12? 15:28:19	22 Q. Is it fair to say that different non-ionic 15:30:24



Page 282		Page 284			
1	surfactants having different chemical structures	15:30:27	1	Is it fair to say that cyclodextrins	15:32:44
2	exhibit different solubilizing abilities?	15:30:31	2	materially impact the solubility of drug molecules	15:32:47
3	MR. MARGOLIS: Objection. Vague.	15:30:34	3	in aqueous liquid preparations?	15:32:49
4	THE WITNESS: Not from that statement	15:30:36	4	MR. MARGOLIS: Objection. Vague.	15:32:53
5	it's not, no.	15:30:37	5	THE WITNESS: It so much depends upon	15:32:55
6	Q. Is it fair to say that in general?	15:30:39	6	the drug and which cyclodextrin you're	15:32:58
7	MR. MARGOLIS: Objection. Vague.	15:30:41	7	looking at. They're not necessarily very	15:33:02
8	THE WITNESS: No. I think you're taking	15:30:45	8	efficient for formulation or used as	15:33:06
9	that statement out of context.	15:30:48	9	formulation excipients.	15:33:11
10	Q. Well, then pretend I didn't show you that	15:30:50	10	Q. Is it fair to say that cyclodextrins can	15:33:13
11	statement. Is it fair to say that different	15:30:53	11	materially impact the solubility of drug molecules	15:33:16
12	non-ionic surfactants having different chemical	15:30:57	12	in aqueous liquid preparations?	15:33:20
13	structures exhibit different solubilizing abilities?	15:30:58	13	MR. MARGOLIS: Objection. Vague. Calls	15:33:22
14	MR. MARGOLIS: Objection. Vague.	15:31:02	14	for a legal conclusion.	15:33:23
15	THE WITNESS: It is vague. And I will	15:31:03	15	THE WITNESS: For a limited number of	15:33:26
16	reiterate what I believe I said earlier in	15:31:06	16	drugs that may be the case, yes.	15:33:29
17	the proceedings, that would depend very much	15:31:08	17	Q. You can put that document aside.	15:33:32
18	on the similarity or the difference in	15:31:13	18	MR. HASFORD: I'm handing the court	15:33:42
19	structure.	15:31:15	19	reporter what I would ask to be marked as	15:33:43
20	Q. Okay. You can put this document aside.	15:31:16	20	Lawrence Exhibit 15.	15:33:45
21	MR. HASFORD: I'm handing the court	15:31:32	21	For the record, Lawrence Exhibit 15	15:33:46
22	reporter what I would ask to be marked as	15:31:33	22	corresponds to item number 9 in Articles in	15:33:48
Page 283		Page 285			
1	Lawrence Exhibit 14.	15:31:34	1	Academic Journals on Dr. Lawrence's	15:33:53
2	For the record, Lawrence Exhibit 14	15:31:35	2	curriculum vitae.	15:33:54
3	corresponds to item number 8 in Articles in	15:31:37	3	(Whereupon, Plaintiff's Deposition	15:34:31
4	Academic Journals on Dr. Lawrence's	15:31:41	4	Exhibit No. Lawrence 15 was marked for	15:34:31
5	curriculum vitae.	15:31:44	5	Identification.)	15:34:31
6	(Whereupon, Plaintiff's Deposition	15:32:09	6	THE WITNESS: I can't believe that	15:34:31
7	Exhibit No. Lawrence 14 was marked for	15:32:09	7	picture.	15:34:31
8	Identification.)	15:32:10	8	(Discussion off the record.)	15:34:32
9	Q. Are you the M. Jayne Lawrence who co-authored	15:32:10	9	Q. Are you the M. Jayne Lawrence who authored	15:34:32
10	Lawrence Exhibit 14?	15:32:13	10	Lawrence Exhibit 15?	15:34:40
11	A. I am.	15:32:15	11	A. I am.	15:34:41
12	Q. Does Lawrence Exhibit 14 correspond to item	15:32:15	12	Q. Does Lawrence Exhibit 15 correspond to item	15:34:41
13	number 8 in Articles in Academic Journals on your	15:32:18	13	number 9 in Articles in Academic Journals on your	15:34:44
14	curriculum vitae?	15:32:22	14	curriculum vitae?	15:34:47
15	A. It does.	15:32:23	15	A. It does.	15:34:48
16	Q. Take a look at first page, page 27.	15:32:24	16	Q. Turn, if you would, to page 423, and let me	15:34:49
17	A. Yes.	15:32:26	17	direct your attention to the conclusion. About	15:34:52
18	Q. The bottom of the left-hand column, second to	15:32:27	18	halfway through the first paragraph of the	15:34:58
19	last sentence reads, "For example, cyclodextrin	15:32:29	19	conclusion you write, "Before attempting to	15:35:00
20	complexes have been used for increasing the apparent	15:32:33	20	formulate a drug the limitations of each type of	15:35:03
21	aqueous solubility of drug molecules and also for	15:32:37	21	system need to be thoroughly understood."	15:35:07
22	reducing their surface activity."	15:32:40	22	Is that a true statement?	15:35:09

Page 286	<p>1 MR. MARGOLIS: Objection. Vague. 15:35:10</p> <p>2 THE WITNESS: In the context of using 15:35:13</p> <p>3 surfactant systems to solubilize drugs, yes. 15:35:15</p> <p>4 Q. In the next sentence you write. "For example, 15:35:19</p> <p>5 it is no use trying to increase the aqueous 15:35:21</p> <p>6 solubility of a water-soluble hydrophilic drug in an 15:35:24</p> <p>7 aqueous-based surfactant system." 15:35:29</p> <p>8 Is that a true statement? 15:35:31</p> <p>9 MR. MARGOLIS: Objection. Vague. 15:35:33</p> <p>10 THE WITNESS: Yeah, it's vague. It 15:35:34</p> <p>11 isn't the best written. There are some drugs 15:35:37</p> <p>12 that are quite water soluble and will 15:35:39</p> <p>13 actually form mixed aggregates with 15:35:40</p> <p>14 surfactants, which I didn't know about at the 15:35:43</p> <p>15 time. 15:35:45</p> <p>16 Q. Did you qualify your statement in any way in 15:35:45</p> <p>17 Lawrence Exhibit 15? 15:35:48</p> <p>18 A. In Lawrence Exhibit 15? 15:35:50</p> <p>19 Q. The document we're looking at. 15:35:53</p> <p>20 A. Oh. No. No. No. This is the document -- 15:35:55</p> <p>21 when I wrote this, I believed that to be true. I've 15:35:57</p> <p>22 subsequently realized that's not true because 15:36:01</p>	Page 288	<p>1 For the record, Lawrence Exhibit 16 15:37:33</p> <p>2 corresponds to item number 12 in Articles in 15:37:36</p> <p>3 Academic Journals on Dr. Lawrence's 15:37:41</p> <p>4 curriculum vitae. 15:37:42</p> <p>5 (Whereupon, Plaintiff's Deposition 15:38:14</p> <p>6 Exhibit No. Lawrence 16 was marked for 15:38:14</p> <p>7 Identification.) 15:38:15</p> <p>8 Q. Are you the M. Jayne Lawrence who authored 15:38:15</p> <p>9 Lawrence 16? 15:38:31</p> <p>10 A. I am. 15:38:31</p> <p>11 Q. Does that correspond to item number 12 in 15:38:32</p> <p>12 Articles in Academic Journals on your curriculum 15:38:35</p> <p>13 vitae? 15:38:37</p> <p>14 A. It does. 15:38:38</p> <p>15 Q. Take a look at page 258, please, and let me 15:38:38</p> <p>16 direct your attention to the Introduction, the last 15:38:43</p> <p>17 full sentence in the left-hand column. It says, 15:38:46</p> <p>18 "When dispersed in water surfactant molecules 15:38:49</p> <p>19 self-associate to form a wide variety of equilibrium 15:38:52</p> <p>20 phase structures in which the hydrophobic chains are 15:38:57</p> <p>21 removed from contact with water." 15:39:00</p> <p>22 Is that a true statement? 15:39:02</p>
Page 287	<p>1 certain drugs can be quite soluble, but have some 15:36:04</p> <p>2 amphiphilic nature. 15:36:09</p> <p>3 Q. When did you realize that? 15:36:10</p> <p>4 A. Probably -- just let me -- I have to look at 15:36:12</p> <p>5 that. When were the Olympic Games in Barcelona? 15:36:19</p> <p>6 Q. You're asking the wrong guy. 15:36:38</p> <p>7 A. I remember I had a student who was Spanish 15:36:41</p> <p>8 and brought me back a mug and she was doing the work 15:36:45</p> <p>9 on it at the time. So I realized probably just 15:36:48</p> <p>10 after I'd written this review when I realized that 15:36:51</p> <p>11 you could form with some quite hydrophilic 15:36:55</p> <p>12 compounds, and sodium diclofenac is one of them, you 15:36:59</p> <p>13 can form mix with micelles, and I didn't know at the 15:37:02</p> <p>14 time. 15:37:05</p> <p>15 Q. Do you remember about what time that was when 15:37:06</p> <p>16 you came to that realization? 15:37:07</p> <p>17 A. It would have been not much difference from 15:37:09</p> <p>18 this. I can't remember the exact time, though. 15:37:11</p> <p>19 Q. You can put Exhibit 15 aside. 15:37:13</p> <p>20 MR. HASFORD: I'm handing the court 15:37:29</p> <p>21 reporter what I would ask to be marked as 15:37:30</p> <p>22 Lawrence Exhibit 16. 15:37:32</p>	Page 289	<p>1 A. Yes. 15:39:03</p> <p>2 Q. Is it fair to say that the aggregate that 15:39:04</p> <p>3 would be formed by tyloxapol in an aqueous liquid 15:39:06</p> <p>4 preparation is different from the aggregate that 15:39:10</p> <p>5 would be formed in the same aqueous liquid 15:39:12</p> <p>6 preparation by a different non-ionic surfactant with 15:39:15</p> <p>7 a different chemical structure? 15:39:18</p> <p>8 MR. MARGOLIS: Objection. Vague. 15:39:21</p> <p>9 THE WITNESS: Yes, I don't understand 15:39:22</p> <p>10 how you mean is different. 15:39:23</p> <p>11 Q. Would there be any difference? 15:39:24</p> <p>12 MR. MARGOLIS: Objection. Vague. 15:39:28</p> <p>13 THE WITNESS: Polymeric surfactants 15:39:31</p> <p>14 self-assemble into micelles. That's very 15:39:33</p> <p>15 well-established with surfactants such as 15:39:37</p> <p>16 Pluronic. They, as far as I know, form into 15:39:39</p> <p>17 traditional micelles with the hydrophobic 15:39:47</p> <p>18 core and with the polyoxyl chains on the 15:39:51</p> <p>19 outside. There'd be no thermodynamic reason 15:39:54</p> <p>20 for them not to. 15:39:56</p> <p>21 Q. Would the aggregate that would be formed by 15:39:57</p> <p>22 tyloxapol in an aqueous liquid preparation be any 15:39:59</p>

Page 290	Page 292
1 different in any way from the aggregate that would 15:40:03	1 Q. Take a look, if you would, at Table 3. Is it 15:42:27
2 be formed in the same aqueous liquid preparation by 15:40:06	2 fair to say that there are a wide variety of 15:42:31
3 a different non-ionic surfactant with a different 15:40:10	3 non-equilibrium surfactant systems that can be used 15:42:34
4 chemical structure? 15:40:13	4 in aqueous drug formulations? 15:42:37
5 MR. MARGOLIS: Objection. Vague. 15:40:14	5 MR. MARGOLIS: Objection. Vague. 15:42:41
6 THE WITNESS: Potentially. Potentially 15:40:16	6 THE WITNESS: There are, yes. 15:42:43
7 not. It depends how different the structures 15:40:18	7 Q. You can put this document aside. 15:42:44
8 are. 15:40:21	8 MR. HASFORD: I'm handing the court 15:42:57
9 Q. Why does it depend on how different the 15:40:22	9 reporter what I would ask to be marked as 15:42:58
10 structures are? 15:40:24	10 Lawrence Exhibit 17. 15:43:00
11 A. A number of parameters affect the 15:40:25	11 For the record, Lawrence Exhibit 17 15:43:01
12 self-assembly of the micelles. The hydrophobic 15:40:31	12 corresponds to item number 16 in Articles in 15:43:04
13 chain, the ratio, the balance of the hydrophobic 15:40:39	13 Academic Journals on Dr. Lawrence's 15:43:08
14 chain in the head group, and concentration they're 15:40:44	14 curriculum vitae. 15:43:10
15 at, salt concentration, pH, all of those will 15:40:50	15 (Whereupon, Plaintiff's Deposition 15:43:35
16 affect -- I don't think I'm answering the question. 15:40:53	16 Exhibit No. Lawrence 17 was marked for 15:43:36
17 What was your question again? I think I've got off 15:40:54	17 Identification.) 15:43:37
18 the point. I'm sorry. 15:40:57	18 Q. Are you the M. Jayne Lawrence who co-authored 15:43:37
19 Q. Well, I might need the court reporter to read 15:40:58	19 Lawrence Exhibit 17? 15:43:41
20 it back because now I can't see it on the screen. 15:41:00	20 A. I am. 15:43:43
21 A. Sorry. 15:41:00	21 Q. Does Lawrence Exhibit 17 correspond to item 15:43:44
22 (Question read back as follows:) 15:41:00	22 number 16 in Articles in Academic Journals on your 15:43:47
Page 291	Page 293
1 "QUESTION: Why does it depend on how 15:40:22	1 curriculum vitae? 15:43:51
2 different the structures are?" 15:40:24	2 A. It does. 15:43:52
3 MR. HASFORD: The previous question. 15:40:24	3 Q. Take a look, if you would, at page 58, and in 15:43:53
4 A. It predominantly depends on the ratio between 15:41:16	4 the section entitled Discussion, the first full -- 15:44:02
5 the hydrophobic chain and the hydrophobic head 15:41:19	5 the first sentence, rather, states, "The non-ionic 15:44:06
6 group. The relative driving force is -- the driving 15:41:24	6 surfactants used in the present study have 15:44:17
7 force for aggregation from the hydrophobic chain and 15:41:28	7 structural features in common with 15:44:20
8 the head groups providing the repulsive force to 15:41:31	8 phosphatidylcholines, but the vesicles they form 15:44:22
9 stop the aggregation. 15:41:40	9 have physicochemical properties that differ 15:44:26
10 Q. Would the resulting solutions need to be 15:41:43	10 significantly from those of the phospholipid 15:44:30
11 tested to determine the differences between them? 15:41:46	11 liposomes." 15:44:34
12 A. They would. 15:41:49	12 Is that a true statement? 15:44:34
13 Q. Take a look, if you would -- actually, take a 15:41:50	13 A. Yes. 15:44:36
14 look, if you would, at Table 2 on page 258 of 15:41:55	14 Q. Is it also fair to say that different 15:44:40
15 Lawrence Exhibit 16. Tell me when you're ready. 15:42:01	15 non-ionic surfactants may have structural 15:44:43
16 A. Yes. 15:42:10	16 similarities, yet have physicochemical properties 15:44:46
17 Q. Is it fair to say that there are a wide 15:42:11	17 that differ significantly? 15:44:49
18 variety of equilibrium surfactant systems that can 15:42:14	18 MR. MARGOLIS: Objection. Vague. 15:44:51
19 be used in aqueous drug formulations? 15:42:18	19 THE WITNESS: It's -- this is part -- I 15:44:54
20 MR. MARGOLIS: Objection. Vague. 15:42:22	20 think there's a -- to understand that 15:45:14
21 THE WITNESS: Potentially there are, 15:42:26	21 statement you need to appreciate the 15:45:18
22 yes. 15:42:27	22 difference between having a zwitterionic 15:45:19

Page 294		Page 296			
1	phospholipid head group and the polymeric	15:45:24	1	the hydrophilic nature of the surfactant and, as a	15:48:08
2	non-ionic head group. And I think I've	15:45:27	2	consequence, it is made harder to achieve the	15:48:12
3	stated earlier that very different structures	15:45:30	3	correct balance of the hydrophobic and hydrophilic	15:48:15
4	would have very different effects. So, the	15:45:35	4	portions of the surfactant required for production	15:48:20
5	similarity in this case is its two	15:45:38	5	of a microemulsion; instead this balance has to be	15:48:22
6	hydrophobic chains and what we call a	15:45:42	6	achieved by the use of a cosurfactant."	15:48:26
7	backbone, a semi-polar backbone. The head	15:45:45	7	Is it fair to say that small structural	15:48:30
8	groups are very different. So, those are	15:45:51	8	differences in non-ionic surfactants can cause	15:48:33
9	some structural similarities. There's also	15:45:55	9	considerable changes in their physical and chemical	15:48:37
10	some quite big differences.	15:45:57	10	properties?	15:48:40
11	Q. In general, is it also fair to say that	15:45:59	11	MR. MARGOLIS: Objection. Vague. Calls	15:48:41
12	different non-ionic surfactants may have structural	15:46:03	12	for speculation.	15:48:42
13	similarities, yet have physicochemical properties	15:46:07	13	Q. You may answer.	15:48:44
14	that differ significantly?	15:46:10	14	A. You need to read the previous statement which	15:48:44
15	MR. MARGOLIS: Objection. Vague.	15:46:12	15	is talking specifically about sucrose esters and	15:48:47
16	THE WITNESS: You would really have to	15:46:14	16	polyglycerol fatty acid esters. They are very	15:48:58
17	look at that on a case-by-case basis.	15:46:18	17	different molecules than the non-surfactants we're	15:49:04
18	Q. Would you have to test the different	15:46:20	18	talking about here. A sugar has a much more -- one	15:49:09
19	surfactants to determine that?	15:46:22	19	sugar is much more hydrophilic than several	15:49:14
20	MR. MARGOLIS: Objection. Vague. Calls	15:46:24	20	polyoxyethylene chains. So, in this case, it makes	15:49:18
21	for speculation.	15:46:25	21	a huge difference in the properties.	15:49:20
22	THE WITNESS: No, not necessarily.	15:46:27	22	Q. In general, is it fair to say that small	15:49:23
Page 295		Page 297			
1	Q. You can put this document aside.	15:46:28	1	structural differences in non-ionic surfactants can	15:49:27
2	MR. HASFORD: I'm handing the court	15:46:44	2	cause considerable changes in their physical and	15:49:30
3	reporter what I would ask to be marked as	15:46:46	3	chemical properties?	15:49:33
4	Lawrence Exhibit 18.	15:46:47	4	MR. MARGOLIS: Objection. Vague.	15:49:34
5	For the record, Lawrence Exhibit 18	15:46:48	5	THE WITNESS: For normal common	15:49:35
6	corresponds to item number 18 in Articles in	15:46:50	6	polyoxyethylene ester surfactants and	15:49:37
7	Academic Journals on Dr. Lawrence's	15:46:54	7	unrelated molecules, no, it doesn't make a	15:49:42
8	curriculum vitae.	15:46:55	8	huge difference. There's a very gradual	15:49:45
9	(Whereupon, Plaintiff's Deposition	15:47:18	9	difference, and I state that in a number of	15:49:48
10	Exhibit No. Lawrence 18 was marked for	15:47:19	10	papers.	15:49:50
11	Identification.)	15:47:20	11	Q. You may put Exhibit 18 aside.	15:49:52
12	Q. Are you the M. Jayne Lawrence who authored	15:47:20	12	MR. HASFORD: I'm handing the court	15:50:16
13	Lawrence Exhibit 18?	15:47:42	13	reporter what I'd ask to be marked as	15:50:18
14	A. I am.	15:47:43	14	Lawrence Exhibit 19.	15:50:20
15	Q. Does Lawrence Exhibit 18 correspond to item	15:47:44	15	For the record, Lawrence Exhibit 19	15:50:21
16	number 18 in Articles in Academic Journals on your	15:47:47	16	corresponds to item number 20 in Articles in	15:50:23
17	curriculum vitae?	15:47:50	17	Academic Journals on Dr. Lawrence's	15:50:27
18	A. It does.	15:47:51	18	curriculum vitae.	15:50:28
19	Q. Take a look, if you would, at page 827. Let	15:47:52	19	(Whereupon, Plaintiff's Deposition	15:50:53
20	me direct your attention to the right-hand column.	15:47:58	20	Exhibit No. Lawrence 19 was marked for	15:50:53
21	About halfway down it says, "Therefore, the addition	15:48:02	21	Identification.)	15:50:54
22	of one extra unit causes a considerable increase in	15:48:04	22	Q. Are you the M. Jayne Lawrence who co-authored	15:50:54

Page 298		Page 300			
1	Lawrence Exhibit 19?	15:50:57	1	the drug-solubilizing capacity of most of the	15:52:56
2	A. I am.	15:50:59	2	commonly used surfactants is too low to be of	15:52:59
3	Q. Does Lawrence Exhibit 19 correspond to item	15:50:59	3	widespread practical use?	15:53:02
4	number 20 in the Articles in Academic Journals on	15:51:02	4	MR. MARGOLIS: Objection. Vague.	15:53:05
5	your curriculum vitae?	15:51:06	5	THE WITNESS: I believe so, yes.	15:53:10
6	A. It does.	15:51:07	6	Q. Take a look, if you would, at the next page.	15:53:13
7	Q. Take a look at the first sentence in the body	15:51:08	7	It's going to be page 799. In the first full	15:53:18
8	of the document. You state, "It is well-established	15:51:11	8	paragraph it says, "The physicochemical	15:53:27
9	that the molecular geometry of a surfactant	15:51:14	9	characterization and solubilization behavior of	15:53:30
10	influences the nature of the aggregate it forms when	15:51:17	10	DDCPNO are reported here. The properties of this	15:53:34
11	dispersed in aqueous solution at low	15:51:20	11	surfactant are compared with those of a	15:53:38
12	concentrations."	15:51:24	12	nonbiodegradable N-oxide derivative of comparable	15:53:43
13	Is that a true statement?	15:51:25	13	hydrophobic chain length (namely, N,	15:53:47
14	A. Yes.	15:51:26	14	N-dimethyldodecylamine-N-oxide (DDNO) to investigate	15:53:51
15	Q. You can put this document aside.	15:51:26	15	the consequences of inserting a propoxy linker	15:53:58
16	MR. HASFORD: I'm handing the court	15:51:33	16	moiety between the hydrophobe and head group."	15:54:02
17	reporter what I would ask to be marked	15:51:34	17	Do you see that?	15:54:05
18	Lawrence Exhibit 20.	15:51:37	18	A. Yes.	15:54:07
19	For the record, Lawrence Exhibit 20	15:51:38	19	Q. In Lawrence Exhibit 20, did you report the	15:54:07
20	corresponds to item 33 in Articles in	15:51:39	20	results of adding a propoxy linker to a non-ionic	15:54:10
21	Academic Journals on Dr. Lawrence's CV.	15:51:42	21	surfactant?	15:54:14
22	(Whereupon, Plaintiff's Deposition	15:52:08	22	A. Yes, I did.	15:54:16
Page 299		Page 301			
1	Exhibit No. Lawrence 20 was marked for	15:52:08	1	Q. Does a propoxy linker have three carbon atoms	15:54:18
2	Identification.)	15:52:09	2	and an oxygen atom?	15:54:21
3	Q. Are you the M. Jayne Lawrence who co-authored	15:52:09	3	A. Yes.	15:54:27
4	Lawrence Exhibit 20?	15:52:13	4	Q. Would you characterize adding a propoxy	15:54:27
5	A. I am.	15:52:14	5	linker to a non-ionic surfactant as a major chemical	15:54:30
6	Q. Does Lawrence Exhibit 20 correspond to item	15:52:14	6	change or a minor chemical change?	15:54:34
7	number 33 in Articles in Academic Journals on your	15:52:17	7	MR. MARGOLIS: Objection. Vague. Lack	15:54:37
8	curriculum vitae?	15:52:20	8	of foundation.	15:54:42
9	A. It does.	15:52:21	9	THE WITNESS: I think you should look at	15:54:42
10	Q. Was Lawrence Exhibit 20 published in 2000?	15:52:22	10	the results here because it's actually very	15:54:44
11	A. It was.	15:52:26	11	interesting. You highlighted before in one	15:54:46
12	Q. Take a look, if you would, at the	15:52:27	12	of my papers about adding a unit making a big	15:54:52
13	Introduction?	15:52:30	13	change, and I stated that's because it was a	15:54:56
14	A. Yes.	15:52:30	14	sugar moiety. You have to remember with	15:55:00
15	Q. And the first two sentences read,	15:52:31	15	non-ionic -- non -- N-oxide surfactants, that	15:55:03
16	"Surfactants have been investigated as agents to	15:52:35	16	is an all-or-nothing change. You have a head	15:55:11
17	solubilize poorly water soluble drugs in	15:52:37	17	group, an oxide head group, or you don't have	15:55:13
18	pharmaceutical formulations for many years.	15:52:40	18	an oxide head group. So you find any changes	15:55:15
19	Unfortunately, however, the drug-solubilizing	15:52:43	19	making with this type of non-ionic surfactant	15:55:18
20	capacity of most of the commonly used surfactants is	15:52:46	20	greater than the polyoxyethylene surfactant,	15:55:21
21	too low to be of widespread practical use."	15:52:50	21	and I've stated that in a number of my	15:55:26
22	As of 2000, was it understood in the art that	15:52:53	22	papers.	15:55:27

Page 302			Page 304		
1	So, there are changes, but actually	15:55:27	1	MR. HASFORD: I'm handing the court	15:57:33
2	they're not as much as you might expect.	15:55:29	2	reporter what I would ask to be marked as	15:57:34
3	There were less than I expected. In some	15:55:33	3	Lawrence Exhibit 21.	15:57:36
4	cases it behaved very similarly, but it was	15:55:35	4	For the record, Lawrence Exhibit 21	15:57:37
5	what we expected.	15:55:39	5	corresponds to item number 47 in Articles in	15:57:40
6	Q. And would you characterize adding a propoxy	15:55:40	6	Academic Journals on Dr. Lawrence's	15:57:43
7	linker to a non-ionic surfactant as a minor chemical	15:55:43	7	curriculum vitae.	15:57:45
8	change?	15:55:47	8	(Whereupon, Plaintiff's Deposition	15:58:09
9	MR. MARGOLIS: Objection. Asked and	15:55:47	9	Exhibit No. Lawrence 21 was marked for	15:58:10
10	answered. Vague.	15:55:49	10	Identification.)	15:58:11
11	THE WITNESS: It would depend on what	15:55:49	11	Q. You are the M. Jayne Lawrence who co-authored	15:58:11
12	type of non-ionic surfactant.	15:55:51	12	Exhibit 21?	15:58:14
13	Q. Take a look at the Conclusion of your paper.	15:55:53	13	A. I am.	15:58:15
14	In the first sentence you state, "The introduction	15:55:58	14	Q. Does Lawrence Exhibit 21 correspond to item	15:58:15
15	of a linker moiety into a surfactant containing a	15:56:01	15	number 47 in Articles in Academic Journals on your	15:58:18
16	small head group has been shown to greatly alter the	15:56:04	16	curriculum vitae?	15:58:21
17	physicochemical and solubilization behavior of a low	15:56:07	17	A. It does.	15:58:22
18	molecular weight surfactant."	15:56:10	18	Q. Turn, if you would, to page 866, and look at	15:58:23
19	Is it fair to say that a structural change in	15:56:13	19	the first full paragraph. The first sentence reads,	15:58:30
20	a non-ionic surfactant can greatly alter the	15:56:16	20	"From the discussion just presented, it is clear	15:58:35
21	physicochemical and solubilization behavior of the	15:56:19	21	that the membrane-active effects of a surfactant are	15:58:38
22	surfactant?	15:56:22	22	a complex interplay of several competing effects."	15:58:41
Page 303			Page 305		
1	MR. MARGOLIS: Objection. Vague.	15:56:23	1	Is that a true statement?	15:58:44
2	THE WITNESS: I've said all the way	15:56:25	2	MR. MARGOLIS: Objection. Vague. Calls	15:58:46
3	through this by looking at the structure and	15:56:27	3	for speculation.	15:58:47
4	understanding the behavior it's possible to	15:56:31	4	THE WITNESS: I haven't read this paper	15:58:50
5	predict these changes. With this type of	15:56:33	5	for a long time, so I hope it's correct. But	15:58:52
6	moiety, sorry, this type of head group, it's	15:56:37	6	without re-reading it --	15:58:57
7	a very small head group, I would expect the	15:56:42	7	Q. Do you have any reason to believe that it's	15:58:58
8	linker to have a big change. If I then	15:56:44	8	not a true statement?	15:59:01
9	transferred that to a polyoxyethylene	15:56:47	9	A. I would hope it would be correct.	15:59:02
10	surfactant or some other polymer head group,	15:56:49	10	Q. You can put that document aside.	15:59:03
11	I would expect the change to be minimal.	15:56:51	11	MR. HASFORD: I'm handing the court	15:59:15
12	Q. In general, is it fair to say that a	15:56:53	12	reporter what I would ask to be marked as	15:59:17
13	structural change in a non-ionic surfactant can	15:56:55	13	Lawrence Exhibit 22.	15:59:19
14	greatly alter the physicochemical and solubilization	15:56:58	14	For the record, Lawrence Exhibit 22	15:59:20
15	behavior of the surfactant?	15:57:02	15	corresponds to item number 49 in Articles in	15:59:22
16	A. It would depend on --	15:57:03	16	Academic Journals on Dr. Lawrence's	15:59:27
17	MR. MARGOLIS: Objection. Asked and	15:57:03	17	curriculum vitae.	15:59:28
18	answered.	15:57:04	18	(Whereupon, Plaintiff's Deposition	15:59:52
19	Q. You may answer.	15:57:04	19	Exhibit No. Lawrence 22 was marked for	15:59:53
20	A. It depends on the surfactant you're looking	15:57:05	20	Identification.)	15:59:54
21	at.	15:57:08	21	Q. Are you the M. Jayne Lawrence who co-authored	15:59:54
22	Q. You can put this document aside.	15:57:08	22	Lawrence Exhibit 22?	15:59:57

Page 306		Page 308	
1	A. I am.	15:59:58	
2	Q. And does Lawrence Exhibit 22 correspond to	15:59:59	
3	item number 49 in Articles in Academic Journals on	16:00:04	
4	your curriculum vitae?	16:00:08	
5	A. It does.	16:00:10	
6	Q. Turn to page 82, please, in Conclusions, and	16:00:10	
7	look at the right-hand column. About halfway down	16:00:19	
8	it says, "The differences arise because the	16:00:23	
9	solubility of ionic surfactants increases as a	16:00:25	
10	function of temperature, whereas the solubility of	16:00:30	
11	non-ionic surfactants decreases."	16:00:32	
12	Is this a true statement?	16:00:35	
13	MR. MARGOLIS: Objection. Vague.	16:00:37	
14	THE WITNESS: I can't even see it.	16:00:39	
15	Sorry.	16:00:41	
16	Q. It's about halfway down, right below the	16:00:41	
17	acronym LTPB.	16:00:45	
18	A. Okay.	16:00:47	
19	Q. Let me know if you need me to read it again.	16:00:48	
20	A. If I'm honest, I'm not too sure about the	16:01:02	
21	first part, but certainly the second part is right.	16:01:04	
22	Q. Which part is the second part that you're	16:01:07	
Page 307		Page 309	
1	referring to?	16:01:09	
2	A. The solubility of non-ionic surfactants	16:01:09	
3	decreases, correct.	16:01:12	
4	Q. Would you expect non-ionic surfactants to	16:01:14	
5	have greater solubilizing capabilities at higher or	16:01:17	
6	lower temperatures?	16:01:20	
7	A. Higher.	16:01:21	
8	Q. You may put this document aside.	16:01:23	
9	A. That would be -- you have to be very careful	16:01:26	
10	which non-ionic surfactants because some non-ionic	16:01:30	
11	surfactants don't exhibit that behavior in their	16:01:35	
12	pharmaceutically accessible temperature regime.	16:01:36	
13	Q. Is the temperature dependency of the	16:01:46	
14	solubilizing effect of non-ionic surfactants	16:01:50	
15	predictable or unpredictable?	16:01:54	
16	MR. MARGOLIS: Objection. Vague. Calls	16:01:57	
17	for speculation.	16:01:58	
18	THE WITNESS: What was the question? Is	16:02:00	
19	the solubility --	16:02:01	
20	Q. Is the temperature dependency --	16:02:02	
21	A. Ah. Yeah.	16:02:02	
22	Q. -- of the solubilizing effects of non-ionic	16:02:04	
1	surfactants predictable or unpredictable?	16:02:06	
2	MR. MARGOLIS: Objection. Vague. Calls	16:02:09	
3	for speculation.	16:02:10	
4	THE WITNESS: It is vague because the	16:02:11	
5	solubility properties of some drugs will	16:02:14	
6	increase and decrease, some will become polar	16:02:15	
7	and non-polar as a function of temperature.	16:02:18	
8	Q. Take a look -- I'm sorry. Let me mark a new	16:02:21	
9	document.	16:02:36	
10	MR. HASFORD: I'm handing the court	16:02:41	
11	reporter what I would ask to be marked as	16:02:43	
12	Lawrence Exhibit 23.	16:02:45	
13	For the record, Lawrence Exhibit 23	16:02:46	
14	corresponds to item number 87 in Articles in	16:02:50	
15	Academic Journals on Dr. Lawrence's CV.	16:02:55	
16	(Whereupon, Plaintiff's Deposition	16:03:22	
17	Exhibit No. Lawrence 23 was marked for	16:03:22	
18	Identification.)	16:03:23	
19	Q. Are you the M. Jayne Lawrence who co-authored	16:03:23	
20	Lawrence Exhibit 23?	16:03:30	
21	A. I am.	16:03:32	
22	Q. Does Lawrence Exhibit 23 correspond to item	16:03:33	
1	number 87 in Articles in Academic Journals on your	16:03:37	
2	curriculum vitae?	16:03:40	
3	A. It does.	16:03:42	
4	Q. Take a look, if you would, at the second	16:03:42	
5	sentence. It says, "This wide usage is due to the	16:03:45	
6	fact that surfactants display diverse structures in	16:03:49	
7	aqueous environments depending on their	16:03:53	
8	concentration, the temperature, pH, and the presence	16:03:56	
9	of other species in the system (i.e., ions and	16:03:58	
10	oils)."	16:04:02	
11	Is it true that surfactants display diverse	16:04:02	
12	structures in aqueous environments depending on	16:04:06	
13	their concentration, the temperature, pH, and the	16:04:09	
14	presence of other species in the system?	16:04:11	
15	MR. MARGOLIS: Objection. Vague.	16:04:14	
16	THE WITNESS: Can you repeat that	16:04:16	
17	question?	16:04:18	
18	Q. Certainly. Is it true that surfactants	16:04:18	
19	display diverse structures in aqueous environments	16:04:21	
20	depending on their concentration, the temperature,	16:04:24	
21	pH, and the presence of other species in the system?	16:04:27	
22	MR. MARGOLIS: Objection. Vague.	16:04:31	

Page 310	<p>1 THE WITNESS: It is vague. You have to 16:04:33</p> <p>2 remember the number of surfactant structures 16:04:37</p> <p>3 possible is absolutely huge. So, if you take 16:04:41</p> <p>4 surfactants as a whole, ionic, cationic, 16:04:46</p> <p>5 anionic, zwitterionic, non-ionic, that 16:04:54</p> <p>6 statement will be true. 16:05:12</p> <p>7 Q. Is it true that surfactants display diverse 16:05:14</p> <p>8 properties in aqueous environments depending on 16:05:19</p> <p>9 their concentration, the temperature, the pH, and 16:05:22</p> <p>10 the presence of other species in the system? 16:05:25</p> <p>11 A. How are you defining -- 16:05:27</p> <p>12 MR. MARGOLIS: Objection. Vague. 16:05:27</p> <p>13 THE WITNESS: Yeah. How are you 16:05:29</p> <p>14 defining properties? 16:05:30</p> <p>15 Q. Well, let me say it this way. Is it true 16:05:31</p> <p>16 that surfactants display diverse physical and 16:05:33</p> <p>17 chemical properties in aqueous environments 16:05:36</p> <p>18 depending on their concentration, the temperature, 16:05:39</p> <p>19 the pH, and the presence of other species in the 16:05:42</p> <p>20 system? 16:05:46</p> <p>21 MR. MARGOLIS: Objection. Vague. Calls 16:05:47</p> <p>22 for speculation. 16:05:48</p>
Page 311	<p>1 THE WITNESS: Yes. Remember, we're 16:05:49</p> <p>2 talking here in this context from anything 16:05:51</p> <p>3 from naught to a hundred percent of 16:05:55</p> <p>4 surfactants. So, we're not talking about 16:05:58</p> <p>5 concentrations of surfactants that will be 16:06:00</p> <p>6 routinely used in pharmaceutical 16:06:03</p> <p>7 formulations. So, I think that's slightly 16:06:06</p> <p>8 out of context. 16:06:07</p> <p>9 Q. You can put this document aside. 16:06:09</p> <p>10 MR. HASFORD: I'm handing the court 16:06:18</p> <p>11 reporter what I would ask to be marked as 16:06:20</p> <p>12 Lawrence Exhibit 24. 16:06:22</p> <p>13 For the record, Lawrence Exhibit 24 16:06:23</p> <p>14 corresponds to item number 102 in Articles in 16:06:25</p> <p>15 Academic Journals on Dr. Lawrence's 16:06:31</p> <p>16 curriculum vitae. 16:06:32</p> <p>17 A. Can I just point something out about that 16:06:33</p> <p>18 reference? 16:06:37</p> <p>19 Q. Oh, you certainly may. Of course. 16:06:38</p> <p>20 A. That reference was first published in 2002 16:06:39</p> <p>21 and is reference 39 on my list. It was re-published 16:06:45</p> <p>22 because it was a very highly cited paper by the 16:06:50</p>
Page 312	<p>1 journal. So, it's actually dating from 2000 and -- 16:06:55</p> <p>2 from 2000. 16:06:55</p> <p>3 Q. Okay. Thank you for that clarification. 16:07:33</p> <p>4 (Whereupon, Plaintiff's Deposition 16:07:33</p> <p>5 Exhibit No. Lawrence 24 was marked for 16:07:34</p> <p>6 Identification.) 16:07:34</p> <p>7 Q. Are you the M. Jayne Lawrence who co-authored 16:07:34</p> <p>8 Lawrence Exhibit 24? 16:07:37</p> <p>9 A. I am. 16:07:38</p> <p>10 Q. Does Lawrence Exhibit 24 correspond to item 16:07:38</p> <p>11 number 102 in Articles in Academic Journals on your 16:07:41</p> <p>12 curriculum vitae? 16:07:45</p> <p>13 A. Yes, but I do want to stress that this is a 16:07:46</p> <p>14 re-publication, an exact copy of the paper that is 16:07:49</p> <p>15 39 on this reference, and I think should be viewed 16:07:54</p> <p>16 in that context. This is a special issue of the 16:07:59</p> <p>17 journal, which is why it's a supplement just for a 16:08:03</p> <p>18 few papers that were very highly cited. 16:08:06</p> <p>19 Q. Is there anything else you would like to 16:08:11</p> <p>20 explain about that paper? 16:08:13</p> <p>21 A. No. That's fine. 16:08:14</p> <p>22 Q. Please, if you would like to. 16:08:15</p>
Page 313	<p>1 Take a look, if you would, on page 176, and 16:08:17</p> <p>2 let me direct your attention to the left-hand 16:08:20</p> <p>3 column. The last full sentence says, "On dispersal 16:08:22</p> <p>4 in water, surfactants self-associate into a variety 16:08:27</p> <p>5 of equilibrium phases, the nature of which stems 16:08:31</p> <p>6 directly from the interplay of the various inter and 16:08:34</p> <p>7 intermolecular forces as well as entropy 16:08:38</p> <p>8 considerations." 16:08:42</p> <p>9 Is that a true statement? 16:08:43</p> <p>10 MR. MARGOLIS: Objection. Vague. 16:08:45</p> <p>11 THE WITNESS: In the context of that 16:08:52</p> <p>12 paragraph, yes. 16:08:53</p> <p>13 Q. You can put that document aside. 16:08:54</p> <p>14 What did you do to prepare for your 16:08:59</p> <p>15 deposition today? 16:09:00</p> <p>16 MR. MARGOLIS: I just ask you not to 16:09:05</p> <p>17 reveal the communications between yourself 16:09:07</p> <p>18 and the attorneys, but you can otherwise 16:09:09</p> <p>19 answer his question generally. 16:09:11</p> <p>20 THE WITNESS: I did re-reading of the 16:09:13</p> <p>21 relevant material that I used to prepare the 16:09:17</p> <p>22 declaration in the first place. 16:09:22</p>



Page 314	Page 316
1 Q. Which material was that? 16:09:24	1 A. Just the day. 16:11:36
2 A. Well, it was obviously the patents, the 16:09:26	2 Q. Do you remember how many hours it was? 16:11:37
3 patent histories, I looked at the references that I 16:09:30	3 A. I didn't count. 16:11:39
4 had cited and tried to, you know, basically remember 16:09:33	4 MR. HASFORD: We have nothing further at 16:11:46
5 what I had written and why I'd written it. 16:09:41	5 this point. 16:11:47
6 Q. Did you review any documents other than those 16:09:43	6 MR. MARGOLIS: If we could just go off 16:11:50
7 that you cite in your declaration in preparation for 16:09:45	7 the record for a couple of minutes and we 16:11:52
8 today's deposition? 16:09:49	8 could talk. 16:11:53
9 A. I did read some related information that I 16:09:51	9 THE VIDEOGRAPHER: We only have about 16:11:53
10 thought might be useful. For example, I remember I 16:09:57	10 five minutes left on the tape. 16:11:53
11 refreshed my memory of the last patent case I did 16:10:02	11 MR. MARGOLIS: That should probably be 16:11:53
12 and information like that. 16:10:07	12 fine. You know what, let's just go off the 16:11:53
13 Q. What other materials did you review? 16:10:08	13 record. 16:11:55
14 A. Other patents that I'd read at the same time 16:10:11	14 THE VIDEOGRAPHER: The time is 16:11:55
15 that aren't in here for various reasons, papers that 16:10:24	15 approximately 4:13 p.m. We are off the 16:12:03
16 I'd read that supported the work. I just did quite 16:10:29	16 record. 16:12:09
17 a bit of reading, general reading around looking 16:10:33	17 (Recess from 4:13 to 4:18.) 16:16:59
18 back to what I was reading at the time that I made 16:10:35	18 THE VIDEOGRAPHER: The time is 16:16:59
19 the statements. 16:10:38	19 approximately 4:18 p.m. We are back on the 16:17:37
20 Q. When you reviewed the opinions you provided 16:10:39	20 record. 16:17:41
21 in those other cases, did it refresh your 16:10:41	21 MR. MARGOLIS: Lupin doesn't have any 16:17:42
22 recollection as to what those opinions were? 16:10:43	22 questions. I'm just going to designate the 16:17:45
Page 315	Page 317
1 A. Oh, no, I didn't read all the opinions. I 16:10:45	1 transcript confidential. 16:17:48
2 just read some of the information around it. 16:10:48	2 MR. HASFORD: On what basis? Because we 16:17:50
3 Q. Did any of that -- 16:10:50	3 didn't go into any confidential information, 16:17:51
4 A. -- so. Sorry. 16:10:51	4 I don't think. 16:17:53
5 Q. Go ahead. Did any of that refresh your 16:10:52	5 MR. MARGOLIS: Yeah, I'm sorry. I 16:17:54
6 recollection as to the opinions you provided in 16:10:55	6 haven't had a chance to look back to make 16:17:55
7 those other cases? 16:10:57	7 sure that there wasn't. I don't recall 16:17:57
8 A. No. I didn't go that far into it. 16:10:59	8 anything specifically right now. 16:18:00
9 Q. Okay. Did you review any documents that 16:11:02	9 MR. HASFORD: Okay. Well, why don't 16:18:02
10 contradicted any of your opinions set forth in your 16:11:05	10 you -- why don't you look at it after we're 16:18:02
11 declaration? 16:11:08	11 off the record and e-mail it because I'd 16:18:04
12 A. To be honest, no. 16:11:14	12 prefer that we don't designate it 16:18:07
13 Q. With whom did you meet in preparation for 16:11:16	13 confidential ab initio. Look back at it once 16:18:10
14 your deposition today? 16:11:18	14 it comes out. If you see anything in there, 16:18:13
15 A. I met with the attorneys yesterday. 16:11:20	15 give me a call or shoot me an e-mail and we 16:18:14
16 Q. Which attorneys? 16:11:22	16 can talk about it or we can do portions. I 16:18:16
17 A. The two people sitting here. 16:11:25	17 just don't want us to blanket designate the 16:18:18
18 Q. These two gentlemen? 16:11:27	18 whole thing -- 16:18:20
19 A. Yes. 16:11:29	19 MR. MARGOLIS: Okay. 16:18:20
20 Q. Okay. How long did you meet with Lupin's and 16:11:29	20 MR. HASFORD: -- because that's kind of 16:18:21
21 Innopharma's counsel in preparation for your 16:11:34	21 contrary to the protective order, you know. 16:18:21
22 deposition today? 16:11:36	22 MR. MARGOLIS: That's fair. As long as 16:18:23

Page 318

1 the -- 16:18:23

2 MR. HASFORD: I won't argue that you 16:18:25

3 waived anything. 16:18:27

4 MR. MARGOLIS: Okay. As long as that's 16:18:27

5 fine. I can't recall right now. 16:18:30

6 MR. HASFORD: I won't argue that you 16:18:31

7 waived anything. 16:18:33

8 MR. MARGOLIS: Okay. 16:18:34

9 MR. HASFORD: Innopharma, you got 16:18:34

10 anything? 16:18:36

11 MR. ABE: I have nothing further. 16:18:36

12 MR. HASFORD: Okay. All right. 16:18:39

13 Q. Well, thank you, Doctor. 16:18:39

14 A. Thank you. Some of those papers I've not 16:18:40

15 seen for years. 16:18:45

16 THE VIDEOGRAPHER: The time is 16:18:47

17 approximately 4:19 p.m., Friday, September 4, 16:18:52

18 2015. This is the end of tape number five 16:19:00

19 and completes the videotaped deposition of 16:19:03

20 Dr. Jayne Lawrence. We are off the record. 16:19:06

21 (Whereupon, the deposition was

22 concluded at 4:19 p.m.)

Page 319

1 I HEREBY CERTIFY that I have read this transcript of

2 my deposition and that this transcript accurately

3 states the testimony given by me, with the changes

4 of corrections, if an, as noted.

5

6

7 X \_\_\_\_\_

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9 Subscribed and sworn to be before this day of

10 2014

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<b>A</b>				
<b>ab</b> 317:13	155:17 157:2,5	<b>affirm</b> 16:20	48:13 53:15 54:2	<b>appear</b> 18:20 176:17
<b>Abe</b> 4:7 16:17,17 19:16	161:16 171:20,20	<b>afternoon</b> 205:4,10,11	<b>anionic</b> 310:5	176:21 177:8,12
19:21 318:11	172:4,5 176:8,16,20	<b>agent</b> 172:22 173:3,10	<b>answer</b> 17:16,20 18:1	242:14
<b>abilities</b> 282:2,13	177:7,16 189:19	174:3 180:20 235:15	19:15 20:13,20 21:9	<b>appearance</b> 226:7
<b>ability</b> 142:10 169:8	191:6 203:12 217:12	<b>agents</b> 173:21 189:21	22:1,2,9 25:7 26:2,11	<b>appears</b> 242:5
<b>able</b> 73:8 79:21 88:7	296:16	190:8 299:16	26:15 30:7 31:8 34:1	<b>appendices</b> 5:12 18:12
101:3,19 127:9	<b>acids</b> 173:17,17	<b>aggregate</b> 266:13 289:2	34:21 35:7,9,13,14	18:17
142:12 146:9 158:8,9	<b>acknowledged</b> 62:15	289:4,21 290:1	40:1 41:11 42:3 43:7	<b>Appendix</b> 19:4,5
163:11,16 260:9	<b>acronym</b> 29:15 306:17	298:10	44:15 52:21 58:19	<b>APPERANCES</b> 4:1
261:21	<b>ACS</b> 14:14	<b>aggregates</b> 286:13	77:3,13 80:8 84:16	<b>applicable</b> 103:18
<b>absence</b> 170:12 218:14	<b>act</b> 173:10 174:5,6	<b>aggregation</b> 12:9 82:14	85:7 93:5 96:3 104:5	138:10
266:7	<b>Acta</b> 10:7	86:7 291:7,9	106:5 110:19 123:8	<b>applicants</b> 178:22
<b>absolute</b> 114:6 157:4	<b>acted</b> 53:6	<b>ago</b> 25:19 32:11,17	132:22 134:18 135:6	231:3
<b>absolutely</b> 310:3	<b>action</b> 1:5,11 15:14	38:14 56:6 129:2	135:21 136:1 142:8	<b>application</b> 6:17 69:2,5
<b>absorbed</b> 270:15	181:1	<b>agree</b> 15:10 19:16,19	145:16 146:3,9,15,18	69:9,13 237:18 238:1
<b>Absorption</b> 5:15	<b>active</b> 49:6,11 50:19	198:4 214:8 217:15	147:21 148:13,22	238:3,5,16 239:1
<b>abstract</b> 109:15 126:9	51:1 72:13 171:10	235:7,21	149:20 151:2 154:5	<b>applications</b> 7:14 45:16
126:11,14,21 129:3,6	213:21 214:1 258:8	<b>agreement</b> 131:7	165:18 220:12 222:16	68:13,15,20 147:8
261:18	<b>activities</b> 20:6,7 21:15	<b>Ah</b> 307:21	224:7 228:7 234:21	152:14 237:11
<b>academia</b> 55:6,10	21:18,19 22:12	<b>ahead</b> 96:16 274:18	239:20 244:11 246:18	<b>applies</b> 190:20
<b>academic</b> 9:9,20 10:8	<b>activity</b> 25:1 133:15,21	315:5	259:5 261:13 268:9	<b>apply</b> 19:17 142:13
10:15 11:10,17 12:8	283:22	<b>al</b> 6:12 15:13,14 207:3	269:3 270:3,12	190:2,11,18 203:14
12:14 13:11,18 14:8	<b>acts</b> 31:21	208:6	271:14 273:3 275:19	<b>Appointments</b> 54:21
14:16,22 21:20 32:7,9	<b>add</b> 35:20 272:2,8	<b>alcohol</b> 127:8 128:15	296:13 303:19 313:19	55:18
32:16,19 63:8,10,19	<b>added</b> 180:22 181:6,22	129:11	<b>answered</b> 35:2 40:17	<b>appreciate</b> 293:21
63:20 65:21 66:4	217:1 251:22	<b>alkaline</b> 189:22	93:4 104:4 112:13	<b>appreciation</b> 274:9
205:14,20 276:8	<b>adding</b> 102:12 300:20	<b>alkyl</b> 127:7 128:14	121:7 147:16 222:22	<b>approach</b> 255:17
279:14 280:3,21	301:4,12 302:6	129:11 281:15	228:12 236:6,13	<b>appropriate</b> 39:16
281:8 283:4,13 285:1	<b>addition</b> 49:11 295:21	<b>allowed</b> 145:19	237:5 271:15 302:10	42:13 43:1,4,18 59:18
285:13 288:3,12	<b>additives</b> 266:7	<b>all-or-nothing</b> 301:16	303:18	85:19 133:12,13,14
292:13,22 295:7,16	<b>address</b> 17:7 131:14,19	<b>Alston</b> 4:3 16:17	<b>answering</b> 132:10	133:15 163:4 271:6
297:17 298:4,21	131:22 224:8	<b>alter</b> 302:16,20 303:14	133:18 290:16	271:10 273:19
299:7 304:6,15	<b>adequately</b> 274:11	<b>alternative</b> 81:19	<b>answers</b> 32:12 133:8	<b>appropriately</b> 108:5
305:16 306:3 308:15	<b>adjusted</b> 125:11	255:16	221:18 223:20	<b>appropriately</b> 15:21
309:1 311:15 312:11	<b>adjuvant</b> 233:10,10,11	<b>altogether</b> 181:15	<b>antibiotic</b> 233:7	80:17 81:1 136:12,18
<b>accelerated</b> 235:18	<b>administer</b> 122:21	<b>American</b> 45:6 188:4,5	<b>antimicrobial</b> 37:19	204:21 205:5 254:19
<b>accept</b> 46:14	<b>administered</b> 27:21	188:6	38:2,10,17 253:5,8	255:3 316:15,19
<b>acceptable</b> 124:16	29:18 233:14	<b>amineoxide</b> 13:7	<b>antioxidant</b> 217:16	318:17
129:10 233:8	<b>administering</b> 155:21	<b>amine-N-oxide</b> 255:20	218:9	<b>approximation</b> 158:9
<b>acceptance</b> 254:1	<b>administration</b> 59:4,9	255:22 256:4	<b>antioxidants</b> 216:11	<b>aqueous</b> 9:6 12:11
<b>accepted</b> 31:10 56:11	108:1 145:8 160:7	<b>ammonium</b> 127:12	217:1,10,20,20 218:1	23:15 34:17 35:10
<b>access</b> 262:5	161:12 164:4,21	<b>amount</b> 35:19,19,21,21	218:6	36:8,15 39:11,19 40:6
<b>accessible</b> 307:12	211:21 212:1,2	44:7 49:21 80:1	<b>anti-inflammatory</b>	40:14,22 41:3,9,18
<b>accuracy</b> 78:3,4,15	277:10	88:17 114:14 212:17	80:5 155:15,19 156:4	44:1 50:18,22 62:3,7
<b>accurately</b> 17:17 18:5	<b>adopted</b> 144:1	212:22 227:13 230:8	156:6 168:15	62:14,16 65:3,9,18
77:17 78:2 158:12	<b>advanced</b> 14:20 260:9	231:17 238:17 271:1	<b>anybody</b> 54:13 73:13	67:22 69:10 75:19
170:14 171:1 172:7	260:14 261:7,21	<b>amounts</b> 50:1 88:6	85:15 99:2,18 109:22	80:4 86:2,17,22 87:12
319:2	<b>advancement</b> 150:2	101:20	138:3 182:9 249:14	87:20 88:16 98:17
<b>Ace-Federal</b> 16:2,5	<b>Advances</b> 8:4	<b>amphiphilic</b> 67:8	<b>anyway</b> 118:10 157:17	99:6,10,15 100:8,11
<b>achieve</b> 273:17 274:14	<b>advantage</b> 277:9	166:18 266:1 287:2	164:4	100:20 101:11,16
296:2	<b>advice</b> 236:16	<b>analogous</b> 66:20	<b>Apologies</b> 132:11 177:4	102:2,9 107:8,16,22
<b>achieved</b> 256:2 296:6	<b>advise</b> 53:20	<b>analysis</b> 10:4 219:2	<b>apologize</b> 107:20 128:7	108:15 109:18 110:16
<b>acid</b> 29:16 33:5 105:15	<b>advised</b> 153:9	220:3,13,16	175:2,14 195:9	111:12,21 112:10
105:21 119:9 124:8	<b>advisory</b> 279:3	<b>analytically</b> 82:10	198:17 254:5 265:1	114:12 116:9 118:4
127:9 129:10,13	<b>affect</b> 49:12 169:12	<b>analyzed</b> 37:2	274:18 277:5 281:14	124:15 125:10,17
	213:20 257:4 272:5	<b>Angeles</b> 4:6	<b>apparent</b> 113:11	126:3,15 127:10
	290:11,16	<b>anion</b> 29:19 32:2 48:1	283:20	128:7 129:7 131:15

<p>131:22 132:3,18 133:4 151:5 156:19 156:20 159:6,13 160:11 161:5,20 162:5,19 164:6,11 167:8,13 168:4,19 169:12 171:14 175:9 188:13,19 189:5 211:10,17 217:10,17 218:1,10 283:21 284:3,12 286:5 289:3 289:5,22 290:2 291:19 292:4 298:11 309:7,12,19 310:8,17 <b>aqueous-based</b> 65:8 286:7 <b>Archaeology</b> 25:5 <b>architecture</b> 266:20 <b>area</b> 21:4 27:3 39:4 41:12 73:7 184:10 <b>areas</b> 19:11 20:2,9,14 20:16 21:7,11,12,13 21:21 22:4,6,14 23:19 23:20 24:1,9,11,13,17 25:3,4 258:5 <b>argue</b> 222:9 318:2,6 <b>Arrhenius</b> 218:19 219:3 220:14 <b>art</b> 36:19 79:22 83:1 84:11,19 85:1,10 86:21 87:10,19 88:5 88:14 97:22 98:17 99:3,5,14 100:11,20 101:6,10,15 102:1,9 106:14 107:7,15,22 108:15 109:10,17 110:16 111:12,20 112:3,10 120:8 121:2 121:17 122:8,14 123:14 125:17 126:3 127:6 133:4 137:5 138:4,9,13,14,16 139:15,21 140:5 141:21 142:4,9 143:5 143:8,17,22 144:5,9 144:14 145:7,13,20 146:5,12 148:18 149:5,12,13,14,16 150:7,15 151:18,22 152:9 153:17 154:1 154:15,16,17,19 155:6,9 159:6,13 160:11 161:19 162:18 163:18 187:3,12 188:10,17 189:3 209:21 210:7,15,20 218:9 220:6,20</p>	<p>227:21 228:3,4,9 243:5 246:21 247:4 247:17 248:2 249:15 252:13 256:4 260:13 261:6 299:22 <b>Arthur</b> 187:5 <b>article</b> 66:7 67:9,14,21 207:3,22 208:12 <b>articles</b> 9:9,19 10:8,14 11:10,17 12:7,14 13:10,17 14:8,16,21 65:20 66:3 205:14,19 279:13 280:3,20 281:8 283:3,13 284:22 285:13 288:2 288:12 292:12,22 295:6,16 297:16 298:4,20 299:7 304:5 304:15 305:15 306:3 308:14 309:1 311:14 312:11 <b>artisan</b> 249:8 <b>arts</b> 144:12 <b>aryl</b> 127:8 128:14 129:11 <b>ascorbic</b> 217:12 <b>ascribed</b> 137:6 <b>Ashford</b> 17:10 <b>aside</b> 52:2,17 53:1,13 53:22 55:9 117:21 209:6 237:8 239:8 241:22 257:6 259:8 262:8 264:7 267:3 279:8 280:15 282:20 284:17 287:19 292:7 295:1 297:11 298:15 303:22 305:10 307:8 311:9 313:13 <b>asked</b> 17:19 18:8 25:7 35:5,6 40:16 54:13 90:5 92:7 93:3,7 104:3 130:12 147:15 222:21 223:8,9 228:12 236:6,12 237:4 274:14 302:9 303:17 <b>asking</b> 21:5 22:5 24:6,7 34:8 48:10,17 96:4 102:21 103:20 131:19 138:6 139:1 148:22 149:2,3,9 162:3 177:6 185:2 195:11 220:18 236:20 237:1 239:17 245:11 258:21 287:6 <b>aspect</b> 148:8 149:1 <b>aspects</b> 7:8 148:10,12 <b>aspirin</b> 168:16</p>	<p><b>assay</b> 162:7 <b>assayed</b> 42:12 <b>assays</b> 218:21 <b>assessed</b> 269:8 278:4 <b>assessing</b> 44:7 <b>assessment</b> 88:8 <b>assigned</b> 232:20 238:6 <b>associated</b> 277:4 <b>Association</b> 9:4 188:6,6 <b>assume</b> 18:1 35:19 102:11 119:21 <b>assuming</b> 35:17 93:22 112:17 241:16 <b>assumptions</b> 35:15 <b>asymmetric</b> 266:4 <b>atom</b> 301:2 <b>atoms</b> 301:1 <b>attempt</b> 237:7 <b>attempting</b> 285:19 <b>attention</b> 54:20 58:6 62:21 69:16 96:17 98:8 106:8 107:1 108:8 110:13 113:3 114:9 152:21 183:1,8 186:17 189:16 192:1 194:3 203:6 205:13 206:10 209:9 213:5,8 214:13 218:16 225:8 233:5 240:17 255:8 255:11 258:2 260:6 263:7 267:21 268:12 268:17 269:12 272:13 273:7 275:6 277:1,22 285:17 288:16 295:20 313:2 <b>attorney</b> 137:17 <b>attorneys</b> 3:4,15 4:4 135:22 153:10 313:18 315:15,16 <b>attractive</b> 269:20 <b>audio</b> 15:8 <b>authored</b> 50:17,21 51:3 187:22 241:20 267:19 285:9 288:8 295:12 <b>authorities</b> 163:6 <b>authorization</b> 163:3 <b>automatically</b> 241:15 <b>available</b> 79:12 83:12 85:8 121:14 261:17 <b>Avenue</b> 2:3 3:5,17 15:20 <b>average</b> 143:14 <b>avoid</b> 220:17 <b>awards</b> 24:22 89:4 <b>aware</b> 29:15 37:21 39:2 51:11 145:8 194:14 <b>A-O3</b> 115:19</p>	<p><b>A-02</b> 227:14,15 <b>A-03</b> 113:22 114:21 115:9,16 227:16 <b>A-04</b> 116:2,4 229:15,19 <b>A-05</b> 229:15,20 <b>A-06</b> 229:21 <b>A-07</b> 229:22 <b>A-08</b> 230:1 <b>a.m</b> 2:5 15:22 80:17 81:1 136:12,18 <b>A1</b> 6:18  <b>B</b> <b>B</b> 5:6 6:1 7:1 8:1 9:1 10:1 11:1 12:1 13:1 14:1 38:21 39:6 108:22 243:7 244:3,7 244:18 245:1,6,21 246:15 247:6 249:10 250:3 <b>back</b> 47:1 69:15 71:19 81:4 90:4 106:7 112:22 131:10 133:22 136:21 151:10 155:2 171:16 185:12 186:16 191:22 193:5,19 195:3 202:9 205:8 209:8 212:10 213:4 221:18 223:8 225:6 255:6,8 287:8 290:20 290:22 314:18 316:19 317:6,13 <b>backbone</b> 294:7,7 <b>bacteria</b> 105:11 251:2 251:9 <b>bacterial</b> 211:8 <b>bad</b> 200:4 <b>balance</b> 77:5 273:12,19 290:13 296:3,5 <b>Barcelona</b> 287:5 <b>base</b> 161:16 <b>based</b> 21:5 35:3,20 36:7 48:10 77:19 78:6 96:4 99:3,21 101:9,14 101:18,18,22 102:7 102:21 106:13 107:6 107:14,20 108:13 109:8,16 111:19 112:8 125:15 126:1 127:21 158:13 160:4 168:8 170:17 171:2 220:4,18 249:2 258:4 <b>basic</b> 85:18 150:5 184:10 272:18 <b>basically</b> 162:12 314:4 <b>basing</b> 220:12 <b>basis</b> 126:19 127:16,20</p>	<p>127:21 128:1 129:17 129:21 130:1,9,18 131:1,6,7 166:21 169:17,19 202:11 256:8 294:17 317:2 <b>Bates</b> 180:11 189:14 190:22 192:13 194:1 195:20 196:7 203:6 213:6 252:19 <b>battery</b> 82:13 <b>Bausch</b> 1:3,4 16:10,13 <b>BBA</b> 10:6 <b>bears</b> 180:11 189:14 190:22 192:13 194:1 195:20 196:7 203:6 213:6 252:19 <b>beginning</b> 213:16 <b>begins</b> 185:15 194:17 258:3 <b>behalf</b> 16:10,13 233:2 238:9 <b>behave</b> 42:22 43:3 66:19 <b>behaved</b> 302:4 <b>behavior</b> 74:15 169:9 169:11 171:8 300:9 302:17,21 303:4,15 307:11 <b>behaviour</b> 269:7 272:20 278:3 <b>believe</b> 23:4 39:12,14 40:2 56:16 65:7,12,14 66:5,16,17 94:20 97:10 99:18 103:4 104:13,20 106:21 108:18 109:22 116:6 147:16 152:11 164:14 164:15 172:10 176:10 177:11,19 180:4 186:4 192:6 198:12 199:3 201:2 203:17 221:1 223:16 224:7 235:3 237:6 239:21 243:18 244:5 263:15 264:5 268:10 269:4 271:15 273:4 277:13 278:9 280:14 282:16 285:6 300:5 305:7 <b>believed</b> 286:21 <b>Bendamustine</b> 238:18 <b>benzalkonium</b> 124:19 127:11 132:5,20 133:5,20 <b>best</b> 77:13 272:7,8 286:11 <b>Beta-Cyclodextrin</b> 10:5</p>
--	---	--	--	--

<p><b>Beta-lactam</b> 233:7  <b>better</b> 8:15,16 163:17                  209:4 220:15 269:22  <b>beyond</b> 269:14  <b>big</b> 294:10 301:12                  303:8  <b>biggest</b> 35:18  <b>Bilayers</b> 7:6  <b>bind</b> 175:12  <b>binder</b> 106:21 110:12  <b>binding</b> 174:3  <b>bioavailability</b> 73:19  <b>Biochimica</b> 10:6  <b>Biodegradable</b> 13:7  <b>biology</b> 258:6  <b>biomedical</b> 146:4  <b>Biopharmaceutical</b>                  5:16  <b>Biophysica</b> 10:7  <b>biostatistics</b> 37:11,16  <b>Bird</b> 4:3 16:17  <b>bisulfite</b> 217:11  <b>bit</b> 20:7 96:16 110:6                  116:17 124:12 133:1                  150:5 157:19 314:17  <b>bizarre</b> 130:3  <b>blanket</b> 317:17  <b>body</b> 156:7 159:1 181:2                  208:16 212:2 269:7                  270:15 273:18 274:12                  274:16 278:3 280:7                  298:7  <b>book</b> 7:10,17,22 8:9,14                  50:21 51:2,3,4 63:4,7                  63:16 64:2,7,10,17                  65:2,11 187:14,21                  240:4 241:17 255:10  <b>Books</b> 62:22 240:11                  257:12,20 259:14,22                  262:14 263:1 264:16                  265:13  <b>borax</b> 179:1  <b>bottle</b> 121:9,13 123:10                  123:19 140:21  <b>bottom</b> 55:1 133:17                  180:16 183:3,16                  184:3 194:16 196:9                  196:18 199:6,9 203:7                  214:11 275:7 283:18  <b>brain</b> 75:3  <b>break</b> 17:18,20 80:14                  136:9,10 204:10,14  <b>brief</b> 83:8  <b>British</b> 63:8,18 95:19                  188:4  <b>broad</b> 208:19  <b>broadly</b> 97:8 207:14</p>	<p>258:4  <b>bromfenac</b> 27:21 28:6                  30:5,8 33:1,8 47:13                  52:4,10,13,15,18                  124:9,11,16 126:17                  127:10 132:4,16,18                  133:5 155:18 156:3                  156:11,16,21 157:1                  163:22 164:7,12,17                  165:3,12,15,22                  168:17 228:18 230:8  <b>bromobenzoyl</b> 119:4  <b>brought</b> 287:8  <b>Bryan</b> 3:8 16:12  <b>bryan.diner@finneg...</b>                  3:12  <b>building</b> 3:16 15:20                  163:16  <b>Burdock</b> 192:3,9,13,17                  192:20 193:10,16,20                  194:10,20  <b>buy</b> 201:8,8,9  <b>B2</b> 6:16</p> <p style="text-align: center;"><b>C</b></p> <p><b>C</b> 3:1,8 15:1 74:13  <b>calcium</b> 103:18 173:8                  173:13 175:12,13                  180:21,22 181:7                  182:1,13,15,18,20                  183:11 184:1,6,15                  185:6  <b>calcium-depleting</b>                  181:1  <b>calculations</b> 261:22                  262:1,6  <b>California</b> 4:6  <b>call</b> 128:16 294:6                  317:15  <b>called</b> 53:20 190:10                  216:11  <b>Calls</b> 84:13 87:5 98:19                  126:6 146:6,13 154:3                  154:10 158:4 159:8                  159:15 160:14 227:22                  228:11 234:5,20                  236:13 239:4 244:9                  252:15 270:1 284:13                  294:20 296:11 305:2                  307:16 308:2 310:21  <b>candidate</b> 269:21 278:2  <b>capabilities</b> 307:5  <b>capability</b> 223:18  <b>capacity</b> 53:10 82:16                  83:13 168:8 280:12                  299:20 300:1  <b>carbon</b> 301:1</p>	<p><b>carbonate</b> 180:21  <b>careful</b> 275:5 307:9  <b>carefully</b> 92:17,18                  239:20  <b>carried</b> 113:12 119:17  <b>Carriers</b> 8:8  <b>carry</b> 97:22 106:15                  120:10 121:4,20                  122:9 123:5  <b>carrying</b> 122:15 123:15  <b>case</b> 17:14 18:17,21                  19:2 20:22 24:3,5,8                  42:9 45:18 46:3,9,13                  46:16 47:1,2,8,11                  52:2,17 53:1,11,13,22                  69:18,21 70:2,7,14                  71:3,7,11,17,18 72:5                  72:22 73:10 90:13,19                  91:3,9,16 92:4 97:17                  98:11 105:1 107:4                  108:11 113:6 131:12                  134:15 135:3,10,14                  135:18 136:4 180:2                  184:22 186:21 192:4                  192:18 195:8,13                  196:14 202:21 209:15                  212:16,20 233:1                  238:8 239:11 243:21                  245:14 252:11 276:3                  276:4 284:16 294:5                  296:20 314:11  <b>cases</b> 45:10 70:17,18,21                  143:10,19 144:2                  198:10 199:16 222:8                  302:4 314:21 315:7  <b>case-by-case</b> 169:17,19                  294:17  <b>cast</b> 181:20,21 191:15                  201:5  <b>catalysts</b> 216:12  <b>categorically</b> 106:6  <b>cationic</b> 66:18 310:4  <b>cause</b> 296:8 297:2  <b>causes</b> 295:22  <b>causing</b> 281:17  <b>caution</b> 239:14  <b>Celsius</b> 113:13 114:16                  119:1,7 230:10  <b>certain</b> 92:12 93:1,10                  93:20 94:9 121:15                  148:22 170:10 174:3                  199:16 216:3 230:8                  242:22 245:11 287:1  <b>certainly</b> 20:2 33:15                  63:11 87:18 93:8                  108:12 115:8 157:4                  167:19,20 210:11</p>	<p>246:12,12 275:6                  306:21 309:18 311:19  <b>certainty</b> 153:16 154:1                  155:5,8  <b>Certified</b> 2:6  <b>CERTIFY</b> 319:1  <b>cetera</b> 75:15 162:11                  212:4  <b>chain</b> 79:14,16,16                  83:13 216:14 281:15                  290:13,14 291:5,7                  300:13  <b>chains</b> 81:20 266:12                  288:20 289:18 294:6                  296:20  <b>chair</b> 21:15  <b>challenges</b> 271:3,5,9  <b>chance</b> 317:6  <b>change</b> 80:15 136:8                  254:16 266:8 301:6,6                  301:13,16 302:8,19                  303:8,11,13  <b>changed</b> 43:12 162:11  <b>changes</b> 169:10 226:6                  296:9 297:2 301:18                  302:1 303:5 319:3  <b>chapter</b> 51:3,4 63:16                  64:2,7,10,17 65:2,18  <b>chapters</b> 7:10,17,22 8:9                  8:14 50:21 62:22                  63:4,7 65:7,11 240:5                  240:11 241:17 255:10                  257:11,20 259:13,22                  262:13 263:1 264:16                  265:13  <b>characteristics</b> 9:4                  235:16  <b>characterization</b> 11:13                  74:4,8,12,16 75:7                  85:18,20 86:2 300:9  <b>characterize</b> 82:6,10                  85:10 87:2 162:18                  301:4 302:6  <b>characterized</b> 81:13,22                  86:15 114:12  <b>characterizing</b> 161:19  <b>charge</b> 167:2,4  <b>charged</b> 167:1  <b>charges</b> 173:6,9,11  <b>check</b> 64:9,15 66:16                  106:1 108:21 109:12                  138:22 170:2 244:13                  249:16  <b>checked</b> 244:12 250:6  <b>checking</b> 82:11  <b>chelate</b> 173:8  <b>chelated</b> 190:6</p>	<p><b>chelates</b> 189:22  <b>chelating</b> 172:22 173:2                  173:10,21 174:2                  189:21 190:8  <b>chelation</b> 173:15                  174:11,15 175:4  <b>chelator</b> 174:5  <b>chemical</b> 7:8 10:13                  45:6 49:13 75:10,17                  76:22 77:7,9,10,18,19                  77:21 78:5,7,8,12                  79:2,3,5 80:2 82:1,19                  82:21 85:10 87:2                  95:12,16,22 96:7                  116:9 117:4,5,12,16                  118:2 124:7,9,12                  156:11 157:12,22                  158:1,3,13,14,15,18                  161:20 162:19 169:2                  169:4 170:4,6,7,15                  171:2,3,5,21,22 172:7                  214:19 215:2,4,7,20                  216:18,21 217:2                  219:14,18 220:6,20                  224:5,16 225:12,16                  225:17 226:1,2                  260:14 261:8 282:1                  282:12 289:7 290:4                  296:9 297:3 301:5,6                  302:7 310:17  <b>chemicals</b> 177:13                  182:22 258:8  <b>chemistry</b> 9:7 44:13,17                  44:18,19,20,22 45:3,4                  45:9 54:9,14  <b>chief</b> 21:16,18 56:17  <b>chloride</b> 124:20 127:12                  132:6,20 133:5,20                  238:17  <b>choose</b> 141:4  <b>chosen</b> 198:19  <b>circumstance</b> 222:6  <b>circumstances</b> 38:8                  61:10 80:10 84:22                  100:15 167:12 175:8                  211:16 222:17  <b>citation</b> 66:14 129:7                  281:13  <b>cite</b> 143:3 206:16                  208:12 213:1 231:21                  231:22 254:13 314:7  <b>cited</b> 311:22 312:18                  314:4  <b>Civil</b> 1:5,11 15:14  <b>claim</b> 18:16,20 19:1,5                  27:14 45:21 46:6,19                  90:6 92:8 97:15,16,22</p>
---	--	---	--	---

<p>98:9,9,17 99:6,16 100:11,20 101:5,11 101:16 102:2,9,14,22 103:1,6,9,21,22 104:14,17 106:9,15 107:2,2,8,16,22 108:9 108:10,15,20 109:18 110:13,16 111:12,21 112:10,14 114:9,10 114:22 115:10,17 116:5 130:13,14 131:4 137:3,6,13,22 147:4,8 152:18 153:4 153:8,12,13,14,22,22 154:8 155:4,5 212:6 212:17,21 231:22 232:4 233:5,5,17,20 234:1,2,8,16,17 235:4 235:4,14 236:2,4,4,11 237:3,12 238:11,13 238:14,16 239:1,1,7 242:6,6,11 <b>claimed</b> 116:9 118:5 125:17 126:3 153:17 154:2 155:6,9 <b>claims</b> 92:11,22 93:2,9 93:10,14,15,19,20 94:8,10 97:1,4 104:12 107:5 114:1,2 134:22 137:12,21 147:5,13 147:18 148:1 151:18 151:22 152:9,17 175:20 176:6,17,21 177:8 186:5,7 203:21 231:4 234:7 242:5 243:6,19 244:1,5,16 244:21 245:4,19 246:13,22 247:5,19 248:4,9,17 249:2,9,19 249:19,20,21 250:1 250:17 251:21 254:10 <b>claims-recited</b> 251:16 <b>claim-recited</b> 251:1,9 <b>clarification</b> 20:15 34:4 34:8 179:5 312:3 <b>clarified</b> 35:8 <b>clarify</b> 20:7 33:4 35:4 278:17,21 <b>clarifying</b> 32:14 <b>clarity</b> 130:4 <b>class</b> 7:6 277:11 <b>classes</b> 89:8 <b>classic</b> 66:15 <b>classifications</b> 166:22 <b>classified</b> 166:20 <b>clause</b> 114:11 <b>clear</b> 88:12 96:6 100:18</p>	<p>104:8 105:12 140:3 170:22 179:9,19 181:18 184:8 199:15 200:17 201:1,3 304:20 <b>clearer</b> 248:15 <b>clearly</b> 130:17 191:14 191:17 198:5,12 220:12 222:13 <b>clinical</b> 36:17,20 37:1,2 37:3,4,7 268:2 <b>close</b> 167:5 254:17 <b>closely</b> 47:15 77:14 <b>closest</b> 227:21 228:3,4 228:9 <b>cloud</b> 169:11 <b>CMC</b> 256:14 257:3 <b>CmE1-25m</b> 281:17 <b>coat</b> 170:1 <b>coefficient</b> 165:15 <b>coli</b> 105:10 251:8 <b>colleagues</b> 55:20 <b>collected</b> 250:19 <b>collectively</b> 91:22 196:1 196:4 <b>College</b> 21:20 57:3 89:9 <b>Colloid</b> 12:6 <b>colloidal</b> 60:10 <b>Colloids</b> 14:15 <b>column</b> 97:14 98:8 107:1 108:7 110:13 113:3 117:14 123:21 125:2,3 127:2 128:6 183:3,4,17,20 195:21 203:8 213:9 214:12 218:17 233:4 246:8 275:7 276:22 283:18 288:17 295:20 306:7 313:3 <b>columns</b> 117:15 183:10 183:14,16 <b>combination</b> 13:15 49:9 261:15 <b>come</b> 140:21 <b>comes</b> 143:12 317:14 <b>comment</b> 61:20 199:18 234:8,10 236:19 270:12 <b>comments</b> 224:13 234:22 <b>commercially</b> 83:11 <b>common</b> 54:4 187:20 293:7 297:5 <b>commonly</b> 151:20 187:2,11 217:9,16,21 217:22 299:20 300:2 <b>communications</b></p>	<p>239:15 313:17 <b>companies</b> 54:6 160:22 <b>company</b> 15:13 53:7,8 55:11 56:4,6,8,13,22 57:7,10,16 58:3 67:13 68:18 160:19 <b>comparable</b> 300:12 <b>compare</b> 235:6 <b>compared</b> 157:5 300:11 <b>comparing</b> 87:11,19 88:15 <b>comparison</b> 227:13,21 228:9,14 <b>compendia</b> 253:15 254:1 <b>compendial</b> 133:14 <b>competing</b> 304:22 <b>complement</b> 110:9 <b>completely</b> 121:15 149:14 <b>completes</b> 318:19 <b>complex</b> 83:19 84:1 139:14 140:4 169:21 190:16 268:5 304:22 <b>complexes</b> 10:6 180:21 189:22 283:20 <b>complicated</b> 50:5 83:4 84:7 <b>component</b> 54:7 114:14 117:18 212:18 213:1 231:18 <b>components</b> 118:20 119:5 <b>composition</b> 229:5,6 233:6,9,18 235:14,17 <b>compositions</b> 87:13,21 88:17 227:12 230:11 <b>compound</b> 31:7 32:6 77:2 78:10 79:7 105:9 126:7 134:17 135:5,12,19 147:19 162:1 174:19 175:7 182:10,11 268:20 269:13,14,19,20,22 <b>compounds</b> 127:12 191:18 269:6 287:12 <b>compressed</b> 233:12,13 <b>comprising</b> 118:19 119:4 124:15 233:9 233:10 235:14 <b>computer</b> 262:6,7 <b>computing</b> 261:20 <b>concentration</b> 36:1 76:8,19 168:3 266:19 266:21 290:14,15 309:8,13,20 310:9,18</p>	<p><b>concentrations</b> 167:14 167:16 298:12 311:5 <b>concept</b> 43:22 44:1 116:7 211:10,16 225:16 226:1,5 268:2 <b>concern</b> 121:10 <b>concerned</b> 71:3 73:6 84:4 112:4 <b>concerning</b> 46:5 52:3 <b>concluded</b> 318:22 <b>conclusion</b> 154:4,11 228:1,12 234:5,20 236:13,21 239:4 248:8,16 252:16,21 252:22 253:18,20 284:14 285:17,19 302:13 <b>conclusions</b> 236:15 249:1 306:6 <b>Condensed</b> 7:15 9:8 <b>condition</b> 43:16 247:9 270:8 <b>conditions</b> 88:3 113:13 117:6 214:4 215:16 215:17,18 216:2 221:12 223:3,12 224:2,21 227:5 235:5 235:19 249:21 250:1 <b>conduct</b> 36:22 38:13,16 41:2,8,17 42:1,7,16 87:11,19 88:15 <b>conducted</b> 30:4,9 32:1 36:20 38:9 40:21 41:19,21 42:4,6 <b>conducting</b> 14:5 144:21 145:1 <b>Conference</b> 215:12 <b>confidential</b> 53:9 58:15 62:13 67:12 317:1,3 317:13 <b>confirmed</b> 230:19 247:12 <b>confused</b> 224:12 246:4 274:14 <b>confusing</b> 184:7 200:14 <b>confusion</b> 191:21 247:20 <b>connection</b> 90:12,19 91:3,9,15 92:4 97:17 98:10 104:22 107:3 108:11 113:5 131:11 135:10,17 136:4 180:1 186:20 192:4 192:17 195:7,13 196:13 202:21 209:14 212:20 243:20 245:13 252:11</p>	<p><b>connections</b> 56:2 <b>consecutive</b> 243:11 <b>consequence</b> 296:2 <b>consequences</b> 300:15 <b>consider</b> 19:11 20:2,16 21:7 24:10,21 25:2 36:18 50:12 92:11,22 93:8,18 95:1 97:16,20 98:9,14 104:9 107:2 108:10 130:13 134:14 135:2,9 141:10 143:8 143:17,22 144:5,9,14 154:21 228:2,4 247:18 248:2,6 251:21 <b>considerable</b> 271:4,9 295:22 296:9 297:2 <b>considerations</b> 50:12 161:17 313:8 <b>considered</b> 33:11,17 34:17 36:3,8 40:10 94:6,18 131:11 135:17 136:3 145:12 145:19 188:17 189:3 225:14 <b>considering</b> 232:7 235:9 <b>consist</b> 258:10 <b>consistent</b> 243:15 245:7 245:22 246:15 <b>consisting</b> 49:9 172:18 <b>constant</b> 229:14,18 <b>construction</b> 18:16,20 19:1,5 130:13,14 131:4 137:3,13,22 147:9 152:18 212:6 <b>constructions</b> 231:16 <b>consult</b> 54:13 72:18,21 248:5 <b>consultant</b> 56:5 <b>consulted</b> 51:15 52:3 52:18 53:2,14 54:1,5 54:9,16,19 70:4 73:3 <b>consulting</b> 55:19 <b>contact</b> 266:13 288:21 <b>contain</b> 29:4 30:1 65:7 169:13 <b>contained</b> 139:2 151:6 <b>container</b> 43:17 113:11 117:20,22 118:21 119:6,20 120:3,10 121:4,20 122:9,13 123:5,11,13 141:4 <b>containers</b> 119:17,19 <b>container-liner-closu...</b> 214:3 <b>containing</b> 28:10 29:1</p>
--	--	---	---	---

<p>29:7,12,19 30:10,20 32:2 33:10,16 34:16 47:17,20 48:1,5,13 49:6 50:19 51:1 53:3 53:15 72:9,11 73:12 126:16 129:9 132:5 132:20 155:16 229:5 229:7 302:15 <b>contains</b> 139:12 <b>contaminants</b> 140:12 <b>contaminated</b> 43:20 <b>contamination</b> 43:20 <b>content</b> 51:5,8,18,21 119:8 <b>contents</b> 64:22 <b>context</b> 20:21 21:18 53:5 89:16,22 94:1 95:22 107:19 148:1 216:17,20 222:15 223:6 274:2,6 282:9 286:2 311:2,8 312:16 313:11 <b>continue</b> 15:9 276:4 <b>CONTINUED</b> 4:1 <b>continuous</b> 65:9,18 86:14 151:6 <b>contracts</b> 57:5 58:15 60:13 <b>contradicted</b> 315:10 <b>contrary</b> 317:21 <b>contributed</b> 51:5,8,18 51:21 <b>controlled</b> 233:7 <b>controlling</b> 120:18 <b>conventional</b> 256:2 <b>conversations</b> 15:5 <b>convert</b> 258:7 <b>copied</b> 242:6 <b>copy</b> 19:6 188:22 189:1 207:22 232:12 237:18 242:6 312:14 <b>core</b> 168:9,10 280:11 289:18 <b>CORP</b> 1:4 <b>correct</b> 23:21 51:3 57:3 58:22 60:7 63:14 75:7 117:15 124:9,10 130:6,20 131:2,6,12 131:18,21 136:5 138:5,22 139:4 148:1 148:3,4 154:6,13 181:8 182:3 199:22 200:9 201:12,16,17 201:20,21 202:7,8 215:15 226:19 232:1 233:21 241:20 243:21 245:14 247:10,15</p>	<p>248:11,19 249:3,6,17 250:4,7 265:17 267:14,19 275:3 279:1,6 296:3 305:5,9 307:3 <b>correcting</b> 113:10 117:19 <b>correction</b> 117:21 <b>corrections</b> 319:4 <b>correspond</b> 240:10 250:2 257:19 259:21 262:22 265:12 267:15 280:2 281:7 283:12 285:12 288:11 292:21 295:15 298:3 299:6 304:14 306:2 308:22 312:10 <b>corresponds</b> 205:19 240:4 257:11 259:13 262:13 264:15 267:8 279:13 280:20 283:3 284:22 288:2 292:12 295:6 297:16 298:20 304:5 305:15 308:14 311:14 <b>cosmetics</b> 189:20 <b>cosurfactant</b> 296:6 <b>counsel</b> 16:7 19:16,17 239:11,16 315:21 <b>count</b> 251:2 316:3 <b>country</b> 96:1 <b>counts</b> 211:8 251:15,17 <b>couple</b> 234:22 316:7 <b>coupled</b> 160:4 261:15 <b>course</b> 88:13 98:15 122:11 133:2 311:19 <b>court</b> 1:1 15:16 16:1,20 18:7 45:8,10 46:14 47:5,6 53:10 70:1,5,6 70:12,14,17,18,21 71:11 84:15 134:20 137:4 195:9 205:15 207:18 232:8 237:14 239:22 257:7 259:9 262:9 264:8 265:6 267:4 279:9 280:16 282:21 284:18 287:20 290:19 292:8 295:2 297:12 298:16 304:1 305:11 308:10 311:10 <b>courts</b> 144:1 147:4 153:2 <b>covalent</b> 260:10 <b>covering</b> 27:4,4 <b>co-author</b> 279:5 <b>co-authored</b> 206:6 257:16 259:18 262:19</p>	<p>265:17 279:21 281:4 283:9 292:18 297:22 299:3 304:11 305:21 308:19 312:7 <b>co-founded</b> 57:6 <b>co-workers</b> 255:15 <b>creativity</b> 141:22 142:5 145:2 <b>credence</b> 219:5,14 <b>credit</b> 63:19,20 <b>credited</b> 60:12 <b>criteria</b> 37:19,22 38:2 38:11,18,21 39:6 42:11 108:22 109:12 243:7 244:3,7,18 245:1,6,21 246:14 247:6 249:10 250:3 254:1 <b>criteria-B</b> 242:15 <b>critical</b> 168:3 <b>cross-referenced</b> 184:20 <b>cubic</b> 266:5 <b>current</b> 12:5 60:15 <b>currently</b> 55:22 57:2 89:8 <b>curriculum</b> 19:6,8 23:5 54:18 58:8 63:3 65:20 66:2,22 68:10 68:12 89:3 205:21 206:4 240:6,12 257:20 259:14 260:1 262:14 263:2 265:13 279:15 280:4,22 281:9 283:5,14 285:2 285:14 288:4,12 292:14 293:1 295:8 295:17 297:18 298:5 299:8 304:7,16 305:17 306:4 309:2 311:16 312:12 <b>CV</b> 5:18 7:10,17,22 8:9 8:14,18 9:10,20 10:9 10:15 11:11,18 12:8 12:15 13:11,18 14:9 14:17,22 24:19 58:6 62:10,11,19 146:9,9 205:12 255:10 257:12 264:16 267:9 298:21 308:15 <b>cyclodextrin</b> 283:19 284:6 <b>cyclodextrins</b> 284:1,10 <b>Cyclosporin</b> 72:15</p>	<p><b>damage</b> 156:8 <b>damaging</b> 141:12 <b>Dan</b> 16:15 <b>DANIEL</b> 3:19 <b>data</b> 159:21 218:22 219:2,3 220:2 250:18 <b>database</b> 163:16 <b>dating</b> 312:1 <b>day</b> 122:22 251:2,4,17 316:1 319:9 <b>days</b> 251:15 <b>DDCPNO</b> 300:10 <b>DDNO</b> 300:14 <b>deal</b> 67:7,8 68:21 117:11 118:2 211:7 225:16 226:2,6 <b>dealing</b> 46:18 50:17,22 64:3,8,11,18 65:3 66:8 67:1,10,15,22 69:2,6,10 73:11 130:5 261:3 <b>deals</b> 67:5 117:16 <b>dealt</b> 71:20 <b>debate</b> 157:3 222:9 <b>decide</b> 216:2 270:4 <b>decided</b> 160:16 <b>decision</b> 268:20 278:4 <b>declaration</b> 5:10 18:11 18:17,21 19:2,5 22:17 22:19 23:2,5 69:16 74:1 80:12 81:7 88:22 90:4,12,19 91:3 91:9,15 96:16 97:11 106:4 128:22 130:10 130:19 131:3 133:22 137:2 141:20 142:20 147:1 151:11 166:10 171:17 172:9,12 175:16 178:17 179:21 180:5,6 186:16 189:9 189:10 191:22 192:9 193:6,8 195:4,16 202:19 203:1 209:9 209:18 211:1 212:6,7 212:11,12,16 225:6 226:10 227:2,10 228:16 229:12,16 230:16 231:15,21 242:1 243:19 248:13 250:9 252:6,7 254:6,8 254:12 313:22 314:7 315:11 <b>decrease</b> 127:11 251:2 308:6 <b>decreases</b> 306:11 307:3 <b>defend</b> 71:17 <b>Defendant</b> 3:15 4:4</p>	<p><b>defendants</b> 1:10,14 15:14 16:16,18 <b>defendees</b> 71:18 <b>deficient</b> 220:13 <b>define</b> 57:13 89:20 117:6 130:17 209:3 221:6 222:14 223:2 223:19 235:5 241:7 <b>defined</b> 44:9 94:20 191:10 <b>defines</b> 210:18 <b>defining</b> 209:2 225:3 310:11,14 <b>definite</b> 222:7,18,20 <b>definitely</b> 46:2,22 67:20 188:15 <b>definiteness</b> 153:21 154:8 155:3 <b>definition</b> 36:7 95:16 95:18,19 130:7 143:4 143:7,12,16,21 144:4 156:22 175:22 209:21 210:2,19 222:10 223:17 235:10,22 236:3,10 237:2,7 <b>definitions</b> 143:9,18 144:1 <b>definitive</b> 236:19 <b>definitively</b> 234:10 247:22 <b>degradation</b> 216:3 217:2 218:20 225:17 226:3 <b>degraded</b> 43:9 272:7 <b>degrees</b> 113:13 114:15 118:22 119:7 230:10 235:19 <b>Del</b> 4:15 16:3 <b>deliver</b> 73:14 258:11,14 259:1 <b>delivery</b> 7:9 8:6,10 10:12 11:6 12:4 14:19,20 23:11 40:11 40:20 42:17,18,20 58:21 95:6,11 150:18 271:6 273:17 274:15 275:22 276:11 277:8 <b>demonstrate</b> 266:8 <b>demonstrated</b> 261:4 269:19 277:9 <b>demonstrating</b> 130:15 <b>depend</b> 36:1,11 41:5,6 41:14 49:20,21,22 50:8 75:12,21 76:2,4 76:5 79:10,20 86:7,9 86:12 87:6 135:8 148:8 161:11,13</p>
<b>D</b>				
<p><b>D</b> 5:1 15:1</p>				

164:3,20 170:11 282:17 290:9 291:1 302:11 303:16 <b>dependency</b> 307:13,20 <b>dependent</b> 82:7 85:21 <b>depending</b> 35:22 36:12 50:14 82:16 262:5 309:7,12,20 310:8,18 <b>depends</b> 20:12 31:20 36:6 49:18 79:8 83:22 84:1 161:14,15 190:16 211:14 266:19 284:5 290:7 291:4 303:20 <b>depicted</b> 172:7 <b>deponent</b> 15:11 <b>deposed</b> 17:11 <b>deposition</b> 1:15 2:1 15:8,18 17:13 18:13 47:10,12 80:19 81:3 136:14,20 205:1,7,22 208:8 232:13 237:20 240:7 254:21 255:5 257:13 259:15 262:16 265:9 267:10 279:17 281:1 283:6 285:3 288:5 292:15 295:9 297:19 298:22 304:8 305:18 308:16 312:4 313:15 314:8 315:14 315:22 318:19,21 319:2 <b>derivative</b> 300:12 <b>describe</b> 58:9 81:15 162:3 <b>described</b> 58:11 190:8 253:9 <b>describing</b> 128:17 <b>DESCRIPTION</b> 5:8 6:3 7:3 8:3 9:3 10:3 11:3 12:3 13:3 14:3 <b>descriptive</b> 156:5 <b>design</b> 83:17 84:5,8,9 229:13,17 <b>designate</b> 316:22 317:12,17 <b>designation</b> 180:15 <b>designed</b> 37:2,7 74:22 83:16 258:10,14,22 <b>designing</b> 50:13 84:20 <b>desired</b> 160:6 <b>desk</b> 188:22 <b>destroys</b> 83:13 <b>detailed</b> 109:14 111:7,8 112:19 <b>deteriorate</b> 124:22 226:17	<b>determine</b> 24:7 87:8 133:4 147:2 272:16 272:18 291:11 294:19 <b>determined</b> 168:7,11 171:10 241:13 <b>determining</b> 153:4,7 280:11 <b>develop</b> 268:21 278:5 <b>Development</b> 268:18 <b>Dexel</b> 46:10 70:19 <b>dicalcium</b> 182:18 <b>diclofenac</b> 6:5 207:4 208:1 287:12 <b>differ</b> 43:22 82:21 250:11,16 293:9,17 294:14 <b>difference</b> 184:11 243:15 282:18 287:17 289:11 293:22 296:21 297:8,9 <b>differences</b> 97:12 184:11 291:11 294:10 296:8 297:1 306:8 <b>different</b> 35:5 44:10 75:1,9,10,17,18 76:21 76:22 77:9,10,20,21 78:7,8,11 79:4,5,9,10 80:1,2,3 81:17 83:14 87:12,20 88:6,9,16 92:21 95:16 97:3 119:21 132:17 133:2 141:9 143:16 157:7 157:11,12,17,21 158:2,2,15,15,17,17 159:19 161:4 162:12 170:6,7 171:4,4 172:17 181:12,14,17 181:19,20,21 182:16 182:21,22 191:16,18 218:7 223:5,5 225:13 225:14 248:1 269:22 272:21 281:22 282:1 282:2,11,12,13 289:4 289:6,7,10 290:1,3,3 290:7,9 291:2 293:14 294:3,4,8,12,18 296:17 <b>differently</b> 79:20 <b>difficult</b> 20:13 33:22 39:22 114:3 135:7 157:15 261:21,22 <b>dilutability</b> 257:2 <b>Dimethyldodecylami...</b> 14:13 <b>Diner</b> 3:8 16:12,12 <b>direct</b> 54:20 58:6 62:21 69:16 96:16 98:8	106:8 107:1 108:8 110:13 113:3 114:9 152:21 183:1,8 186:17 189:15 192:1 203:5 205:13 206:10 209:9 213:5,8 214:13 218:16 224:17 225:7 233:5 240:17 255:8 255:11 258:2 260:6 263:7 267:21 268:11 268:17 272:12 273:7 275:6 276:22 277:22 285:17 288:16 295:20 313:2 <b>directed</b> 116:8 155:15 233:17 <b>directing</b> 197:8,10 <b>direction</b> 194:3 <b>directly</b> 313:6 <b>disagree</b> 126:19 127:16 127:20 128:1 <b>disagreement</b> 129:17 130:1,9,18 131:1,6 <b>discipline</b> 258:5 <b>disciplines</b> 22:11 <b>disclose</b> 227:5 <b>disclosed</b> 118:5 214:22 215:6,18 <b>disclosure</b> 117:2 124:1 127:7 <b>discrepancy</b> 111:10 <b>discuss</b> 114:6 204:17 213:11 252:3 <b>discussed</b> 106:17 108:21 110:6 162:11 162:13,15 170:9 230:20 <b>discusses</b> 114:5 <b>discussing</b> 258:19 <b>discussion</b> 121:10 130:22 228:17 285:8 293:4 304:20 <b>disease</b> 27:18 49:3 155:21 <b>disodium</b> 6:6 172:19 173:20 174:1,12,16 175:5 181:1,7 182:1 182:13,16,20 183:2 183:11 184:1,5,6,14 184:16 185:5,6 190:3 190:12,18 191:4,11 191:17 192:16,20,22 193:9,9,11,12,17,17 193:19 194:11,22 196:2,21 197:5,12 198:1,22 199:7,13 200:13 201:19 202:3	202:6 203:15 207:4 207:10,11,14 208:1 208:20,21 209:3 <b>dispense</b> 25:17,19 <b>dispensed</b> 28:6,9,21,22 29:5,8,13 <b>dispersal</b> 76:9 313:3 <b>dispersed</b> 44:8 266:1 266:22 288:18 298:11 <b>display</b> 309:6,11,19 310:7,16 <b>dispute</b> 150:21 <b>disputed</b> 137:6 147:3 <b>dissolution</b> 235:16 <b>distinct</b> 73:15,17 182:22 <b>distinction</b> 221:12 223:12 224:3,22 <b>distinctly</b> 181:21 <b>distress</b> 28:17 <b>distributed</b> 274:11 <b>District</b> 1:1,1 15:16,16 <b>diverse</b> 258:5 309:6,11 309:19 310:7,16 <b>divorce</b> 225:22 <b>dmargolis@goodwin...</b> 3:22 <b>doctor</b> 21:2 81:6 131:5 137:1 146:11 175:14 178:14 185:2 195:9 202:15 205:10 267:13 318:13 <b>document</b> 92:16 134:13 135:2,9 181:10 207:17 209:6 231:21 231:22 237:8 239:8 249:5 254:13 257:6 259:8 260:19 264:7 267:3 273:2 278:17 278:22 279:6,8 280:7 280:15 282:20 284:17 286:19,20 292:7 295:1 298:8,15 303:22 305:10 307:8 308:9 311:9 313:13 <b>documents</b> 127:14 134:13 135:2,13,16 136:3 198:14 201:11 202:14 242:22 243:13 278:19 314:6 315:9 <b>doing</b> 78:21 84:20 110:2 120:17 133:13 133:13 150:8,12 262:6,7 287:8 <b>dominates</b> 79:19 <b>dosage</b> 214:2 233:12 <b>dose</b> 73:18 87:7 118:6	118:13 160:5,6 161:11 258:12,15 259:2 270:14 271:20 <b>dosing</b> 271:21 <b>Double-Chain</b> 12:10 <b>doubt</b> 62:15 <b>Dr</b> 15:11 17:5,9 80:19 81:3 136:14,20 146:20 205:1,7,20 240:5 254:21 255:5 257:12 259:14 262:14 264:16 267:9 279:14 280:21 283:4 285:1 288:3 292:13 295:7 297:17 298:21 304:6 305:16 308:15 311:15 318:20 <b>drive</b> 274:20 <b>driving</b> 291:6,6 <b>drop</b> 113:15 119:9 120:4 122:18,19 123:19 132:5,19 133:6 140:21 228:19 <b>dropper</b> 123:10 <b>drops</b> 30:1,2 118:18 119:3 120:2,4 122:21 230:12 <b>drug</b> 5:14 7:8 8:5,7,10 10:12 11:6,7 12:4 14:19,20 23:11 33:2,8 40:11,19 42:10,17,20 43:9 48:22 58:21 73:14 76:16,19 80:5 81:21 83:7,14 87:7,7 118:6 145:8 151:8 155:19 156:4,6 158:8 158:21 159:2,18,19 160:5,6,16,17,22 162:5,9 163:2 170:2 255:21 256:6 258:12 258:15 259:2 268:1,6 268:12,14 271:6,22 272:6,17 273:5,8,11 273:18 274:16 275:22 276:2 277:2,8,10 278:2 283:21 284:2,6 284:11 285:20 286:6 291:19 292:4 <b>drugs</b> 31:14 49:18,22 50:1,2 59:3,9,19 168:11,13,14,16 169:21 258:11,14 259:1 270:9 275:10 275:17 276:10 281:19 284:16 286:3,11 287:1 299:17 308:5 <b>drug's</b> 169:22 272:18
---	---	--	--	---



<p>278:11  <b>drug-solubilizing</b>                  299:19 300:1  <b>due</b> 140:15 309:5  <b>duly</b> 17:1  <b>DUNNER</b> 3:3  <b>dynamic</b> 261:16  <b>Dynamics</b> 14:10  <b>D.C</b> 3:6 16:6</p> <hr/> <p style="text-align: center;"><b>E</b></p> <p><b>E</b> 3:1,1 5:1,6 6:1 7:1                  8:1 9:1 10:1 11:1                  12:1 13:1 14:1 15:1,1                  105:10 251:8  <b>earlier</b> 196:5 200:17                  208:17 242:18 247:12                  251:18 271:16 282:16                  294:3  <b>earth</b> 190:1  <b>ease</b> 73:19  <b>easily</b> 99:19  <b>edetate</b> 45:20 89:12                  102:19 103:5,10,14                  104:1,7,18 105:4,13                  105:16,22 172:16,17                  172:19 173:14,18,19                  174:2 175:20 176:7,8                  176:12,17,21 177:8                  177:16,17,20,20                  178:11 179:2,4,10,15                  180:12,16 181:5,13                  182:2,13,14 183:1,10                  184:1,4,4,14,14 185:4                  185:4,13,22 189:19                  190:19,19,20 191:6                  191:10,14,17 193:9                  193:12,17 196:19                  197:4 198:1 200:4,8                  200:10,13 201:15                  203:8,11  <b>edetates</b> 196:1,4  <b>edetic</b> 105:15,21                  171:19 172:4 176:7                  176:16,20 177:7,16                  189:19 191:6 203:12  <b>edited</b> 50:21 51:2  <b>edition</b> 51:6,9,19,22                  179:22 186:19 187:9                  187:15 188:1 189:10                  191:3,8 209:13,19                  210:1,5,13  <b>EDTA</b> 29:15,19,19                  32:2,3,9,15 45:20                  48:1,1,3,5,13,13,20                  53:15,15,17 54:1,2,4                  54:7,10,14 61:19,22</p>	<p>64:18 67:15,19 69:6                  89:12,13 102:15                  103:2 105:5 171:19                  172:4,8,16,18,22                  173:2,10,14,21 174:2                  174:12,16 175:5,21                  176:7,12,13 177:16                  178:11 179:1,3,9,15                  182:16,17,20,21                  190:3,4,12,13 191:5,5                  191:10,11 192:16,20                  192:21 193:9,11,16                  193:19 194:8,10,11                  194:22 195:22 196:2                  196:3,3,10,15,19,20                  197:2,4,8,12,15,19                  198:1 199:1,7,13                  200:11 201:19 202:4                  202:6 203:15,16                  206:15 207:11,14,14                  208:20,22 209:5  <b>education</b> 138:11 144:6                  146:2  <b>effect</b> 6:5 9:12 79:18                  80:3 117:3 124:21                  127:11 158:22 219:1                  220:17 226:16 256:20                  272:3 307:14  <b>effective</b> 72:8 216:12                  238:18 268:22 278:6  <b>effectively</b> 119:20                  162:3  <b>effectiveness</b> 37:19                  38:3,10,17 253:5,6,8  <b>effects</b> 6:11 80:4                  171:11 207:4,7,22                  208:5 280:8 294:4                  304:21,22 307:22  <b>efficacy</b> 46:18 131:15                  131:20,22 132:4,19                  133:6 242:4 244:2,7                  244:18 245:1,6,21                  246:14 247:1,6 248:9                  248:17 249:2,9 250:3                  253:4,8,22 269:12  <b>efficient</b> 284:8  <b>Eighth</b> 2:3 3:17 15:20  <b>either</b> 66:18 68:15,20                  131:8 146:16 177:13  <b>electrical</b> 6:8 207:5                  208:2  <b>Electrically</b> 14:4  <b>electrolyte</b> 257:3,4  <b>electrolytes</b> 76:19                  256:14  <b>Elworthy</b> 255:15  <b>EMA</b> 54:19</p>	<p><b>emphasized</b> 280:10  <b>encompass</b> 211:11,17                  216:21  <b>encountered</b> 138:13                  139:15,21 140:5,8,17                  142:11 214:4 271:5                  271:10 275:10,16  <b>encyclopedia</b> 8:12                  198:18  <b>engineer</b> 146:4  <b>engineering</b> 95:13,16                  95:21 96:1,8 258:7  <b>enhanced</b> 281:19  <b>enhancement</b> 256:1  <b>enhancing</b> 6:11 207:7                  208:4  <b>enormous</b> 268:14  <b>ensure</b> 43:9,12,15,17                  43:18,19,20 44:11                  50:4 111:17 112:6                  116:22 133:14,21                  187:18  <b>entails</b> 40:12  <b>enteral</b> 212:3  <b>entirety</b> 92:11,22 93:8                  93:14,18,22 94:14                  126:10  <b>entitled</b> 58:7 62:22                  65:20 196:14 197:2                  197:19 207:3,22                  214:14 227:3 265:20                  268:18 271:3 272:13                  293:4  <b>entries</b> 184:5,15 185:5                  198:11  <b>entropy</b> 313:7  <b>entry</b> 55:1 180:12,16                  181:5 182:2,13 183:2                  183:4,15 185:12,14                  185:18 192:16,20                  193:20 194:20 196:14                  197:2,14,19 199:1,7                  200:8 201:15,19                  202:6 203:8  <b>environmental</b> 214:4  <b>environments</b> 272:21                  309:7,12,19 310:8,17  <b>EP</b> 108:22 242:15                  243:7 244:2,7,18                  245:1,6,21 246:14                  247:6 249:10 250:3                  250:11  <b>equals</b> 281:17  <b>equation</b> 219:3 220:14  <b>equilibrium</b> 171:13                  288:19 291:18 313:5  <b>error</b> 198:13 202:10</p>	<p>243:16  <b>errors</b> 198:15 200:22                  202:13 242:19 243:1                  243:7,12  <b>especially</b> 125:12,18                  126:4  <b>ESQ</b> 3:7,8,19 4:7  <b>essential</b> 272:17  <b>essentially</b> 96:21 97:6                  219:4 235:17 247:13                  247:16  <b>establish</b> 138:15  <b>established</b> 278:13  <b>ester</b> 128:19 129:13                  203:12 297:6  <b>esters</b> 127:9 263:10,19                  296:15,16  <b>estimate</b> 77:16 167:21  <b>estimates</b> 219:6,15  <b>et</b> 6:12 10:7 15:13,14                  75:15 162:11 207:3                  208:6 212:4  <b>ether</b> 281:16  <b>ethylenediaminetetr...</b>                  6:7 194:21 207:5,10                  208:2,21 209:5  <b>ethylenediaminetetr...</b>                  29:16 171:20 172:5  <b>European</b> 11:7 38:20                  39:6 51:6 109:1,11                  111:6 242:14 243:8                  244:3,7,18 245:2,6,21                  246:15 247:7 249:10                  250:4 253:10,13  <b>Evaluation</b> 13:13  <b>evidence</b> 134:21 135:8                  147:5 153:2,6 186:12                  213:2 249:3  <b>exact</b> 167:20 287:18                  312:14  <b>exactly</b> 178:12  <b>EXAMINATION</b> 5:2                  17:3  <b>examined</b> 234:10  <b>examiner</b> 145:18  <b>example</b> 24:4,11 30:13                  31:9 43:8 62:8 76:6                  78:13 79:12 86:16                  102:11,13 106:18                  108:3 113:4,5,21                  114:20 115:8,15,20                  116:2,3 117:10,11                  118:1,1 128:14                  131:10,11,14,17,21                  133:19 140:16,22                  156:8 209:18 225:20                  227:11,13,20 228:8</p>	<p>228:18 229:4,13,17                  230:7,19 231:2,3                  245:12,13 246:4,6,6,7                  250:22 251:8 256:13                  270:7 277:2 283:19                  286:4 314:10  <b>examples</b> 83:17 110:21                  117:8 119:16 120:10                  121:4,20 122:10,15                  123:3,5,15 139:18                  140:7,18 141:1,14                  225:5 227:3  <b>excellent</b> 136:10  <b>exception</b> 266:10  <b>excerpts</b> 180:6 189:10  <b>excipient</b> 52:15 54:4                  85:16 202:11  <b>excipients</b> 29:10 50:3                  52:8,13,14 53:18                  72:16 76:11,12,18                  86:11 186:20 187:3,5                  187:10,12,18 188:2                  188:11,18 189:4,11                  191:4,9 201:22 272:1                  277:18 284:9  <b>excluding</b> 150:19  <b>exclude</b> 191:11  <b>excuse</b> 48:21  <b>exert</b> 158:22  <b>exhibit</b> 5:10,14 6:5,16                  6:17 7:4,12,18 8:4,10                  8:15 9:4,12 10:4,11                  11:4,13 12:4,9 13:4                  13:13 14:4,10,18 18:9                  18:10,14,16 97:10                  106:21 110:12 180:4                  180:6 189:8,9 192:6,7                  195:15 203:1 204:9                  205:17,18 206:1,3,7,9                  206:15,19 207:2,13                  207:20,21 208:9,11                  208:13,19 212:5,7                  232:10,11,14 237:16                  237:17,21 240:2,3,8                  240:10,14 241:7,20                  243:18 252:5,6 255:9                  257:9,10,14,17,19                  258:2 259:12,16,19                  259:21 260:3,6                  262:11,12,17,20,22                  263:4 264:10,15                  265:8,10,12,17 267:6                  267:7,11,19 272:12                  279:11,12,18,22                  280:2,18,19 281:2,5,7                  282:2,13 283:1,2,7,10                  283:12 284:20,21</p>
---	---	--	---	--

<p>285:4,10,12 286:17 286:18 287:19,22 288:1,6 291:15 292:10,11,16,19,21 295:4,5,10,13,15 297:11,14,15,20 298:1,3,18,19 299:1,4 299:6,10 300:19 304:3,4,9,12,14 305:13,14,19,22 306:2 307:11 308:12 308:13,17,20,22 311:12,13 312:5,8,10 <b>exhibits</b> 5:12 18:12,17 202:16,17 <b>exist</b> 75:2 157:7 266:11 <b>existing</b> 73:15 <b>Exosurf</b> 28:13,16 30:13 <b>expect</b> 80:1 123:12 125:17 126:3 158:9 302:2 303:7,11 307:4 <b>expected</b> 302:3,5 <b>expense</b> 277:4 <b>expensive</b> 268:5 <b>experience</b> 19:9 40:3 94:17 121:18 143:12 144:21,22 145:4 146:1 165:5 <b>experienced</b> 158:7 <b>experiment</b> 87:11,19 88:15 <b>experimental</b> 113:4,4 113:21 114:20 115:8 115:15 116:2,3 117:8 117:10,10,13,22 118:1 119:16 120:10 121:4,20 122:10,15 123:3,15 131:10,11 131:14,17,21 227:3 227:10,20 228:8,17 229:4,12,17 230:7,19 231:2 245:12,13 246:6,7 261:15 <b>expert</b> 19:12 20:3,10,14 20:17,21 21:1,3,7,21 22:7 23:10,19 24:4,9 24:12,15,21 25:2,3,8 25:11,20,22 26:6,9,13 26:16,20 27:1,7 36:17 37:10,16,18 38:1,6,8 38:20 39:4,6,10,19 40:6,11,14 44:13,22 45:9,11 53:6 62:15 70:2,4,7,11,14,16,22 71:2,13,16,20 73:4,7 94:18 95:1 154:22 <b>expertise</b> 21:12,14,17</p>	<p>21:19 22:3,10,11,15 24:10 26:3 40:2,3,19 45:2 144:19 <b>experts</b> 143:9,18 278:20 <b>explain</b> 48:6 57:1 89:19 93:13 99:8 138:2 148:2 256:11 312:20 <b>explained</b> 63:17 78:12 <b>explains</b> 220:1 <b>explanation</b> 175:22 <b>explicit</b> 116:21 178:8 191:20 198:9 <b>explicitly</b> 144:8 223:22 <b>exposure</b> 273:18 274:15 <b>extend</b> 160:19 <b>extensively</b> 61:17 <b>exterior</b> 266:13 <b>external</b> 120:18 <b>extra</b> 295:22 <b>extraneous</b> 256:15,16 <b>extremely</b> 258:4 <b>extrinsic</b> 153:2,5 186:12 213:1 <b>eye</b> 27:19 30:1,2 49:3 113:15 118:18 119:3 119:9 120:2,4 122:18 122:19,22 123:19 132:5,19 133:6 140:20,21 141:13 150:18 228:18 230:12 270:8 <b>eyedrop</b> 132:15 <b>eyes</b> 124:18 200:4 226:15 <b>e-mail</b> 317:11,15 <b>E-X-O-S-U-R-F</b> 28:15 <b>e.g</b> 129:7</p> <p style="text-align:center"><b>F</b></p> <p><b>facetious</b> 133:1 <b>fact</b> 168:1 178:9 309:6 <b>factors</b> 138:11 213:16 213:20 214:9 <b>fail</b> 153:15 <b>failure</b> 269:14 <b>fair</b> 50:5 66:21 79:1 83:19 176:5 177:14 200:16 281:22 282:6 282:11 284:1,10 289:2 291:17 292:2 293:14 294:11 296:7 296:22 302:19 303:12 317:22 <b>fairly</b> 109:2,4,7 151:8 166:8 254:17 260:22</p>	<p><b>fall</b> 268:6 <b>falls</b> 40:2 112:15 <b>familiar</b> 156:17,18,18 169:5,6,7 171:13 222:5 <b>far</b> 97:19 98:13 100:7 102:4 117:17 157:2 223:1 289:16 315:8 <b>FARABOW</b> 3:2 <b>faster</b> 218:20 <b>fate</b> 269:7 278:3 <b>fatty</b> 127:9 129:13 296:16 <b>Fax</b> 3:10,21 4:9 <b>FDA</b> 54:16 <b>features</b> 293:7 <b>feel</b> 232:6 236:17 <b>felt</b> 108:3 <b>field</b> 23:10 25:11 27:1,7 41:4 44:22 70:21 83:20 94:18 95:2 138:12 142:12,13 <b>fields</b> 278:20 <b>fifth</b> 194:4 273:16 <b>figures</b> 167:20 169:7 <b>filed</b> 69:1,5,9 <b>filled</b> 118:21 119:5 <b>find</b> 20:12 22:2 60:15 116:12,17 121:18 165:16,20 241:14 301:18 <b>findings</b> 78:18 <b>fine</b> 312:21 316:12 318:5 <b>finger</b> 193:6 <b>finished</b> 165:17 195:10 <b>Finnegan</b> 3:2 16:9,12 <b>firm</b> 16:2 <b>first</b> 17:1,12,19 68:17 71:17 73:13 82:5,6 89:2 114:14 118:15 126:14 135:9,13 136:3 138:7 147:4 152:22 153:12 155:14 158:8 172:14 177:10 178:19 187:1 189:18 189:18 195:21 206:10 208:15 212:18,22 213:15 216:10 217:9 218:18 223:17 226:12 227:2 228:16 230:6 230:16 231:18 235:3 240:17 242:10 250:9 252:22 260:7,7 265:22 268:13 271:3 272:15 277:1,11,15 280:6 281:11,11</p>	<p>283:16 285:18 293:4 293:5 298:7 299:15 300:7 302:14 304:19 304:19 306:21 311:20 313:22 <b>five</b> 23:7 32:17 119:3 255:4 316:10 318:18 <b>fixed</b> 57:4 <b>Floor</b> 2:4 4:5 <b>focus</b> 58:17,20 59:1,13 92:12 93:1,9,19 94:9 97:3 274:19 276:7 <b>focused</b> 59:2,7 95:21 <b>focuses</b> 94:12 <b>folder</b> 265:4 <b>follow</b> 109:13 114:3 242:14 <b>followed</b> 199:14 <b>following</b> 171:21 209:21 <b>follows</b> 17:2 242:13 290:22 <b>Food</b> 145:8 <b>foods</b> 189:20 <b>footnote</b> 96:17 206:16 <b>force</b> 219:2 291:6,7,8 <b>forces</b> 313:7 <b>form</b> 88:7 102:16 103:3 103:11 104:2,19 105:5 167:8,12 168:19 169:8 172:15 173:17,19 176:12 180:22 181:7,12 182:1 189:21 190:6 214:2 233:12 260:12 260:21 266:2,19 271:6 286:13 287:11 287:13 288:19 289:16 293:8 <b>Formation</b> 11:13 <b>formed</b> 7:6 289:3,5,21 290:2 <b>forms</b> 179:16 184:12 266:18 298:10 <b>formula</b> 99:21 191:15 281:16 <b>Formulary</b> 51:13,16 <b>formulate</b> 31:21 48:6,9 86:22 101:4 160:11 161:5,10 162:5 163:17 164:20 187:17 272:17 277:7 285:20 <b>formulated</b> 47:13,15 47:16,18,22 48:4,12 48:22 49:2,5 50:1 57:9,22 <b>formulating</b> 57:15 59:3</p>	<p>59:8 62:3,7,13 65:3,8 67:22 68:4 69:10 144:20 158:7 159:6 159:11,13 163:1 188:13,19 189:5 273:5 <b>formulation</b> 14:4 23:11 23:12 30:19 31:20 40:4 41:6,14 42:18,19 42:22 43:3,12,15,18 44:12 46:13 48:8,18 49:9,12,14,19 50:18 50:22 54:15 59:22 60:5,6 61:5,13,19 62:16 64:12,19 65:17 67:11,16 68:8 69:3,7 71:5,14,15,16 72:8,9 72:11,14,17,20 73:6 73:11,14,16 76:16 85:16 86:8,15,17 87:3 87:8 88:6 95:9 96:13 98:22,22 99:9 100:8 109:19 110:1 111:13 112:4 113:22 114:21 115:9,16 116:2,4 118:12,13 122:18,20 132:14 133:10,11 139:12 140:10,12,13 140:16,20 141:4,8 142:11 145:5 150:18 162:10 163:12 164:3 165:2,11 187:16,19 211:15,20 218:13 223:19 226:14 229:13 229:18 230:9 239:6 268:2 269:21 271:3,6 271:7,8,11 272:2,3,7 272:14 275:10,17 277:17 284:8,9 <b>formulations</b> 26:16,17 30:15,17 31:2,3,4,17 31:19 42:10,11 48:2 48:19 53:19 54:5,6 59:1 60:8,10 61:2 62:9 89:16 90:1 108:4 110:22 111:3 112:15,17 121:11 139:2 140:8 150:8,17 150:22 151:6 155:16 155:22 165:22 187:4 187:13 189:20 218:6 221:13 223:13 224:3 224:22 227:11 230:8 258:13,22 259:6,7 263:9,18 264:3,4 291:19 292:4 299:18 311:7</p>
--	--	---	---	---

<p><b>formulator</b> 49:1  <b>formulators</b> 188:21  <b>forth</b> 212:16 231:15              249:21 250:1 254:9              315:10  <b>forward</b> 261:14,19  <b>found</b> 117:2 175:20  <b>foundation</b> 43:6 49:16              77:2 82:4 83:3 85:5              85:14 87:5 109:21              122:1 123:17 132:8              134:19 135:5 142:7              145:15,22 157:14              158:20 160:14 162:22              169:15 219:22 220:10              234:5,20 236:6 239:4              264:1 271:13 275:20              301:8  <b>founded</b> 57:6  <b>four</b> 60:21 69:18              113:14 114:16 118:18              119:7 172:17 173:6              185:10 205:6 227:11              230:10 254:20  <b>fourth</b> 194:15 217:6  <b>free</b> 33:5 157:2,5              161:16 173:16 190:7  <b>free-radical-mediated</b>              216:14  <b>frequency</b> 270:14              271:21  <b>frequent</b> 217:19  <b>frequently</b> 32:6,7 34:10              34:11 218:4  <b>Friday</b> 2:5 15:22 80:17              81:1 136:12,18              204:21 205:5 254:19              255:3 318:17  <b>front</b> 146:19 169:7              232:19 238:5  <b>fulfills</b> 108:22  <b>full</b> 63:20 111:7 112:5              152:22 177:12 178:3              195:21 216:9 217:6              218:18 260:7 263:7              288:17 293:4 300:7              304:19 313:3  <b>full-time</b> 56:21 57:1,2  <b>function</b> 162:8 166:7              173:21 174:2 306:10              308:7  <b>funded</b> 56:1 68:18  <b>fungal</b> 211:8  <b>fungi</b> 251:14,17  <b>further</b> 82:16 179:5              235:14 316:4 318:11</p>	<p style="text-align: center;"><b>G</b></p> <p><b>G</b> 15:1  <b>Games</b> 287:5  <b>GARRETT</b> 3:2  <b>gene</b> 40:11 42:17 58:21              95:5,8,11 96:12  <b>general</b> 102:7 137:20              144:21 220:18 234:22              281:16 282:6 294:11              296:22 303:12 314:17  <b>generally</b> 48:17 71:6              139:4 145:8 155:15              162:8 172:16 225:14              226:1,5 258:21              313:19  <b>gentlemen</b> 315:18  <b>geometry</b> 298:9  <b>getting</b> 24:2 140:19              163:2 244:14 275:22  <b>give</b> 22:3 33:20 77:13              83:16 99:2 101:3              139:17 177:12 178:2              225:4,19 317:15  <b>given</b> 24:22 269:12              272:10 319:3  <b>gives</b> 163:14,17 210:18  <b>giving</b> 124:18 226:15  <b>glad</b> 264:13  <b>Glaxo</b> 55:7  <b>glycol</b> 127:9 129:13,13              281:16  <b>go</b> 15:10 43:21 56:1              59:19 60:14 64:14              83:16 90:10 109:11              110:20 111:5 112:14              151:10 155:2 159:6              159:13 161:19 187:18              187:20 193:19 204:8              204:12,14,16 212:10              221:18 223:8 242:1              243:17 249:15 254:15              274:18 315:5,8 316:6              316:12 317:3  <b>goal</b> 68:4 116:22  <b>GODWIN</b> 3:14  <b>goes</b> 124:2 183:19              220:15 225:4 275:8  <b>going</b> 15:3 21:10 22:9              22:19 42:22 44:16              82:8,17,17 97:10              125:4 132:9 133:10              141:12,18 148:2              158:22 164:20 199:14              201:2 204:8,18 209:3              218:13 225:19 243:18              244:14 270:10,15,16</p>	<p>272:2,8 300:7 316:22  <b>good</b> 15:2 17:5,6 26:3              37:13 39:15 45:3              63:9,21 77:16 80:14              83:9 136:9 156:7              204:10 205:4,10,11              210:19 239:9 267:18  <b>Goodwin</b> 2:3 15:19              16:15  <b>Gosh</b> 56:14  <b>grab</b> 173:4  <b>gradual</b> 297:8  <b>gram</b> 105:11 180:20  <b>grams</b> 227:14,15,16,16              229:15,19,20,21,22              230:1  <b>grant</b> 59:21 60:2 61:3              61:11,14,15,18 62:2,6  <b>grants</b> 58:7,9 60:22              61:8,21 62:12  <b>GRAS</b> 187:21  <b>great</b> 261:14,19 268:5  <b>greater</b> 36:14 113:16              113:18 114:13 228:20              228:21 301:20 307:5  <b>greatly</b> 302:16,20              303:14  <b>ground-breaking</b>              149:22  <b>group</b> 32:11 55:7 76:6              78:14 79:17,18,19              83:9 166:19,21              255:20 290:14 291:6              294:1,2 300:16              301:17,17,18 302:16              303:6,7,10  <b>groups</b> 81:17,18 173:12              291:8 294:8  <b>GSK</b> 57:19 60:12  <b>guess</b> 108:2 118:3              204:14 248:7 261:17  <b>guidance</b> 101:7  <b>guidelines</b> 215:12  <b>guy</b> 287:6</p>	<p>200:13 201:22 202:12  <b>handing</b> 18:7 205:15              207:18 232:8 237:14              239:22 257:7 259:9              262:9 264:8 265:6              267:4 279:9 280:16              282:21 284:18 287:20              292:8 295:2 297:12              298:16 304:1 305:11              308:10 311:10  <b>handling</b> 214:5  <b>hand-in-hand</b> 59:19  <b>happens</b> 265:5  <b>happy</b> 116:13  <b>hard</b> 22:2 25:7 143:11              148:21 170:13 225:21  <b>harder</b> 261:3 296:2  <b>Harmonization</b> 215:12  <b>Hasford</b> 3:7 5:4 16:9,9              17:4 18:7 19:14,19              80:13 81:5 136:7,22              204:8,16 205:9,15              207:18 232:8 237:14              239:17,22 254:15              255:7 257:7 259:9              262:9 264:8,14 265:6              267:4 279:9,20              280:16 282:21 284:18              287:20 291:3 292:8              295:2 297:12 298:16              304:1 305:11 308:10              311:10 316:4 317:2,9              317:20 318:2,6,9,12  <b>head</b> 76:5 78:14 79:18              79:19 81:17,18 83:9              166:19,21 173:12              290:14 291:5,8 294:1              294:2,7 300:16              301:16,17,18 302:16              303:6,7,10  <b>headache</b> 277:3  <b>headed</b> 22:18  <b>heading</b> 197:8 255:12  <b>heat</b> 120:19  <b>heavy</b> 190:1  <b>held</b> 2:2 26:5,8,19 27:6              39:5,18 44:21  <b>help</b> 138:15  <b>HENDERSON</b> 3:2  <b>heterocyclic</b> 255:20  <b>hexagonal</b> 266:4  <b>high</b> 47:6 144:18 219:4              219:19  <b>higher</b> 154:18 218:20              220:7,22 307:5,7  <b>highlighted</b> 25:3              301:11</p>	<p><b>highly</b> 54:7 63:7 258:10              258:13,20,22 311:22              312:18  <b>high-temperature</b>              218:21  <b>hired</b> 56:7,10  <b>histories</b> 152:2,10              178:20 179:14 186:13              204:5 252:3 314:3  <b>history</b> 135:1 137:8              147:6 152:7 153:3,7              153:15 179:8  <b>hit-to-lead</b> 274:19  <b>Hobby</b> 25:5  <b>hold</b> 20:9 22:6 23:18              37:15 38:1 239:13  <b>HOLDINGS</b> 1:4  <b>honest</b> 63:7 162:16              239:7 262:4 306:20              315:12  <b>hope</b> 4:5 305:5,9  <b>Hospital</b> 188:5  <b>hours</b> 316:2  <b>huge</b> 27:3 44:19 49:21              83:10 296:21 297:8              310:3  <b>humidity</b> 120:18              235:20  <b>hundred</b> 121:14 122:17              123:1,4 311:3  <b>hurdles</b> 268:6  <b>hydrate</b> 124:17 129:11  <b>hydrocarbon</b> 83:13  <b>hydrophilic</b> 255:19  <b>hydrophilic</b> 33:1,8 77:6              166:19 233:9,11              286:6 287:11 296:1,3              296:19  <b>hydrophobe</b> 300:16  <b>Hydrophobes</b> 9:17  <b>hydrophobic</b> 76:4 77:5              79:14,17 166:19              266:12 288:20 289:17              290:12,13 291:5,5,7              294:6 296:3 300:13  <b>hydroxide</b> 103:16,17              103:18  <b>hypothetical</b> 88:13  <b>Hypothetically</b> 88:20</p>
<b>I</b>				
<p><b>ICH</b> 120:15 215:11              235:5  <b>ideally</b> 100:5 144:22              145:5  <b>ideas</b> 142:12  <b>identical</b> 87:12,21</p>				

<p>88:16 227:11  <b>Identification</b> 18:15                  206:2 208:10 232:15                  237:22 240:9 257:15                  259:17 262:18 265:11                  267:12 279:19 281:3                  283:8 285:5 288:7                  292:17 295:11 297:21                  299:2 304:10 305:20                  308:18 312:6  <b>identifications</b> 201:6  <b>identified</b> 127:6 240:5                  253:15 268:20 278:3                  279:5  <b>identifies</b> 199:10 202:6  <b>identify</b> 16:7 185:21                  187:3,12 191:4                  199:12  <b>ignore</b> 219:4  <b>III</b> 134:9 146:20  <b>impact</b> 284:2,11  <b>implications</b> 230:22  <b>importance</b> 211:19                  280:10  <b>important</b> 43:2 134:14                  135:3 140:11,13                  144:17 159:3,4                  188:18 189:4 273:5  <b>impossible</b> 42:2 86:19  <b>impressed</b> 264:11  <b>improve</b> 83:7 150:17                  163:12 276:10 277:17  <b>improved</b> 84:6 233:6                  233:18  <b>improvements</b> 73:15                  73:17  <b>impurities</b> 43:10  <b>inactive</b> 214:1  <b>include</b> 65:12 103:17                  111:4 112:20 193:11                  193:17 199:7 217:10                  218:1  <b>included</b> 142:18 167:2                  272:4  <b>includes</b> 25:3 64:6                  100:7 193:9 212:3  <b>including</b> 23:13,15                  175:19 196:2 213:21                  247:14 250:17 264:3                  266:3 272:19  <b>incomplete</b> 111:9  <b>incomprehensible</b>                  222:12  <b>incorporated</b> 1:4                  124:20  <b>incorrect</b> 220:13  <b>incorrectly</b> 207:15</p>	<p><b>increase</b> 251:14 281:18                  286:5 295:22 308:6  <b>increased</b> 274:22  <b>increases</b> 306:9  <b>increasing</b> 255:17                  276:9 283:20  <b>increasingly</b> 258:8                  261:17  <b>incredibly</b> 24:2  <b>indefinite</b> 89:17 90:1,2                  153:13 221:3 222:1,4                  248:10,18  <b>indefiniteness</b> 234:3,18                  239:2  <b>independently</b> 275:3  <b>Index</b> 51:22 180:1,7,11                  180:13,17 181:6                  183:2 184:5,15 185:5                  185:21 186:2,8,11,14                  199:21 200:7,8,10                  201:14  <b>indicate</b> 117:17 248:10  <b>indicates</b> 113:10                  130:16 230:11  <b>indication</b> 101:19                  117:5 175:22  <b>industrial</b> 55:19 95:22                  96:2  <b>Industries</b> 188:7  <b>industry</b> 55:19 56:1,2                  143:13  <b>infants</b> 28:18  <b>inflammation</b> 156:6  <b>inflammatory</b> 27:18                  49:3 155:21  <b>influence</b> 225:18                  272:14  <b>influences</b> 298:10  <b>inform</b> 153:16 155:8                  246:21 247:4  <b>information</b> 33:20                  67:13 79:18 99:22                  100:1,9 101:3 119:22                  121:19 126:22 127:22                  127:22 128:4 146:18                  160:4 219:5 228:7,14                  235:8 236:1 256:10                  256:12,15,16,18                  257:5 270:4,6,7,13,20                  273:4 314:9,12 315:2                  317:3  <b>informs</b> 153:22 155:5                  249:8  <b>infringement</b> 70:7                  71:18  <b>ingredient</b> 49:12 53:21                  72:13 213:22</p>	<p><b>ingredients</b> 49:6 50:19                  51:1 99:1 100:4                  102:12 139:13 151:7                  162:6 213:22 214:1  <b>Inhalation</b> 55:6  <b>inhibit</b> 127:10  <b>inhibited</b> 216:11  <b>initial</b> 112:18 121:10  <b>initio</b> 317:13  <b>inject</b> 86:17  <b>injection</b> 277:5  <b>Innopharma</b> 1:11,11                  1:12,12 4:4 16:18                  19:18 237:10 238:6,9                  318:9  <b>Innopharma's</b> 238:16                  238:22 239:10 315:21  <b>innovations</b> 138:15  <b>innovative</b> 160:21  <b>input</b> 258:5  <b>inserting</b> 300:15  <b>insoluble</b> 157:5 158:10  <b>instabilities</b> 216:4  <b>instance</b> 159:22  <b>instructions</b> 102:5  <b>insufficient</b> 126:22  <b>intact</b> 162:9  <b>integral</b> 40:12,19 53:18  <b>intended</b> 41:7,15 58:22                  117:1 160:5,7 211:20                  277:3  <b>inter</b> 313:6  <b>interact</b> 173:4,6,8,12  <b>interaction</b> 159:3                  169:20 213:22  <b>interchangeably</b>                  208:20  <b>interest</b> 44:8 108:3  <b>interested</b> 50:9,14                  112:16 162:7  <b>interesting</b> 241:10                  301:11  <b>Interestingly</b> 69:12  <b>Interface</b> 12:6  <b>Interfacial</b> 14:11  <b>interfere</b> 15:7  <b>intermolecular</b> 313:7  <b>International</b> 14:6                  215:11,11  <b>interplay</b> 304:22 313:6  <b>interpret</b> 151:18,22                  152:9  <b>interpretation</b> 45:19                  46:4,17  <b>interpreting</b> 101:5                  247:19 248:4  <b>Intestinal</b> 5:14</p>	<p><b>intramuscular</b> 23:14                  212:4  <b>intravenous</b> 23:13                  212:4 264:3  <b>intrinsic</b> 134:21 135:8                  147:4 249:3  <b>introducing</b> 141:11  <b>introduction</b> 288:16                  299:13 302:14  <b>invalid</b> 153:14 234:2,17                  239:2  <b>invalidate</b> 71:19  <b>invalidated</b> 72:2,3,5  <b>invention</b> 124:1,14                  125:11 126:16 129:8                  137:6 153:18 154:2                  155:7,10 226:13  <b>inventor</b> 45:13,15  <b>inventors</b> 144:6 145:11  <b>investigate</b> 300:14  <b>investigated</b> 299:16  <b>investigating</b> 255:16  <b>Investigations</b> 7:4  <b>involved</b> 190:17 255:18  <b>ion</b> 173:6,11 190:7,17  <b>ionic</b> 166:22,22 306:9                  310:4  <b>ionized</b> 173:17,19  <b>ions</b> 173:4 174:3,11,15                  190:1,9 309:9  <b>irrelevant</b> 24:5  <b>irresponsible</b> 249:15  <b>irritate</b> 141:12  <b>irritation</b> 124:18                  226:15  <b>isolation</b> 110:1  <b>issue</b> 68:16 73:1 312:16  <b>issues</b> 166:6  <b>item</b> 63:13,22 66:6                  205:13,19 213:1                  240:4,10 255:9                  257:11,19 259:13,21                  262:13,22 264:15                  265:2,12 267:8,15                  279:13 280:2,20                  281:7 283:3,12                  284:22 285:12 288:2                  288:11 292:12,21                  295:6,15 297:16                  298:3,20 299:6 304:5                  304:14 305:15 306:3                  308:14,22 311:14                  312:10  <b>items</b> 270:20  <b>Ivax</b> 46:10 70:20  <b>I.e</b> 23:13 263:11,19                  309:9</p>	<p style="text-align: center;"><b>J</b></p> <p><b>J</b> 3:7 6:13 208:6  <b>James</b> 4:7 16:17  <b>james.abe@alston.co...</b>                  4:10  <b>Japanese</b> 51:19 253:10                  253:14  <b>Jayne</b> 1:16 2:1 5:3,10                  15:11 16:22 17:9                  18:11 80:19 81:3                  136:14,20 205:2,7                  254:21 255:5 262:19                  265:16 267:18 279:21                  283:9 285:9 288:8                  292:18 295:12 297:22                  299:3 304:11 305:21                  308:19 312:7 318:20  <b>Jeannette</b> 2:6 16:1  <b>jejunum</b> 6:12 207:7                  208:5  <b>Jersey</b> 1:1 15:17  <b>job</b> 56:18  <b>jobs</b> 56:9  <b>joint</b> 55:20 188:4  <b>journal</b> 5:16 9:17 11:7                  12:12 13:8,16 14:7,15                  45:6 66:7 67:9,14,21                  207:3 312:1,17  <b>journals</b> 9:9,20 10:8,15                  11:10,17 12:8,14                  13:11,18 14:9,17,22                  63:10 65:21 66:4                  205:14,20 279:14                  280:3,21 281:8 283:4                  283:13 285:1,13                  288:3,12 292:13,22                  295:7,16 297:17                  298:4,21 299:7 304:6                  304:15 305:16 306:3                  308:15 309:1 311:15                  312:11  <b>judgment</b> 73:8 256:17  <b>justified</b> 277:5  <b>Justin</b> 3:7 16:9  <b>justin.hasford@finn...</b>                  3:11</p> <hr/> <p style="text-align: center;"><b>K</b></p> <p><b>kept</b> 63:21 117:1,2  <b>Kibbe</b> 187:5,5,6  <b>kind</b> 213:7 317:20  <b>King's</b> 21:20 57:3 89:9  <b>know</b> 17:18,22 24:7                  32:12 34:8,14 40:10                  59:18 68:19 70:10                  78:19,20 80:13 96:18</p>
--	---	--	--	--

<p>100:3 103:15 105:10 106:2,3 108:17 109:4 118:4 120:5,6 121:18 122:5 124:5 125:6 126:11 127:3 128:12 133:18 134:11 142:22 146:20 148:11 150:3 151:2 154:14 157:9 165:14 174:7,21 182:9,12 184:10 204:9 206:12,21 211:2 212:13 213:6 213:16 225:9 228:8 231:12 238:12 239:5 240:15 241:14,15,16 253:1,18 265:2 286:14 287:13 289:16 306:19 314:4 316:12 317:21 <b>knowing</b> 25:8 <b>knowledge</b> 21:3 50:16 150:2 163:15 168:22 184:10 <b>known</b> 35:21 45:2 75:2 105:9 155:18 157:7 171:19 172:4 179:1,2 195:22 196:4,19 277:18</p> <hr/> <p style="text-align: center;"><b>L</b></p> <p><b>laboratory</b> 30:16,18,20 31:5 38:15 41:19 42:12 47:18 48:2,19 55:21,22 78:21 <b>lack</b> 77:2 83:2 85:4,13 121:22 132:7 142:6 145:14 157:13 158:19 160:13 163:10,11 169:14 219:21 220:9 234:4,19 236:5 239:3 263:22 271:12 274:9 275:20 301:7 <b>lacks</b> 43:5 49:15 82:3 87:4 109:20 123:16 134:19 135:5 145:21 162:21 <b>lamellar</b> 266:4,10 <b>landscape</b> 50:11 <b>Langmuir</b> 14:14 <b>language</b> 102:14,21 103:1,9,20,22 104:11 104:14,17 137:12,21 147:4 153:4,8 176:5 176:11 221:6,19 244:16,21 245:4,19 246:12 <b>Lanigan</b> 195:5,12,16</p>	<p>195:19 196:16 197:3 197:4,22,22 199:12 199:20 200:6 201:18 202:3,5 <b>Lannigan</b> 199:2,3 <b>lap-based</b> 262:7 <b>large</b> 39:15 41:4,12 53:19 62:12 83:10 140:11,15 151:5 161:9 <b>larger</b> 83:8 <b>largest</b> 35:19 <b>law</b> 2:2 45:11 <b>Lawrence</b> 1:16 2:1 5:3 5:7,11,15 6:2 7:2 8:2 9:2 10:2 11:2 12:2 13:2 14:2 15:11 16:22 17:5,9 18:9,10 18:11,14,16 80:20 81:3 136:15,20 205:2 205:8,17,18 206:1,3,6 206:7,9,15,19 207:2 207:13,19,21 208:9 208:11,12,19 232:10 232:11,14 237:15,17 237:21 240:2,3,8,10 240:14 241:7,20 254:22 255:5,9 257:9 257:10,14,16,17,19 258:1 259:11,12,16 259:18,19,21 260:3,6 262:11,12,17,19,20 262:22 263:4 264:10 264:14 265:2,8,10,12 265:16,17 267:5,7,11 267:19,19 272:12 279:11,12,18,21,22 280:2,18,19 281:2,4,5 281:7 283:1,2,7,9,10 283:12 284:20,21 285:4,9,10,12 286:17 286:18 287:22 288:1 288:6,8,9 291:15 292:10,11,16,18,19 292:21 295:4,5,10,12 295:13,15 297:14,15 297:20,22 298:1,3,18 298:19 299:1,3,4,6,10 300:19 304:3,4,9,11 304:14 305:13,14,19 305:21,22 306:2 308:12,13,17,19,20 308:22 311:12,13 312:5,7,8,10 318:20 <b>Lawrence's</b> 205:20 240:5 257:12 259:14 262:14 264:16 267:9</p>	<p>279:14 280:21 283:4 285:1 288:3 292:13 295:7 297:17 298:21 304:6 305:16 308:15 311:15 <b>lead</b> 49:1 268:19 269:13 <b>leaps</b> 261:14,19 <b>learnings</b> 95:10 <b>least-squares</b> 219:1 220:16 <b>leave</b> 55:2,5,10 <b>lecture</b> 89:18 <b>led</b> 37:1,4 <b>left</b> 184:3 316:10 203:8 275:7 283:18 288:17 313:2 <b>legal</b> 16:4 94:1,3 154:4 154:11 221:5,19 228:1,12 234:5,20 236:13,15,20 239:4 252:16 284:14 <b>length</b> 214:5 300:13 <b>lengthening</b> 281:14,14 <b>lengthy</b> 268:5 <b>let's</b> 116:1 172:14 200:15 202:9 243:17 254:15 316:12 <b>level</b> 26:3 78:3,4 138:8 138:11,16 144:6,18 146:2 274:21 <b>levels</b> 157:4 <b>Lewis</b> 202:20 203:2,11 203:22 204:3,6 <b>LICENSING</b> 1:11,11 <b>light</b> 43:21 74:14 82:14 151:19 152:1,10 153:14 <b>likewise</b> 250:16 <b>limit</b> 105:4 115:21 161:2,4 169:10 176:6 177:15 186:2 <b>limitations</b> 275:21 285:20 <b>limited</b> 89:13 179:15 232:21 233:2 284:15 <b>limits</b> 250:19 <b>line</b> 123:21 124:2,2 133:17 160:19 185:14 194:4,15,16 196:20 197:11 204:18 <b>lines</b> 125:3 127:2 128:5 <b>linker</b> 300:15,20 301:1 301:5 302:7,15 303:8 <b>lipid</b> 66:19 <b>lipids</b> 66:18 67:7 167:2</p>	<p><b>lipophilicity</b> 274:22 <b>liposomes</b> 225:20 293:11 <b>liquid</b> 23:15 39:11,19 40:6,14,22 41:3,9,18 44:2 50:18,22 62:3,7 65:3 67:22 69:10 75:19 80:4 86:2,22 87:12,20 88:16 98:17 99:6,10,15,19,20 100:11,20 101:11,16 102:2,9 107:8,16,22 108:15 109:18 110:16 111:12,21 112:10 114:12 116:10 118:4 124:15 125:10,17 126:3,15 127:10 128:7 129:8 131:15 131:22 132:3,18 133:4 159:6,14 160:11 161:5,20 162:19 164:6,11 167:9,13 168:4,8,10 168:20 169:12 171:14 175:9 188:13,19 189:5 211:11,15,17 218:10 280:11 284:3 284:12 289:3,5,22 290:2 <b>list</b> 19:8 29:10 63:4 66:3 68:12 90:7 99:1 99:3 140:7 187:21 198:10,20 311:21 <b>listed</b> 58:13,14 76:15 76:18 89:2 102:13 240:11 <b>lists</b> 192:21 <b>literature</b> 79:13 157:3 <b>little</b> 110:6 120:21 132:17 143:15 150:5 157:19 184:13 248:1 262:7 <b>liver</b> 269:19 270:10 <b>LLC</b> 1:11,12 <b>LLP</b> 2:3 3:3,14 4:3 <b>log</b> 159:21 160:3 <b>Lomb</b> 1:3,4 16:11,14 <b>London</b> 21:20 <b>long</b> 38:14 42:3 143:11 270:15 276:12 305:5 315:20 317:22 318:4 <b>longer</b> 235:2 241:9 <b>look</b> 19:4 22:16 24:19 54:18 56:15 58:5 60:21 62:18 63:13,22 64:21 65:19 66:6 67:18 68:9 69:15</p>	<p>73:22 78:20 80:11 81:7 88:21 90:3 96:15 97:14 101:6 103:6 106:4,20 108:7 110:11 116:1 118:15 123:20 125:2 126:9 127:1 128:5,21 130:11,12 131:3,9 133:22 137:2,4 138:7 141:17 142:19 146:8 146:22 147:4 150:17 152:20 153:11 155:11 158:8 159:11 160:8 166:9 168:5 171:16 172:11,14 175:14 178:16 179:20 185:12 185:13 186:16 189:8 189:14 190:21,22 191:22 192:12 195:3 195:19 196:6 197:9 197:10 198:22 200:15 201:7,21 202:9,18 206:20 207:16 208:15 209:8 212:11 213:4 214:11 216:8,9 217:6 218:15 223:7 225:6 226:9 227:1,9 228:15 229:11 230:5,15 231:8 236:2 240:14 245:12,16 246:7 248:18 249:19 250:8 252:5,18,21 253:17 254:4,5 260:5 263:6 265:19 271:2 272:11 273:6,16 276:21 277:14,21 280:6 281:11 283:16 287:4 288:15 291:13,14 292:1 293:3 294:17 295:19 298:7 299:12 300:6 301:9 302:13 304:18 306:7 308:8 309:4 313:1 317:6,10 317:13 <b>looked</b> 57:19 111:1 112:17 177:10 188:10 248:10 314:3 <b>looking</b> 31:20 41:15 42:9 59:17 61:8 62:13 66:13 68:3 75:13,13,22 82:13 116:18 117:7 139:5 148:9 156:22 159:20 163:15 169:17,18 182:9 187:16 246:5 276:8 284:7 286:19 303:3,20 314:17</p>
---	--	---	--	---

<p><b>looks</b> 136:7 208:14  <b>Los</b> 4:6  <b>lost</b> 193:13  <b>lot</b> 54:6 56:2 66:20  79:12,17 88:2 157:3,8  166:11 202:13 215:13  215:14 235:2,8 270:4  <b>lots</b> 20:14 54:5 56:9  184:19 218:5  <b>low</b> 86:18 167:14  169:22 219:3,6,15,20  298:11 299:21 300:2  302:17  <b>lower</b> 115:21 220:8,22  307:6  <b>LTPB</b> 306:17  <b>lunch</b> 204:10 205:3  <b>Lupin</b> 1:8,8 3:15 15:14  16:16 19:17 232:3,20  233:2 316:21  <b>Lupin's</b> 233:4,17 234:1  234:16 236:2,9 237:1  239:10 315:20  <b>LUPIN010505</b> 189:15  <b>LUPIN010506</b> 190:22  <b>LUPIN018800</b> 252:19  <b>LUPIN018905</b> 180:11  <b>LUPIN018913</b> 195:20  <b>LUPIN018914</b> 196:7  <b>LUPIN018965</b> 213:6</p> <hr/> <p style="text-align: center;"><b>M</b></p> <p><b>m</b> 1:16 2:1 5:3,10 16:22  262:19 265:16 279:21  281:17 283:9 285:9  288:8 292:18 295:12  297:22 299:3 304:11  305:21 308:19 312:7  <b>main</b> 22:14,14 70:16  71:2,13 76:20 156:19  166:21 202:17 235:3  235:4 257:5 269:13  <b>maintained</b> 235:17  <b>major</b> 301:5  <b>majority</b> 66:17  <b>making</b> 83:10 301:12  301:19  <b>man</b> 271:8  <b>managed</b> 84:9  <b>manufacture</b> 268:3  <b>manufacturers</b> 122:12  <b>manufacturing</b> 214:2,6  <b>Margaret</b> 17:9  <b>Margolis</b> 3:19 16:15,15  19:13 20:4,11,19 21:8  21:22 22:8 26:1,10,14  26:21 27:2,8 30:6</p>	<p>31:6 33:3,12,18 34:18  35:12 36:5,10 37:12  37:20 38:4,22 39:9,13  39:21 40:16 41:10  43:5 44:3,14 45:1,22  46:8,20 49:15 50:7  52:5,20 53:16 54:3,11  57:11,17 58:18 59:5  59:10 61:6 62:4 64:4  64:13,20 65:5 67:3,17  68:2 71:1,8,12 72:6  73:2 75:20 77:1,11,22  78:9 79:6 80:6 82:3  83:2,21 84:3,13 85:4  85:13 86:4 87:4,15  88:1,19 92:14 93:3,12  93:21 94:11 95:3,14  96:10 97:18 98:2,12  98:19 99:17 100:13  100:22 102:17 103:12  104:3 105:6 106:16  107:10,18 109:3,20  110:18 111:14 112:1  112:12 115:1,12,18  118:8 120:12 121:6  121:22 123:6,16  125:20 126:6 127:13  129:20 132:7,21  133:7 134:16,19  135:4,11,19 138:1  139:16 140:6 142:6  144:11,16 145:14,21  146:6,13 147:19  148:20 149:7,18  150:14 151:1 154:3  154:10,20 156:12  157:13 158:4,19  159:8,15 160:13  161:7,22 162:21  164:1,8,13,18 165:4  166:1,4 167:11,17  168:21 169:14 170:8  171:6 174:13,18  175:6,10 176:9  177:18 178:1 179:17  181:9 182:4 184:17  188:20 189:7 191:12  197:6 198:3 200:19  204:13 209:1 210:17  211:13 215:9,22  217:3 218:11 219:21  220:9 221:4,15 222:2  222:21 223:15 224:11  227:22 228:5,11  234:4,19 235:12  236:5,12 237:4 239:3  239:13,19 243:9</p>	<p>244:9 245:9 246:2,5  246:17 247:8 248:12  248:20 249:4,12  250:5 252:1,15 256:7  258:17 259:3 260:18  261:11 263:22 265:5  268:8 269:2,18 270:1  271:12,18 273:1,22  274:5 275:18,20  276:6,18 278:8,15  282:3,7,14 284:4,13  286:1,9 289:8,12  290:5 291:20 292:5  293:18 294:15,20  296:11 297:4 300:4  301:7 302:9 303:1,17  305:2 306:13 307:16  308:2 309:15,22  310:12,21 313:10,16  316:6,11,21 317:5,19  317:22 318:4,8  <b>mark</b> 207:17 264:21  308:8  <b>marked</b> 18:8,14 205:16  206:1 207:19 208:9  232:9,14 237:15,21  240:1,8 257:8,14  259:10,16 262:10,17  264:9 265:7,10 267:5  267:11 279:10,18  280:17 281:2 282:22  283:7 284:19 285:4  287:21 288:6 292:9  292:16 295:3,10  297:13,20 298:17  299:1 304:2,9 305:12  305:19 308:11,17  311:11 312:5  <b>market</b> 48:16,21 49:4  163:6  <b>marketed</b> 48:22 57:22  <b>marketing</b> 163:3  <b>marks</b> 224:14  <b>material</b> 44:8 101:20  178:3,12 181:14,17  184:21 191:19 201:9  313:21 314:1  <b>materially</b> 284:2,11  <b>materials</b> 100:4,6  134:9 181:19 201:9  258:6 277:16 314:13  <b>matrix</b> 233:9,11 235:15  <b>matter</b> 7:16 15:12  34:22  <b>McCormick</b> 2:6 16:2  <b>mean</b> 20:21 31:18 33:5  33:6 34:6 36:22</p>	<p>40:10 44:16 48:6,14  48:16 71:9 74:11  78:2 84:1 90:16,22  91:6,12,19 92:1 93:14  97:20 98:14 122:5  123:9 147:18 148:12  150:4 156:3 165:8  166:16 173:2 180:8  181:12 184:21 189:12  192:10 195:17 203:3  211:22 212:8 222:14  232:17 238:3 247:20  252:8 289:10  <b>meaning</b> 90:6 92:7 94:3  102:19 103:14 114:1  114:22 115:10,17  116:5 130:5 137:4  147:13 153:4,7 176:1  179:5,11 210:7,15  222:7,18,20 223:5  <b>meaningless</b> 62:1  <b>means</b> 138:2,3 156:8  177:21 223:4  <b>meant</b> 75:4 179:19  241:15  <b>measured</b> 119:10  159:21 171:8 227:6  241:11  <b>measurement</b> 221:11  223:11 224:2,21  <b>measures</b> 253:5  <b>measuring</b> 38:9,16  216:5  <b>Media</b> 14:18  <b>medic</b> 27:12  <b>medical</b> 146:11  <b>medication</b> 25:17,19  27:15  <b>medicine</b> 27:1,3,5,7,14  268:4,22 272:17  274:11 277:18 278:6  <b>medicines</b> 8:15,16,17  258:8,9 268:18  275:11,17  <b>medics</b> 146:16,17  <b>meet</b> 315:13,20  <b>membrane</b> 6:9 171:10  207:6 208:3 276:2  <b>membrane-active</b>  304:21  <b>memory</b> 314:11  <b>mention</b> 64:22 120:17  211:4  <b>mentioned</b> 47:1 48:21  61:1 64:16 152:5  221:19  <b>Merck</b> 51:22 180:1,7</p>	<p>180:11,13,17 181:5  183:2 184:5,15 185:5  185:21 186:2,8,11,14  198:18 199:21 200:7  200:8,10 201:14,22  202:11  <b>met</b> 315:15  <b>metabisulfite</b> 217:11  <b>Metabolism</b> 11:8  <b>metal</b> 174:3,11,15  190:1,17  <b>metal-edetate</b> 190:16  <b>method</b> 97:22 98:4  106:15  <b>methodology</b> 241:16  <b>methods</b> 111:7,8  155:20  <b>micellar</b> 9:14 168:9,10  255:17 280:9,11  281:18  <b>micelle</b> 42:10 83:14  168:3  <b>micelles</b> 14:14 81:21  83:8,10 167:8,13,15  168:2,12 169:8,9,10  255:21 266:4 287:13  289:14,17 290:12  <b>Micelle-forming</b> 82:9  <b>microbial</b> 43:20  <b>microbiological</b> 224:6,16  <b>microbiological</b> 211:4  211:7,11,18  <b>microemulsion</b> 49:10  60:8 62:8 71:4 72:11  73:6,14 296:5  <b>microemulsions</b> 8:5  11:5 12:4 65:13 73:4  <b>Microemulsion-Based</b>  14:5,18  <b>microphones</b> 15:4,7  <b>Middlesex</b> 17:10  <b>mil</b> 122:17 123:1  <b>milligrams</b> 180:21  <b>milliliter</b> 123:4  <b>minimal</b> 303:11  <b>minor</b> 301:6 302:7  <b>minute</b> 129:2  <b>minutes</b> 316:7,10  <b>mischaracterizes</b> 123:7  181:10 248:13,21  249:5,13 260:19  261:12 273:2  <b>Mischaracterizing</b>  127:14 200:20  <b>misinterpret</b> 220:2  <b>missing</b> 63:6  <b>mistake</b> 198:8</p>
---	--	--	--	--

<p><b>mix</b> 162:6 287:13  <b>mixed</b> 286:13  <b>mixes</b> 83:12  <b>mixing</b> 100:6  <b>mixture</b> 238:19  <b>Mixtures</b> 13:14 265:21  <b>modeling</b> 262:2  <b>Modelling</b> 7:18 10:4  <b>Models</b> 5:14  <b>moiety</b> 76:5 300:16  301:14 302:15 303:6  <b>moisture</b> 113:10  117:19,21  <b>molecular</b> 7:18 14:10  258:6 261:16 266:20  298:9 302:18  <b>molecularly</b> 44:8  <b>molecule</b> 159:4,19  268:1,22 274:10  278:5  <b>molecules</b> 47:15 66:19  67:8 77:15 166:18  167:3 266:1 268:12  268:14 283:21 284:2  284:11 288:18 296:17  297:7  <b>moment</b> 78:22 126:21  141:16 243:10  <b>money</b> 60:11,12  <b>mono</b> 281:16  <b>monographs</b> 52:7,9,12  187:22  <b>Monolayers</b> 7:5  <b>monosodium</b> 172:18  <b>monostearate</b> 129:14  <b>month</b> 235:18  <b>months</b> 55:2,5,9,16  240:22  <b>morning</b> 15:2 17:5,6  <b>Moser</b> 252:7,10,13,18  253:3,7,15,21  <b>motivated</b> 218:9  <b>mouth</b> 184:19 185:2  <b>mouthful</b> 124:12  <b>mucosal</b> 6:9 207:6  208:3  <b>mug</b> 287:8  <b>multiple</b> 49:6 50:19  51:1 243:12  <b>muscle</b> 156:8  <b>MYLAN</b> 1:12,13  <b>M.J</b> 206:6 257:16  259:18 281:4</p> <hr/> <p style="text-align: center;"><b>N</b></p> <p><b>N</b> 3:1 5:1 15:1 300:13  <b>name</b> 16:3 17:7 29:11</p>	<p>124:7,9,12 156:5  191:19 278:22 279:2  <b>named</b> 45:13,15  <b>names</b> 177:13 178:3  <b>Nanoparticulates</b> 8:7  <b>nasal</b> 23:14  <b>nasty</b> 270:8  <b>National</b> 51:12,15  <b>nature</b> 168:8,10 280:11  287:2 296:1 298:10  313:5  <b>natures</b> 166:21  <b>naught</b> 311:3  <b>NA2</b> 200:5,12 202:1,1  <b>necessarily</b> 84:19 126:8  284:7 294:22  <b>necessary</b> 110:7 121:19  <b>need</b> 17:18 34:19 38:6  38:7 40:8 50:12,13  68:8 80:15 89:20  99:22 100:2,3 112:6  119:22 122:22 141:10  141:11 148:13 157:19  158:16 170:18 171:9  177:2 178:6,15  179:18 219:10 234:13  236:15 246:7 254:16  270:4,6,13,20 271:20  285:21 290:19 291:10  293:21 296:14 306:19  <b>needed</b> 101:20 110:10  161:12  <b>needs</b> 274:2 277:9,11  <b>negating</b> 270:17  <b>negative</b> 105:11 167:1  167:4 173:12 216:12  <b>neutron</b> 7:12,14 8:11  24:4,12,14 42:15  63:11 82:15  <b>never</b> 56:11 171:9  <b>new</b> 1:1,18,18 2:4,4 3:5  3:16,18,18 8:15 15:16  15:19,20,20 82:1,20  84:11,20 85:1,11  159:6,13 160:11  204:9 207:17 269:21  277:16 308:8  <b>non</b> 301:15  <b>nonbiodegradable</b>  300:12  <b>Nonionic</b> 7:7 13:8,14  <b>nonsteroidal</b> 80:5  <b>non-equilibrium</b> 292:3  <b>non-ionic</b> 9:5,13 11:14  12:10 31:12 59:21  60:4 61:8,9 64:3,6,8  66:8,20 67:1,5 68:21</p>	<p>71:4 72:9,12,19 73:12  74:8,17,21 75:1,10,18  76:21 77:8,9,18,20  78:6,7 79:2,4,15 80:1  81:10,12 82:1,20,22  83:9 84:11 85:1,11  86:11 155:20 166:11  166:13,17,22 167:1,2  170:6 171:4 255:19  263:9 177 280:9  281:22 282:12 289:6  290:3 293:5,15 294:2  294:12 296:8 297:1  300:20 301:5,15,19  302:7,12,20 303:13  306:11 307:2,4,10,10  307:14,22 310:5  <b>non-oral</b> 23:13  <b>non-polar</b> 308:7  <b>non-steroidal</b> 155:18  156:4,8  <b>non-surfactants</b> 296:17  <b>normal</b> 29:9 120:2  123:19 266:11 297:5  <b>normally</b> 67:12 120:3  123:12 215:16 235:1  <b>Northwest</b> 16:6  <b>Nos</b> 1:5,11  <b>Notary</b> 2:7  <b>note</b> 15:3 178:21  <b>noted</b> 319:4  <b>notes</b> 72:18,21  <b>Notice</b> 2:2  <b>Novartis</b> 46:10,10 47:1  47:4 70:19,19  <b>novel</b> 7:6 14:19 60:8,10  61:1 62:8 71:3 72:7  74:8,17,21 81:9,12  85:15 86:11 150:17  150:22  <b>novelty</b> 150:20  <b>NSAID</b> 155:19 156:4  158:1,2,13,15,22  163:2 165:8  <b>NSAIDs</b> 157:7,12,17  158:17 159:7,14,18  160:12 161:6,21  162:20 169:13  <b>number</b> 5:8 6:3 7:3 8:3  9:3 10:3 11:3 12:3  13:3 14:3 15:15  22:10 24:10 39:15  43:8 53:19 62:12  63:22 66:6,21 80:18  81:2 128:6 134:7  136:13,19 151:5  157:10 161:4,9</p>	<p>180:11,12 183:5  185:12 189:15 190:22  191:1,16 192:13,21  194:1 195:20 196:7  199:17,22 200:9,11  201:15,16,20 202:7  203:6 204:22 205:6  205:19 206:3 213:6  240:4,11 252:19  254:20 255:4,9  257:11,20 259:13,22  262:13 263:1 264:15  265:13 267:8,15  279:13 280:3,20  281:8 283:3,13  284:15,22 285:13  288:2,11 290:11  292:12,22 295:6,16  297:9,16 298:4 299:7  301:21 304:5,15  305:15 306:3 308:14  309:1 310:2 311:14  312:11 318:18  <b>numbers</b> 181:20,21  201:5  <b>numerical</b> 241:8  <b>numerous</b> 89:4  <b>NW</b> 3:5  <b>N,N-Dimethyl-N</b> 13:5  <b>n-acyl</b> 128:19 263:10  263:19  <b>n-alkylpolyoxyethyle...</b>  281:15  <b>N-dimethyldodecyla...</b>  300:14  <b>N-oxide</b> 300:12 301:15  <b>njote</b> 178:22</p> <hr/> <p style="text-align: center;"><b>O</b></p> <p><b>O</b> 15:1 74:13 146:20  <b>object</b> 124:14 226:13  <b>objection</b> 19:13 20:4,11  20:19 21:8,22 22:8  26:1,10,14,21 27:2,8  30:6 31:6 33:3,12,18  34:18 35:12 36:5,10  37:12,20 38:4,22 39:9  39:13,21 40:16 41:10  43:5 44:3,14 45:1,22  46:8,20 49:15 50:7  52:5,20 53:16 54:3,11  57:11,17 58:18 59:5  59:10 61:6 62:4 64:4  64:13,20 65:5 67:3,17  68:2 71:1,8,12 72:6  73:2 75:20 77:1,11,22  78:9 79:6 80:6 82:3</p>	<p>83:2,21 84:3,13 85:4  85:13 86:4 87:4,15  88:1,19 92:14 93:3,12  93:21 94:11 95:3,14  96:10,10 97:18 98:2  98:12,19 99:17  100:13,22 102:17  103:12 104:3 105:6  106:16 107:10,18  109:3,20 110:18  111:14 112:1,12  115:1,12,18 118:8  120:12 121:6,22  123:6,16 125:20  126:6 127:13 129:20  132:7,21 133:7  134:16 135:4,11,19  138:1 139:16 140:6  142:6 144:11,16  145:14,21 146:6,13  147:19 148:20 149:7  149:18 150:14 151:1  154:3,10,20 156:12  157:13 158:4,19  159:8,15 160:13  161:7,22 162:21  164:1,8,13,18 165:4  166:1,4 167:11,17  168:21 169:14 170:8  171:6 174:13,18  175:6 176:9 177:18  178:1 179:17 181:9  182:4 184:17 188:20  189:7 191:12 197:6  198:3 200:19 209:1  210:17 211:13 215:9  215:22 217:3 218:11  219:21 220:9 221:4  221:15 222:2,21  223:15 224:11 227:22  228:5,11 234:4,19  235:12 236:5,12  237:4 239:3 243:9  244:9 245:9 246:2,17  247:8 248:12,20  249:4,12 250:5 252:1  252:15 256:7 258:17  259:3 260:18 261:11  263:22 268:8 269:2  269:18 270:1 271:12  273:1,22 274:5  275:18 276:6,18  278:8,15 282:3,7,14  284:4,13 286:1,9  289:8,12 290:5  291:20 292:5 293:18  294:15,20 296:11</p>
---	--	--	--	--

<p>297:4 300:4 301:7 302:9 303:1,17 305:2 306:13 307:16 308:2 309:15,22 310:12,21 313:10 <b>objections</b> 175:10 271:18 <b>objects</b> 19:17 <b>obtain</b> 122:9 135:16 <b>obtained</b> 113:10 <b>obvious</b> 166:8 235:21 <b>obviously</b> 21:19 39:1 59:18 97:12 109:11 109:12 120:1 123:1 134:21 148:8 155:1 161:14 163:3 198:17 202:10 234:9 247:11 252:4 272:4 275:3 314:2 <b>occurs</b> 218:20 <b>offered</b> 56:9,12,18 <b>offhand</b> 163:20 <b>office</b> 15:19 146:3 <b>offices</b> 2:3 <b>oh</b> 24:20 80:13 81:11 134:5,7 184:3 223:7 264:18 265:1 286:20 311:19 315:1 <b>oil</b> 13:15 75:14 165:14 272:20 273:19 <b>oils</b> 309:10 <b>okay</b> 18:2 20:18 21:5 23:9 35:10 42:8 48:10,14 56:14 57:4 58:11 60:3,8,18 62:8 69:1 70:18 74:7 90:11 92:21 93:11,18 94:9 95:20 96:19 103:8 108:13 110:14 114:17 115:4,13,21 117:16 122:13 124:6 124:11 126:13 127:4 128:10 129:1,2 130:12 131:9 134:7 134:13 138:5 140:1 142:19 143:15 152:4 159:10 162:17 165:21 168:11 174:22 175:14 175:17 177:5 180:10 183:15 193:15 195:3 195:15 197:19 206:14 207:16 209:7 210:21 212:14 213:10,18 219:12 221:2 225:11 227:1 231:11,13 234:15,15 237:9 238:15 239:19 255:14</p>	<p>264:22 265:2 267:21 274:19 276:21 282:20 306:18 312:3 315:9 315:20 317:9,19 318:4,8,12 <b>Olympic</b> 287:5 <b>once</b> 108:18 141:5,7 142:10 268:19 278:2 317:13 <b>ones</b> 58:11 63:6 66:18 76:14,20 141:15 162:13 188:3 216:6 235:8 249:16 <b>ongoing</b> 275:15 276:17 <b>Oops</b> 264:20 <b>opened</b> 141:8,8 <b>open-ended</b> 157:18 <b>ophthalmic</b> 23:14 26:17 28:19,20,21,22 29:5,7,12 57:9,15,20 58:1 87:1 100:16,17 100:21 108:1 109:19 110:4 111:13,18 112:7 139:10 150:9 150:12 151:9 155:16 212:4 258:13,19,21 269:21 271:11 <b>ophthalmology</b> 26:13 26:17,20 <b>opinion</b> 12:5 45:19 46:4,11,14,17 47:3 72:4,22 73:10 90:5 92:7 94:16 145:11,18 187:9 193:10,15 210:20 217:21 276:13 <b>opinions</b> 71:6,9,10,21 72:1 92:4 97:17 98:11 104:22 107:3 108:11 113:5 131:12 134:14 135:3,10,17 136:4 180:1 186:21 192:4,18 195:7,13 196:13 202:21 209:15 212:16,20 233:1 238:8 243:20 245:14 252:11 314:20,22 315:1,6,10 <b>opposed</b> 97:4 <b>optimal</b> 273:18 274:15 275:22 <b>optimization</b> 133:11 274:20 <b>optimize</b> 133:10 <b>oral</b> 23:12 165:11,22 277:8,10 <b>orally</b> 263:13 <b>order</b> 79:21 100:6</p>	<p>102:12 113:16 114:5 228:19 258:7 272:15 277:7 317:21 <b>ordinary</b> 36:19 79:22 84:10,18,22 85:9 86:21 87:10,18 88:5 88:14 94:21 97:21 98:16 99:5,14 100:10 100:19 101:6,10,15 102:1,8 106:14 107:7 107:15,21 108:14 109:10,17 110:15 111:11,20 112:3,9 120:8 121:2,17 122:8 122:14 123:14 125:16 126:2 133:3 137:5 138:3,9 141:21,22 142:4,5 143:4,8,17,22 144:5 145:2,6,12,20 146:5,12 147:13,18 151:17,21 152:8 154:17,19 159:5,12 160:10 161:18 162:17 176:11 187:11 188:9 188:16 189:2 209:20 210:6,14 218:8 220:5 220:20 243:4 246:21 247:4,17 248:2 <b>organic</b> 45:4 <b>organisms</b> 250:18 <b>Organogels</b> 14:6 <b>orientation</b> 266:14 <b>orientations</b> 266:12 <b>original</b> 114:14 155:2 <b>Outputs</b> 8:18 267:9,16 <b>outside</b> 289:19 <b>overcome</b> 83:15 275:9 275:15 <b>Oxidation</b> 216:10 <b>oxide</b> 81:18 167:6 256:3,5 301:17,18 <b>oxidized</b> 225:20 <b>oxygen</b> 301:2</p> <p style="text-align: center;"><b>P</b></p> <p><b>P</b> 3:1,1,19 15:1 159:21 160:3 <b>package</b> 54:15 <b>packages</b> 160:2,4 <b>packed</b> 233:13 <b>page</b> 5:2,8 6:3 7:3 8:3 9:3 10:3 11:3 12:3 13:3 14:3 18:19,20 22:17,19,22 23:5,7,8 23:9 54:20 60:16,17 62:10,11 63:13 68:9 68:12 69:16 80:11</p>	<p>81:6 88:21 90:4 96:15 117:14 128:22 134:1,4,6 137:1 141:18,20 142:19 146:22 151:10 153:1 153:11 155:11 166:10 171:17 172:11 175:15 178:16 179:20 180:10 183:4 186:17 189:14 190:21 192:1,12 193:22,22 194:16 195:4,19 196:6,18,20 197:11 199:4 201:14 201:18 202:3,5,18 203:6 205:12 206:9 206:19 209:10 213:5 214:12 216:8 218:15 225:7 226:9 227:10 228:15 229:11 230:6 230:15 231:8,10 232:19 238:5,11,15 240:11,14,15 242:1 250:8 252:18 254:6 255:11 258:1 260:5 263:6 265:19 267:21 268:11 271:2 272:11 273:6 276:22 277:14 277:21 280:6 281:11 283:16,16 285:16 288:15 291:14 293:3 295:19 300:6,7 304:18 306:6 313:1 <b>pages</b> 6:14 58:5,8 62:18 63:3 65:19 66:2 196:15 197:3,20 208:7 211:1 212:12 <b>panel</b> 279:3 <b>paper</b> 241:11 302:13 305:4 311:22 312:14 312:20 <b>papers</b> 50:17 63:20 67:6,20 297:10 301:12,22 312:18 314:15 318:14 <b>paragraph</b> 22:16,21 23:3,8 69:17 73:22 81:7 88:22 90:4 92:6 113:8 123:22 124:1 128:22 129:6 134:1,2 134:9 137:2 138:7 139:20 141:18,19 142:20 147:1,1 151:11,12 152:7,13 152:20,22 153:11 155:12 166:9,12 171:17 172:8,14 175:15 178:17 179:21</p>	<p>183:9 186:18 189:18 192:2 193:5,7 195:4 196:18 199:6 202:19 206:11 208:16 209:12 209:17 210:22 213:15 216:10 217:7 218:18 225:7 226:10 227:1,9 228:16 229:12,16 230:5,6,16 231:8,14 231:20 242:3,10 250:9 254:6,8,12 255:12 258:3 260:7 263:8 268:1 277:2 285:18 300:8 304:19 313:12 <b>paragraphs</b> 212:11,15 231:9 <b>parameters</b> 6:8 207:5 208:3 290:11 <b>parenteral</b> 23:12 26:16 58:22 145:5,5 211:20 211:22 <b>parenterally</b> 263:12 <b>part</b> 40:12,19 53:18 54:15 59:11,14 65:18 116:22 130:14 149:13 160:21 189:16 279:4 293:19 306:21,21,22 306:22 <b>partially</b> 82:7 <b>particle</b> 49:10 <b>particles</b> 69:13 140:14 <b>particular</b> 20:22 21:4 21:11 22:4 24:3,5 35:22 42:8,9,16 46:13 53:21 54:2 70:13 83:18 84:6 94:3 98:9 99:21 148:8 159:1 176:12,13 182:10 191:15,15 209:12 211:19 218:17 221:8 221:11,11 223:3,11 223:11,18 224:1,1,20 224:20 241:8 261:4 263:11,19 266:18 267:22 269:11 274:9 278:11,20 <b>particularly</b> 63:18 130:12 139:11 149:22 150:19 165:7 168:14 173:4 261:3 264:5 270:8 <b>particulate</b> 140:11 <b>particulates</b> 141:3 <b>parties</b> 15:9 <b>partition</b> 165:14 <b>partitioning</b> 272:20</p>
--	---	---	---	--



<p><b>party</b> 47:2 52:3,18 53:2 53:14 54:1</p> <p><b>patent</b> 6:16,17 45:11,15 45:21 46:6,19 68:13 68:15,16,20 69:1,5,9 69:12 70:7 71:14,15 71:16,19,22 72:1,5 73:1,5,8,11 90:11,15 90:16,18,21,22 91:2,5 91:6,8,11,12,14,18,19 94:7,15 97:9,15,16 98:1,5,10,18 99:7,16 100:12,21 101:5,7,9 101:12,14,17,19,22 102:3,8,10,15 103:2,7 103:10,16 104:1 106:8,13,15,21 107:3 107:6,9,12,14,17,21 108:1,8,10,14,16 109:16,19 110:11,17 110:20 111:13,19,22 112:9,11,22 113:22 114:7,10,11,21,22 115:9,11,16,17 116:4 116:5,17,20 118:16 123:21 127:2 129:3 131:10 134:22 145:18 147:6,7 151:5,7 152:13 153:3,6 178:21 179:9 232:12 232:16,17,19,20 233:4,17 234:2,7,9,17 235:1,4,7,11 236:3,9 237:1,11,18 238:1 242:5 243:6,17,20 244:1,6,17,22 245:5,8 245:20 246:1,13,16 246:20,22 247:3,5,13 247:15 248:9,17 249:2,8,18,20 250:2 251:22 254:5,10 314:3,11</p> <p><b>patents</b> 45:13 90:6 91:22 92:17,17 94:7 97:13 132:12 135:14 136:2 138:10 139:2,3 146:3 148:9 149:1,3 149:21 152:18 177:10 177:22 186:5 203:19 226:22 232:4,7 235:2 237:11 314:2,14</p> <p><b>patents-in-suit</b> 90:7 91:22 92:3,8,12 93:1 93:9,16,19 94:19 95:2 95:5,8,12 96:7,12,21 97:6 104:12,15,18,22 105:3,14,20 109:9</p>	<p>116:8 117:11 118:2,6 119:15 124:13 125:9 125:16 126:2,15 127:5,7 131:16 132:1 136:5 138:21 139:9 139:15 140:5 142:4 143:5 144:7,10,15 145:7,12,19 146:5,12 147:14,18 148:6,19 149:6,17 150:10,22 151:19 152:1,9 155:14 175:19 176:6 176:18,22 177:9,15 178:4,9,13,20 179:14 186:7,10,14 203:21 204:2,6 226:19 232:5 237:12 247:14,18 248:3 252:14</p> <p><b>patent-in-suit</b> 104:15</p> <p><b>patient</b> 25:18 27:16,22 28:7,10 29:1,8,13,20 42:21 43:2,16 108:2 118:7 258:12,16 259:2 268:4</p> <p><b>patients</b> 73:19</p> <p><b>PCS</b> 241:13,15</p> <p><b>pedestrian</b> 150:1 259:6</p> <p><b>peer-reviewed</b> 239:12 241:17</p> <p><b>PEG</b> 83:9,12</p> <p><b>people</b> 150:8,11,11,16 215:16 222:9 241:14 315:17</p> <p><b>percent</b> 113:9 114:13 121:15 167:22 168:2 229:5,7 230:9,18 231:3 235:20 311:3</p> <p><b>perfect</b> 235:7</p> <p><b>perform</b> 41:13 261:21</p> <p><b>performed</b> 41:5,13 111:16 253:22 255:15</p> <p><b>period</b> 143:14 219:1</p> <p><b>periods</b> 240:21</p> <p><b>permanent</b> 56:7,13</p> <p><b>permeability</b> 6:10 207:7 208:4 275:16 276:1</p> <p><b>permissible</b> 250:19</p> <p><b>permit</b> 221:12 223:12 224:2,21</p> <p><b>person</b> 21:3 79:22 84:10,22 85:9 86:10 86:21 87:2,10,18 88:14 94:16 95:1 97:21 98:16 99:5,14 100:10,19 101:6,10 101:15 102:1,8</p>	<p>106:14 107:7,15,21 108:14 109:17 110:15 111:11,20 112:9 120:8 121:2,17 122:7 122:14 123:14 125:16 126:2 133:3 137:4 141:20,21 142:3,5,9 143:4,7,16,21 144:4 144:18 145:6,20 146:2,4,11 147:3 151:17,21 152:8 154:17,18 159:5,12 160:10 161:18 162:17 187:2,11 188:9,16 189:2 209:20 210:6 210:14 218:8 220:5 220:19 243:4 246:21 247:4,17 248:2</p> <p><b>personally</b> 32:11,15,18 41:21 154:12 155:4</p> <p><b>persons</b> 145:12</p> <p><b>pertaining</b> 89:4</p> <p><b>pgs</b> 5:17 7:9,16,21 8:8 8:13,17 9:8,19 10:7 10:14 11:9,16 12:7,13 13:10,17 14:8,16,21</p> <p><b>pH</b> 50:2 76:11,18 113:13 119:9 124:18 125:4,10,19 126:5 166:7 190:17 226:14 256:21,22 257:2 272:4,21 290:15 309:8,13,21 310:9,19</p> <p><b>Pharm</b> 6:13 208:6</p> <p><b>Pharma</b> 1:4 11:16 12:12 62:12</p> <p><b>pharmaceutical</b> 1:3 7:13 8:12 13:9,16 15:12 21:16 22:13 23:12 24:16,22 27:5 36:21 37:5,8 49:12 52:8,10,13 53:6 55:11 56:4,8,13,17,22 57:7 57:10,16 58:3 59:22 60:5,6 61:4,12,19 64:12,18 67:11,15 68:4,8,18 69:3,6 72:13 73:5,11 89:16 89:22 94:17 143:13 144:19 186:20 187:3 187:4,10,13,19 188:1 188:7,8,11,18 189:4 189:11,20 191:4,9 198:19 200:13 201:22 210:2,7,15 213:12,20 214:20 215:3,8,20 216:13 217:1 222:15</p>	<p>223:6 233:6,18 235:13 253:4 263:9 263:17 277:15 279:3 299:18 311:6</p> <p><b>pharmaceutically</b> 31:10 233:8 307:12</p> <p><b>pharmaceuticals</b> 1:9 1:12 144:20 180:22 181:7 182:1</p> <p><b>pharmaceutics</b> 14:7 89:8,10 258:4</p> <p><b>pharmacist</b> 25:16 27:10 28:1,5 29:5,9 39:2 55:17</p> <p><b>pharmacodynamic</b> 164:11 278:12</p> <p><b>pharmacodynamics</b> 26:9 278:1</p> <p><b>pharmacokinetic</b> 163:22 164:6 273:13 278:12</p> <p><b>pharmacokinetics</b> 11:8 25:22 26:6 278:1</p> <p><b>Pharmacol</b> 6:13 208:6</p> <p><b>pharmacologically</b> 124:16 129:10 258:7</p> <p><b>pharmacology</b> 9:18 12:12 25:20</p> <p><b>Pharmacopeia</b> 37:18 38:2,11,18,21 39:6 51:6,9,12,19 109:1,11 111:6 242:12,15 243:5,8 244:3,8,14,19 245:2,7,22 246:15 247:7 249:10,16 250:4 253:9,10,11,13 253:14,14</p> <p><b>pharmacy</b> 9:18 25:11 25:13,15 96:2 209:14</p> <p><b>phase</b> 65:9,18 151:6 169:11 266:10,10 288:20</p> <p><b>phases</b> 9:8 171:14 266:5 313:5</p> <p><b>phenylacetate</b> 113:15 118:19 119:4 227:5</p> <p><b>phenylacetic</b> 119:9 124:8 129:9 155:17</p> <p><b>phenylbutazone</b> 168:15</p> <p><b>phosphatidylcholines</b> 293:8</p> <p><b>phospholipid</b> 293:10 294:1</p> <p><b>phrase</b> 46:5,18 65:9 74:3,7 102:15 103:2 103:10 104:1,18</p>	<p>139:6 212:17,21 222:5 231:17 242:3</p> <p><b>phrases</b> 45:20 89:12 105:4 176:7,16,20 177:7,15 179:14 191:9</p> <p><b>physic</b> 75:4</p> <p><b>physical</b> 9:7 45:3 49:13 75:9,17 76:22 77:7,8 77:18,19 78:5,6 79:1 79:3 81:22 82:19,21 85:10 87:2 116:8 117:4,11,18 156:10 156:14,16 157:11,22 158:1,13,14,18 159:21 161:19 162:10 162:18 169:1,4 170:4 170:5,15 171:2,3 216:19 224:5,15 225:12,18 226:5,7 296:9 297:2 310:16</p> <p><b>physicochemical</b> 13:4 74:14 75:5 271:21 272:13,18 278:11 293:9,16 294:13 300:8 302:17,21 303:14</p> <p><b>physic-chemical</b> 74:4,7 74:11</p> <p><b>physiochemical</b> 269:6</p> <p><b>Ph.D</b> 1:16 2:2 5:3,11 16:22 18:11 55:21 94:16 145:3 187:5</p> <p><b>pick</b> 15:4</p> <p><b>picture</b> 285:7</p> <p><b>piece</b> 42:3</p> <p><b>pKa</b> 159:22 160:2</p> <p><b>place</b> 15:6 105:4,15,20 261:19 313:22</p> <p><b>placed</b> 219:5,15</p> <p><b>places</b> 187:17,20</p> <p><b>plain</b> 102:14,21 103:1,9 103:20,22 104:11,14 104:17 137:12,21 138:3 147:12,17 176:5,11 244:16,21</p> <p><b>plaintiffs</b> 1:7 3:4 15:13 16:10,13 17:14 231:16 254:9</p> <p><b>Plaintiff's</b> 18:13 205:22 208:8 232:13 237:20 240:7 257:13 259:15 262:16 265:9 267:10 279:17 281:1 283:6 285:3 288:5 292:15 295:9 297:19 298:22 304:8 305:18 308:16</p>
--	---	--	---	--

312:4 <b>plastic</b> 119:20 120:1,3 <b>plasticizers</b> 120:6 <b>platform</b> 57:20 <b>please</b> 15:3,5 16:20 17:7,22 18:19 19:21 20:7 24:20 35:4,16 54:18 57:13 81:6,16 83:6 95:20 98:5 99:8 106:7,7 113:1 134:1 140:9 180:10 203:5 205:12 206:9,12 210:10 212:11 236:8 244:20 268:11 271:17 288:15 306:6 312:22 <b>plethora</b> 86:5 266:5 <b>Pluronic</b> 289:16 <b>plus</b> 160:6 <b>point</b> 25:8 107:13 129:22 130:3 131:3 163:8 167:21 203:18 219:6,15 290:18 311:17 316:5 <b>pointed</b> 231:3 <b>pointing</b> 157:20 182:12 <b>points</b> 169:11 <b>polar</b> 308:6 <b>polyether</b> 127:8 128:15 129:11 <b>polyethylene</b> 81:18 127:8 129:12,13 167:6 256:2,5 <b>polyglycerol</b> 296:16 <b>polymer</b> 83:15 128:15 129:12 303:10 <b>polymeric</b> 289:13 294:1 <b>polymers</b> 67:8 81:19 127:8 <b>polyoxyethylene</b> 128:18 255:19 263:10 263:18 296:20 297:6 301:20 303:9 <b>polyoxyl</b> 113:17 227:15 228:20 229:22 230:1 289:18 <b>polypropylene</b> 118:21 119:6,17,19,22 120:6 120:9 121:3,9,19 122:9,13 123:4,10,13 <b>polysorbate</b> 113:18 227:14 228:22 <b>polyvinylpyrrolidone</b> 102:20 <b>poor</b> 140:15 <b>poorly</b> 276:9 299:17 <b>portions</b> 296:4 317:16	<b>position</b> 56:8,13,21 57:3 254:9 <b>positive</b> 167:1,4 173:6 <b>possess</b> 75:11,19 157:12 <b>possible</b> 132:14 161:5 220:11 256:9 259:4 268:21 272:16 278:5 303:4 310:3 <b>possibly</b> 117:4,4 122:22 169:22 <b>post-doctoral</b> 55:21 <b>potency</b> 274:20 <b>potency/selectivity</b> 273:12 <b>potential</b> 50:11 213:22 214:9 268:6,14 278:2 <b>potentially</b> 161:15 223:4 290:6,6 291:21 <b>pounds</b> 60:9 <b>power</b> 261:20 <b>practical</b> 140:19 210:19 299:21 300:3 <b>practice</b> 25:15 27:14 209:14 <b>practiced</b> 25:13 <b>practicing</b> 25:16 27:10 <b>precedence</b> 236:16 <b>precipitate</b> 117:3 <b>precipitating</b> 238:17 <b>Preclinical</b> 268:19 <b>predict</b> 78:15 169:22 216:6 260:11,15,21 261:9 303:5 <b>predictable</b> 307:15 308:1 <b>predicted</b> 77:8,17 78:5 79:3 158:1,12 170:5 170:14 171:1 <b>predicting</b> 160:2 <b>predominantly</b> 35:17 291:4 <b>prefer</b> 317:12 <b>preferable</b> 256:5 <b>preferably</b> 125:12 <b>preferred</b> 110:22 125:19 126:5 <b>preparation</b> 48:9 58:21 62:3,7 65:4 68:1 69:11 80:4 86:2 87:1 98:17 99:6,8,11,15,20 100:11,20 101:4,11 101:16,21 102:2,9 107:8,16,22 108:15 108:19,20,22 109:18 110:16 111:12,21 112:10 113:16,17,18	114:12,15 124:15 125:10 126:16 127:10 128:7 129:8 132:3,18 133:4 151:9 175:9 188:14,19 189:5 211:11,17 218:10 228:20,21,22 242:12 271:5,10 277:4 289:4 289:6,22 290:2 314:7 315:13,21 <b>preparations</b> 23:15 29:6 31:22 39:11,20 40:7,15,22 41:3,9,18 44:2 50:18 51:1 57:21 75:19 87:12,21 88:16 116:10 118:5 125:18 126:4 131:16 132:1 139:11 150:12 159:7,14 160:12 161:6,20 162:19 164:7,12 167:9,13 168:4,20 169:13 171:14 230:17 231:4 241:4 258:19 284:3 284:12 <b>prepare</b> 87:9 108:4 313:14,21 <b>prepared</b> 19:1 38:15 42:11 73:13 118:20 119:5 <b>preparing</b> 73:4 92:16 <b>prerequisite</b> 42:18,19 <b>prescribed</b> 27:15 120:16 <b>presence</b> 50:3 76:11,12 76:15,16 257:4 309:8 309:14,21 310:10,19 <b>present</b> 4:14 76:9 124:14 125:11 126:16 129:8 172:15 236:17 255:19 293:6 <b>presented</b> 304:20 <b>preservative</b> 46:18 110:8 111:5 112:21 117:1,2 124:19,20,21 127:11 131:15,19,22 132:4,13,19 133:2,6 133:12,15,19,21 226:16 242:4 244:2,6 244:17 245:1,5,20 246:14 247:1,6 248:9 248:17 249:1,9 250:3 253:4,6,8,21 <b>preserved</b> 119:7 132:15 <b>pretend</b> 282:10 <b>prevent</b> 181:1 217:2 <b>previous</b> 54:21 55:18	69:18 70:7 136:1 221:18 222:16 255:12 274:3,7,8,16 275:4 280:7 281:12 291:3 296:14 <b>pre-clinical</b> 271:7 <b>pre-formulation</b> 162:4 <b>pre-registration</b> 55:17 <b>pre-term</b> 28:18 <b>pre-weighed</b> 35:21 <b>primary</b> 198:17 247:21 <b>prior</b> 45:10,18 46:3,16 56:16 127:6 138:14 227:21 228:3,4,9 252:13 <b>private</b> 15:5 <b>probably</b> 24:3,5 25:19 32:17,22 73:21 95:15 115:22 204:13 261:17 262:4 270:19,21 287:4,9 316:11 <b>probenecid</b> 233:10 <b>problem</b> 140:15,17,19 170:22 246:10 276:12 <b>problems</b> 50:11 138:13 138:14 139:14,18,20 140:4 141:5 142:10 142:15 275:10,16 <b>problem-solve</b> 142:10 142:14 <b>proceed</b> 17:14 19:21 <b>proceedings</b> 282:17 <b>process</b> 50:6 160:22 162:4 175:4 190:9 214:2 268:3,5 <b>Procter</b> 2:3 3:14 15:19 16:16 <b>produce</b> 110:21 132:15 <b>produced</b> 255:21 <b>product</b> 27:22 28:6,9 28:12,17,19,20,22 29:7,12,18,22 30:5,8 30:10,12 32:2,5 36:21 37:5,8 47:14,16 48:12 48:14,15,22 49:2,5,8 52:4,19 53:2,14 57:10 57:13,15 58:1 61:22 100:16,17,21 160:19 210:3,8,16 213:12,14 213:21 214:20 215:3 215:8,21 <b>production</b> 81:20 296:4 <b>products</b> 28:21 29:4 38:14 47:18,22 48:5 50:9 144:20 216:13 217:2,4 253:5 <b>professional</b> 19:9 20:6	21:14 22:12 <b>program</b> 145:1 <b>programmes</b> 274:20 <b>progress</b> 269:14 276:20 <b>projects</b> 55:20,21,21 60:14 <b>PROLENSA00006182</b> 192:14 <b>PROLENSA00006183</b> 194:1 <b>PROLENSA00006191</b> 203:7 <b>promising</b> 111:1 112:18 <b>promoting</b> 24:15,18 <b>propensity</b> 225:17 226:2,6 <b>proper</b> 151:17,21 152:8 <b>properly</b> 117:6 <b>properties</b> 9:15 12:9 13:5 14:12 49:13 75:10,18 76:22 77:7,9 77:18,20 78:5,7 79:2 79:4 82:1,19,22 84:6 85:11,17 87:3 156:11 156:14,16 157:12,22 158:2,13,14,18 159:2 161:20 162:19 163:22 164:6,11,17 165:2,11 165:22 166:3 169:2,4 169:8,12 170:4,6,15 171:2,3 190:7 226:7 260:11,16 261:2,5,10 269:6 271:22,22 272:14,19 273:13 278:13 280:9 293:9 293:16 294:13 296:10 296:21 297:3 300:10 308:5 310:8,14,17 <b>property</b> 83:15 <b>proportion</b> 36:14 <b>proportions</b> 36:13 <b>proposed</b> 143:4 231:16 <b>proposing</b> 143:7,16,21 144:4 <b>propoxy</b> 300:15,20 301:1,4 302:6 <b>prosecution</b> 135:1 137:7 147:6 152:1,5 152:10 153:3,7,15 178:20,21 179:8,13 186:13 204:5 231:5 251:22 252:2 <b>protective</b> 317:21 <b>protocol</b> 109:13,14,15 121:16 <b>protocols</b> 214:14,19,22
--	---	---	--	--

<p>215:1,5,7  <b>prove</b> 170:2  <b>proven</b> 145:3  <b>provide</b> 47:2,7,10              71:10 72:1 90:5 92:7              124:15 127:7 129:17              129:21 130:1,9,18              131:1,5,7 133:16              171:21 210:1,5,13              214:18 226:14 236:3              236:9  <b>provided</b> 45:18 46:3,16              143:9,18 314:20              315:6  <b>provides</b> 179:4 209:21              237:2  <b>providing</b> 233:1 238:8              291:8  <b>proximity</b> 167:5  <b>public</b> 2:7 23:18 24:18              26:5,8,19 27:6 37:15              39:5,18 44:21 47:7  <b>publication</b> 5:18 6:18              34:15 51:12 66:21              67:1 188:5 206:3              237:18 238:2  <b>publications</b> 34:13              239:12  <b>publish</b> 78:18 260:3              263:4  <b>published</b> 45:5 63:4,14              63:16 64:2,7,10,17              65:2 66:3,7,22 67:9              67:14,21 299:10              311:20  <b>pulled</b> 265:3  <b>purpose</b> 41:15,16 83:18              160:18  <b>purposes</b> 32:8 137:3,13              137:22 227:21 228:10  <b>pursuant</b> 2:2  <b>put</b> 82:12 88:3 121:12              122:4 137:16 141:4              148:1 185:1 193:6              209:6 237:8 239:8              241:22 257:6 259:8              262:8 264:7 267:3              279:8 280:15 282:20              284:17 287:19 292:7              295:1 297:11 298:15              303:22 305:10 307:8              311:9 313:13  <b>putting</b> 43:17 184:18  <b>p.m</b> 204:21 205:5              254:19 255:3 316:15              316:19 318:17,22</p>	<p style="text-align: center;"><b>Q</b></p> <p><b>qualifications</b> 22:21              143:14  <b>qualified</b> 45:8 70:6,10              174:10 236:17  <b>qualifies</b> 70:12  <b>qualify</b> 21:10 24:18              70:22 230:18 286:16  <b>quaternary</b> 127:12  <b>question</b> 17:19,20,22              18:1,2 20:1,13 21:5              21:10 24:6 25:9              30:21 32:13 33:14,15              34:21 35:5 40:1 42:2              46:12 59:6 60:4 70:8              75:16 80:8 87:17              92:19,21 93:7 96:5              97:2 99:13 100:18              104:8 115:14 116:14              118:10 120:21 125:21              127:19 132:17 133:9              139:7 140:2 143:15              145:17 148:7 150:5              151:3 152:3 155:2              159:10 170:20 184:13              193:13 195:11 210:10              221:16,17 223:8,21              224:13 236:8 244:20              246:11 248:1 271:15              290:16,17,22 291:1,3              307:18 309:17 313:19  <b>questions</b> 17:15,16              316:22  <b>quick</b> 115:3 235:1  <b>quickly</b> 236:18  <b>quite</b> 79:11,17 81:14              83:4 104:8 114:3              116:11 156:5 157:8              169:21 181:18 184:8              198:5 261:5 286:12              287:1,11 294:10              314:16  <b>quotation</b> 224:14  <b>quote</b> 129:6 224:18,19  <b>quoted</b> 224:14</p> <p style="text-align: center;"><b>R</b></p> <p><b>R</b> 3:1 15:1  <b>raft</b> 110:9 111:16 112:5  <b>range</b> 68:7 100:3 108:4              110:7 124:18 125:19              126:5 168:14 226:15              266:17,19 268:13              281:19  <b>ranging</b> 42:14  <b>rat</b> 6:11 207:7 208:5</p>	<p><b>rate</b> 113:9 114:8              230:18  <b>rated</b> 63:8 241:18  <b>ratio</b> 290:13 291:4  <b>rational</b> 83:17  <b>rationality</b> 83:16 84:8              99:20  <b>reached</b> 248:8,16  <b>reaction</b> 216:14  <b>read</b> 29:9 58:12 92:15              92:16 94:6 96:17              106:1 107:5 123:21              124:4 125:6 126:10              127:2 128:11 129:2              134:2,10 135:14              142:22 153:14 200:1              206:11,20 210:9,21              213:15 216:10 219:10              225:8 231:9 234:6,13              235:2 236:18 238:11              240:15 243:7 246:3              252:2,21 274:2,18              275:5 290:19,22              296:14 299:15 305:4              306:19 314:9,14,16              315:1,2 319:1  <b>readily</b> 120:9 121:3              122:8  <b>reading</b> 94:14 235:1              314:17,17,18  <b>reads</b> 113:8 190:6              233:6 283:19 304:19  <b>ready</b> 96:18 116:13,19              124:5 125:7 126:12              127:3 128:12 134:11              134:12 136:8 143:1              206:13,22 207:1              211:2,3 212:13              213:17 219:11 225:10              231:12 238:12 240:15              245:17,18 253:1,18              291:15  <b>realization</b> 287:16  <b>realize</b> 111:9 200:3              287:3  <b>realized</b> 286:22 287:9              287:10  <b>really</b> 22:2,2 35:2 39:22              42:2 63:17,21 79:20              98:3 104:6,6 105:7              115:2,2 146:15              148:21 149:19 150:16              157:15 164:19 174:17              174:20 191:13 198:8              200:3,14,16 234:7              239:6 259:4 270:12              294:16</p>	<p><b>reask</b> 116:14 223:9  <b>reason</b> 17:21 18:4              105:8 150:21 190:8              201:1,2 289:19 305:7  <b>reasonable</b> 78:15              153:16 154:1 155:5,8              271:1 272:10  <b>reasons</b> 31:9,11,13,16              43:8,11,14 151:4              160:20 163:9,13,19              269:13 314:15  <b>recall</b> 30:3 38:19 46:1,2              46:22 89:14 317:7              318:5  <b>receive</b> 60:2 61:7 62:6  <b>received</b> 59:20 61:3,11              61:18 62:2 89:3  <b>receiving</b> 85:15  <b>recess</b> 80:21 136:16              205:3 255:1 316:17  <b>recited</b> 250:16  <b>recognized</b> 24:11  <b>recollection</b> 314:22              315:6  <b>record</b> 15:3,10 17:8              18:10 80:20 81:4              136:15,21 170:22              204:15,17 205:2,8,18              207:21 232:11 237:17              240:3 254:15,22              255:6 257:10 259:12              262:12 264:14 267:7              279:12 280:19 283:2              284:21 285:8 288:1              292:11 295:5 297:15              298:19 304:4 305:14              308:13 311:13 316:7              316:13,16,20 317:11              318:20  <b>Recording</b> 15:9  <b>recordkeeping</b> 63:9,10  <b>records</b> 63:21 64:9  <b>reduces</b> 156:6  <b>reducing</b> 283:22  <b>reduction</b> 251:3,16  <b>refer</b> 90:15,21 91:5,11              91:18,21 104:9              105:15,20 124:11              151:11 180:5 184:5              184:15 185:5 186:7              186:11,14 189:9              192:7 195:15 203:1              203:21 204:3,6              207:14 212:6 216:18              232:16 238:1 244:2,6              244:17,22 246:22              247:5 249:9 252:6</p>	<p><b>reference</b> 132:11 185:2              187:2,11 188:18              189:1,4 192:3,10,13              192:17,21 193:10,16              193:20 194:10,20              195:5,12,16,20              196:16 197:3,4,22              198:1,7 199:12,20              201:18 202:3,5,20              203:2,11,22 204:3,6              206:18,20 207:2              208:12 209:19 212:8              213:2,5,11,19 214:13              214:18 215:1,6,19              216:9 217:15,18              218:16 219:13,18              220:5,19 221:2,7,10              221:22 222:11,19              223:10,22 224:9,19              252:7,10,13,19 253:3              253:7,15,21 311:18              311:20,21 312:15  <b>references</b> 64:15 67:19              127:6 198:17,20              199:16 314:3  <b>referred</b> 166:12 172:16  <b>referring</b> 22:4 136:5              142:15 226:18 307:1  <b>refers</b> 203:12 245:5,20              246:13  <b>reflect</b> 242:14  <b>refresh</b> 314:21 315:5  <b>refreshed</b> 314:11  <b>regarding</b> 22:13 45:19              46:4,17 52:9,13,18              53:2,14 54:1 249:1              254:10  <b>regards</b> 33:20  <b>regime</b> 307:12  <b>Registered</b> 27:9  <b>regulate</b> 118:6,13              258:11,15 259:1  <b>regulations</b> 145:9  <b>regulators</b> 215:14  <b>regulatory</b> 120:15              163:5,8 268:3  <b>reiterate</b> 282:16  <b>relate</b> 95:5,8,12 96:7,12              275:4  <b>related</b> 46:12 47:15              67:6 77:14,15 96:1              147:7 152:13,17              191:1,5 257:3 314:9  <b>relation</b> 6:10 207:6              208:4  <b>relationship</b> 78:13              79:13,14 94:14</p>
--	---	--	--	--

<p>218:19  <b>relative</b> 36:12,12 50:1                  235:20 291:6  <b>relatively</b> 139:10                  167:14  <b>release</b> 233:7  <b>relevant</b> 19:8 24:3,8,8                  138:9 144:9,14 147:8                  152:18 232:6 313:21  <b>reliable</b> 219:19 220:7                  220:21  <b>reliably</b> 160:3  <b>relied</b> 242:22 243:12  <b>rely</b> 153:2 198:14                  249:17  <b>relying</b> 179:22 186:19                  192:3,16 195:5,12                  196:14 202:14,20                  209:13 252:10  <b>remain</b> 224:5  <b>remained</b> 162:9  <b>remaining</b> 113:9 114:8                  224:15 230:18  <b>remains</b> 114:14 229:14                  229:18  <b>remember</b> 32:21 34:14                  56:14 63:17 73:21                  102:4 129:4 162:15                  168:5 221:20 242:20                  243:2,14 249:11                  262:3 287:7,15,18                  301:14 310:2 311:1                  314:4,10 316:2  <b>Remington's</b> 209:13,19                  210:1,5,13  <b>removed</b> 288:21  <b>removing</b> 190:9  <b>repeat</b> 19:22 33:13,15                  40:18 41:11 59:6                  87:16 93:6 115:6                  185:10 215:5 236:7                  244:20 309:16  <b>rephrase</b> 75:16 100:17                  175:3  <b>replacement</b> 255:18  <b>report</b> 68:6 94:12                  114:5 130:14 203:18                  208:17 252:4 261:18                  300:19  <b>reported</b> 281:13 300:10  <b>reporter</b> 2:6 16:1,20                  18:8 28:14 84:15                  195:10 205:16 207:19                  232:9 237:15 240:1                  257:8 259:10 262:10                  264:9 265:7 267:5                  279:10 280:17 282:22</p>	<p>284:19 287:21 290:19                  292:9 295:3 297:13                  298:17 304:2 305:12                  308:11 311:11  <b>Reporters</b> 16:3,5  <b>repositioning</b> 160:18  <b>represent</b> 16:8 17:14  <b>representing</b> 16:4  <b>reproduce</b> 185:10  <b>reproduced</b> 200:12  <b>Reproducibility</b> 73:18  <b>reproducing</b> 184:9  <b>reproduction</b> 230:14  <b>repulsive</b> 291:8  <b>require</b> 251:1,16,17  <b>required</b> 114:8 223:3                  256:16 261:22 262:1                  296:4  <b>requires</b> 251:3,8,14                  273:11,19  <b>research</b> 30:4,9,15,22                  32:1,7,10,11,16,19                  55:7,20 58:7,9,17,20                  59:2,7,13,21 60:15                  61:3,11,17,18 62:2,6                  89:4 144:22 145:1                  276:7  <b>researcher</b> 25:2 39:3                  216:1  <b>researchers</b> 215:14                  255:16  <b>respect</b> 21:14 22:12                  24:21 44:1 111:3                  116:20 138:8 141:2                  148:5,18 149:5,16                  150:10 240:21 241:4  <b>respectively</b> 118:21                  119:6  <b>respects</b> 250:11  <b>respiratory</b> 23:14                  28:17  <b>respond</b> 231:15 254:9  <b>responsibility</b> 109:13  <b>responsible</b> 57:15                  173:15  <b>rest</b> 159:4 210:21  <b>restrict</b> 102:15 103:2                  103:10,17 104:1,18  <b>result</b> 175:4 225:19                  281:18  <b>resulting</b> 261:2 291:10  <b>results</b> 174:11,15,21                  219:19 220:7,21                  230:19 231:2 300:20                  301:10  <b>reveal</b> 239:15 313:17  <b>reverse</b> 266:11</p>	<p><b>review</b> 90:11,18 91:2,8                  91:14 92:3 104:21                  113:4 287:10 314:6                  314:13 315:9  <b>reviewed</b> 134:10                  175:18 178:19 243:13                  243:19 245:13 314:20  <b>Reviews</b> 10:13 14:20  <b>re-publication</b> 312:14  <b>re-published</b> 311:21  <b>re-purposing</b> 160:15  <b>re-read</b> 106:5 177:1                  219:9  <b>re-reading</b> 305:6                  313:20  <b>rheology</b> 86:16  <b>Richardson</b> 55:15,17  <b>ridiculous</b> 122:18,19  <b>right</b> 22:22 23:4 99:13                  116:16 134:7 177:3                  183:18 267:13 306:16                  306:21 317:8 318:5                  318:12  <b>right-hand</b> 183:4,19                  195:21 213:9 214:12                  218:17 276:22 295:20                  306:7  <b>risk</b> 270:10  <b>Road</b> 17:10  <b>Robert</b> 146:20  <b>robot</b> 141:22 142:5  <b>role</b> 28:2,4 56:17  <b>route</b> 160:7 161:11                  164:3,21 212:3 277:8                  277:10  <b>routine</b> 260:22  <b>routinely</b> 311:6  <b>Royal</b> 21:16 56:17                  188:7  <b>rules</b> 84:9 170:10  <b>run</b> 218:22  <b>running</b> 55:20</p>	<p>157:6 161:15 172:15                  172:16,19 173:14,16                  175:21 176:7,8,13,16                  176:20 177:7,16,17                  177:21 178:12 179:2                  179:3,9,15 181:1,8                  182:2,16,17,18,19,20                  182:21 184:6,12,16                  185:6 186:3 190:3,3                  190:12,12 191:4,5,10                  191:11 196:3,3                  203:12,15,15 207:11                  207:14 208:22 290:15  <b>salts</b> 48:3,20 53:17                  76:12 172:17 173:20                  174:1,12,16 175:5                  189:19 190:20 191:6                  195:22 196:2 233:8  <b>sample</b> 227:14,15,16                  229:14,15,19,20,21                  229:21 230:1  <b>satisfied</b> 242:4  <b>satisfies</b> 253:22  <b>satisfy</b> 110:3 242:12  <b>save</b> 270:11  <b>saving</b> 185:9  <b>saying</b> 103:15 130:7                  209:3 217:19,19,20                  218:5  <b>says</b> 23:10 55:1 69:17                  81:9 89:2 90:5 106:3                  114:11 118:18 119:2                  128:6 137:2 138:8                  141:20 153:1,12                  155:14 180:20 183:10                  183:22 185:18 189:19                  190:15 193:8 194:8                  196:9,18,20 197:12                  199:7 217:9,22                  228:17 242:3 245:3                  255:14 260:8 273:11                  273:17 274:8 275:8                  277:2,15 278:1                  281:12 288:17 295:21                  300:8 306:8 309:5                  313:3  <b>scale</b> 123:2  <b>scattering</b> 7:12,15 8:11                  24:4,12,14 42:15                  63:12 74:15 82:15  <b>science</b> 12:6 24:16,22                  144:19 148:3,4                  209:14 222:8  <b>sciences</b> 5:17 7:13                  11:16 13:9,17 94:18                  279:3  <b>scientific</b> 20:5,16 22:11</p>	<p>58:17,20 59:2,7                  160:22  <b>scientifically</b> 222:1,4,7                  222:18,20  <b>scientist</b> 21:16,18 56:17                  277:15  <b>scientists</b> 24:19  <b>scope</b> 153:17 154:2                  155:6  <b>screen</b> 112:18 290:20  <b>screening</b> 112:19  <b>search</b> 165:16 247:21                  275:8,14 276:17,19  <b>searched</b> 165:19  <b>searching</b> 277:16  <b>second</b> 49:11 68:17                  69:12 74:3 81:8                  152:21 185:18 190:6                  196:20 197:11 204:17                  206:11 208:16 209:17                  216:9 225:8 239:13                  250:15 255:12 258:3                  267:22 277:6 283:18                  306:21,22 309:4  <b>secondary</b> 202:16  <b>section</b> 58:7 62:22                  65:20 134:9 194:16                  258:2 259:22 263:1                  265:20 267:22 268:18                  271:2 272:13 277:22                  293:4  <b>sections</b> 278:19  <b>see</b> 23:16 55:3 63:1                  64:22 65:22 69:19                  74:9,19 81:9 89:6                  90:8 92:9 99:10                  100:7 113:19 114:10                  114:18 119:11 123:22                  129:7,15,19 137:9                  138:17 139:22 142:1                  147:10 151:13 152:7                  152:15 153:19 156:1                  162:8 166:14 172:2                  176:3 177:11 179:13                  180:12,15,18 181:3                  183:6,10,12,22 184:2                  185:16,19 187:7                  193:3 194:6,13,18                  195:1 196:11,22                  197:12,17 199:6                  201:14 203:9 206:17                  207:8 211:5 214:16                  216:15 217:13 218:3                  219:8 232:20 233:15                  233:19 235:10 238:6                  238:20 241:1,5,16                  242:8,16 254:2 273:9</p>
---	---	--	--	--

<p>281:20 290:20 300:17 306:14 317:14 <b>seen</b> 234:11 318:15 <b>select</b> 122:15 123:14 160:8 269:22 <b>selection</b> 58:10 268:12 <b>self-assemble</b> 167:15 266:2 289:14 <b>self-assembling</b> 166:20 <b>self-assembly</b> 290:12 <b>self-associate</b> 288:19 313:4 <b>semi-polar</b> 9:16 294:7 <b>semi-solid</b> 86:15 <b>Senju</b> 1:3 15:12 16:10 16:13 <b>sense</b> 153:22 154:9,15 154:16 155:4 <b>sensitive</b> 15:4 256:13 <b>sentence</b> 74:3 81:8 89:2 119:2 125:4 126:14 138:8 141:17,19 152:12,21,22 153:12 155:14 179:12 183:9 187:1 189:18 190:6 190:15 193:8 195:22 206:11 208:15 209:17 210:21,22 217:9 225:8 226:12 227:2 228:16 229:3 230:6 230:16 231:1 240:18 242:10 250:10,15,22 251:7,13 252:22 253:17,20 260:7 265:22 266:9,17 268:13 269:5,11 271:4 272:15 273:7 273:16 274:3 275:4,7 277:1,6,7 278:10 280:6 281:12 283:19 286:4 288:17 293:5 298:7 302:14 304:19 309:5 313:3 <b>sentences</b> 118:15 119:11 172:15 178:19 216:10 218:18 299:15 <b>separate</b> 198:11 201:5 201:6,8,9 <b>separately</b> 233:13 <b>September</b> 1:17 2:5 15:22 80:17 81:1 136:12,18 204:21 205:6 254:19 255:3 318:17 <b>sequester</b> 173:8 <b>sequestering</b> 174:3 180:20 190:10</p>	<p><b>Sequestrene</b> 185:18,22 186:2 194:17 199:10 199:13,17,21,22 200:5,9,11,12 201:16 201:19 202:1,2,7 <b>series</b> 17:15 77:14,15 281:15 <b>serve</b> 53:10 <b>services</b> 57:7 <b>set</b> 65:12,13 212:16 231:15 249:21 250:1 254:9 315:10 <b>SGA</b> 187:21 <b>shape</b> 123:13,19 <b>shelf-life</b> 43:19 141:6 <b>shipment</b> 214:5 <b>shoot</b> 317:15 <b>shorter</b> 218:22 <b>Shorthand</b> 2:6 <b>show</b> 282:10 <b>showed</b> 73:15 255:22 <b>shown</b> 118:20 119:5 240:20 302:16 <b>side</b> 60:12 <b>side-by-side</b> 201:11 <b>sight</b> 270:11 <b>signature</b> 18:19 <b>significance</b> 137:12,21 <b>significant</b> 142:3 153:3 153:6 255:22 277:9 <b>significantly</b> 293:10,17 294:14 <b>similar</b> 97:1 184:9 185:10 229:13,17 250:10 <b>similarities</b> 293:16 294:9,13 <b>similarity</b> 282:18 294:5 <b>similarly</b> 302:4 <b>simple</b> 132:22 139:10 156:9 219:1 258:9 277:3 <b>simpler</b> 120:21 184:13 <b>simply</b> 154:7 260:9,14 261:7 <b>simulations</b> 14:10 261:16 <b>simultaneously</b> 233:14 <b>single</b> 34:14 79:16 <b>site</b> 159:1 <b>sites</b> 258:11,15 259:1 <b>sitting</b> 29:11 106:2 270:22 315:17 <b>situation</b> 247:22 <b>six</b> 55:5,9,16 243:11 <b>size</b> 42:14 122:13 169:9 171:8 241:4 281:18</p>	<p><b>sizes</b> 241:13 <b>skill</b> 36:19 79:22 84:10 84:22 85:9 86:21 87:10,18 88:14 94:22 97:21 98:16 99:5,14 99:19 100:10,19 101:6,10,15 102:1,8 106:14 107:7,15,21 108:14 109:17 110:15 111:11,20 112:9 120:8 121:2,17 122:8 122:14 123:14 125:16 126:2 133:3 137:5 138:9,16 141:21 142:4 143:4,8,17,22 144:5 145:6,13,20 146:5,12 151:17,21 152:8 154:17,19 159:5,13 160:10 161:18 162:17 163:17 187:2,12 188:9,16 189:2 209:20 210:6 210:14 218:9 220:5 220:20 243:5 246:21 247:4,17 248:2 <b>skilled</b> 84:18 88:5 99:2 109:10 112:3 138:4 142:9 147:3 153:16 154:1,16 155:6,9 210:20 249:8,14 <b>skills</b> 145:4 <b>Skip</b> 96:16 <b>skipped</b> 265:3 <b>slight</b> 243:15 <b>slightly</b> 92:21 97:2 157:18 311:7 <b>small</b> 140:14 200:3 213:7 296:7,22 302:16 303:7 <b>smaller</b> 123:2 <b>Society</b> 10:13 21:17 22:13 45:6 56:18 188:8 <b>sodium</b> 6:5 33:7 45:20 45:20 89:12,12 102:15,19 103:2,5,10 103:14,16,17 104:1,7 104:18 105:4,5,12 113:14 118:18 119:3 157:1 172:18 173:14 173:15 175:20,21 176:7,7,11 177:6,16 177:16,20,20 178:11 178:12 179:1,2,2,3,4 179:9,10,15,15 180:13,16 181:5,13 182:2,14 184:4,14</p>	<p>185:4,13,22 191:10 191:10,14 194:8,10 194:17,21 196:19 197:4 198:1 200:4,8 200:10,11 201:15 207:4 208:1 217:10 217:11,11,12,16 218:1 227:4 287:12 <b>Soft</b> 7:15 <b>sole</b> 71:16 <b>solubilities</b> 157:4 <b>solubility</b> 44:1,7 156:19 156:21 158:10 159:22 160:9 166:7 168:11 170:1 272:19 273:20 275:16 276:1,9 283:21 284:2,11 286:6 306:9,10 307:2 307:19 308:5 <b>solubility/permeability</b> 275:9 <b>solubilization</b> 9:15 13:4 82:15 83:7 255:17,21 256:6 280:10 281:19 300:9 302:17,21 303:14 <b>solubilize</b> 31:14,15 81:21 83:14 170:1 286:3 299:17 <b>solubilizing</b> 168:7 280:12 282:2,13 307:5,14,22 <b>soluble</b> 157:2 158:10 158:11 286:12 287:1 299:17 <b>solution</b> 9:6 12:11 33:10,16 34:16 44:9 140:10 162:5 166:20 174:4,8 190:9 298:11 <b>solutions</b> 62:14 138:14 291:10 <b>solvent</b> 266:2,13,21 272:8 <b>solvents</b> 160:8 <b>somebody</b> 36:18 38:7 84:18 88:4 94:20,21 101:3 104:9 109:10 110:20 112:2 143:14 145:3,4 154:14 158:7 163:17 184:9 187:20 210:20 262:5 <b>somebody's</b> 270:11 <b>sophisticated</b> 139:11 258:10,14,20,22 259:5 <b>sophistication</b> 138:12 138:20 139:6,8 149:9</p>	<p><b>sorbitan</b> 128:18 263:10 263:18 <b>sorry</b> 21:15 23:1,3,7 33:13 34:21 35:9 56:15 60:17 72:18 74:4 75:3 78:19 101:13,13 104:7 105:17 106:4 115:2 115:14,21 116:12,15 116:18 117:8,13 118:14 119:13 121:8 122:3 125:22 131:17 132:9 133:13 134:3,5 134:7 146:10 148:12 152:3 161:2 165:7,8 165:17 170:19,19,21 174:14,22 175:1 177:4 182:11 183:13 191:13 193:4,13 195:18 196:15 199:19 200:2 216:16 219:9 221:1 223:7 230:6 238:15 241:12 245:10 246:4,9 247:1 264:18 276:16 278:16,17 290:18,21 303:6 306:15 308:8 315:4 317:5 <b>sort</b> 95:22 157:10 160:20 166:7 168:1 <b>sounds</b> 133:1 <b>sources</b> 247:21 <b>South</b> 4:5 <b>space</b> 185:9 <b>span</b> 212:12 <b>Spanish</b> 287:7 <b>spanning</b> 183:9,13 231:10 <b>spans</b> 183:2,15 196:15 211:1 246:8 <b>spasmodic</b> 243:16 <b>speaking</b> 71:7 <b>special</b> 312:16 <b>specialist</b> 16:4 <b>species</b> 309:9,14,21 310:10,19 <b>specific</b> 86:20 93:6 100:6 102:5 105:9 148:14 157:19 177:21 182:2 227:5 258:11 258:15 259:1 <b>specifically</b> 23:11 61:12 132:2 151:3 235:5 261:1 296:15 317:8 <b>specification</b> 96:22 97:3,7 101:7 104:21 105:3,14,18 111:1</p>
--	--	---	--	--

<p>112:8,16 119:15 121:8 124:13 125:9 125:15 126:1 127:5 135:1 137:7 147:6 151:12,19 153:15 175:19 177:14 186:10 204:2 226:12,18 245:7,22 246:16,20 247:3,13,18 248:3,11 248:14,18 249:7 <b>specifications</b> 135:15 136:2 211:4,7 224:7 224:17 225:3 247:11 <b>specified</b> 99:15 221:12 223:12 224:2,21 <b>specifying</b> 225:4 <b>spectroscopic</b> 42:14 <b>speculate</b> 159:17 <b>speculation</b> 84:14 87:5 98:20 126:7 146:7,14 158:5 159:9,16 160:14 244:10 270:2 294:21 296:12 305:3 307:17 308:3 310:22 <b>speed</b> 138:14 <b>spell</b> 28:14 <b>spent</b> 55:16,19 <b>spherical</b> 266:3 <b>spoke</b> 141:2 <b>spontaneously</b> 266:2 <b>spot</b> 198:21 <b>squeeze</b> 120:4 <b>stable</b> 62:7 <b>stability</b> 11:14 39:10,16 39:19 40:6,14,21 41:2 41:4,8,12,17 42:10,14 42:18,19 43:22 44:9 44:10 68:7 87:11,20 88:7,8,15 89:19,20,20 108:6 110:7,9 111:3,5 112:5,20 113:12 114:5,6,8 116:7,8,9 116:21 117:4,5,12,16 118:2,22 120:14,15 120:17 130:5,8,17,22 140:16 141:2,3,6,7,7 163:10,11 166:6 190:16 209:22 210:2 210:7,15,19 211:10 211:12,17,18 213:12 213:15,20,21 214:10 214:14,19,20,22 215:1,2,5,6,8,20 216:18,21 219:14,19 220:6,21 221:6 222:14 223:4,20 225:4,12,12,13,15,16</p>	<p>225:19 226:2,6 227:3 227:6 230:12 235:19 235:22 241:3 272:6 <b>stabilize</b> 127:9 212:18 212:22 231:18 237:12 238:18,22 <b>stabilized</b> 46:5 <b>stabilizes</b> 31:17,18 <b>stabilizing</b> 80:3,4 216:13,17,20 235:15 <b>stable</b> 43:3,16 46:5 62:3 65:3 67:22 68:6 69:10 86:1,6,22 89:16 89:22 113:15,22 114:12,21 115:10,16 116:4 124:17 125:18 126:4,17 189:21 212:17,21 221:3,13 222:1,12,20 223:13 224:3,22 226:14 228:19 229:6 230:18 231:4,17 232:4 233:6 233:18 234:1,16 235:10 236:3,10 237:2 239:12 240:21 241:9 <b>stage</b> 269:15 <b>stand</b> 61:20 <b>standard</b> 42:11 61:9 74:14 109:5,8 120:13 120:14,15 139:12 153:21 154:8 155:3 189:1 242:4 244:2,7 244:18 245:1,6,21 246:14 247:6 249:9 250:3 251:3 <b>standardized</b> 215:10 215:17 <b>standards</b> 38:21 39:7 242:13,13,15 244:15 250:11,12,16,16 251:1,9,16 <b>stands</b> 29:15 <b>staple</b> 129:14 <b>start</b> 111:2 160:8 204:18 241:12 272:10 <b>started</b> 58:13 276:8 <b>starting</b> 107:13 150:16 <b>starts</b> 125:4 128:6 183:16 195:22 208:16 209:18 273:8 <b>state</b> 17:7 43:13 52:6 75:12 76:9 86:7,8 92:6 119:16 124:14 125:10 126:15 127:6 147:2 148:17 149:4 149:11,13,14,15</p>	<p>150:6,15 162:10 191:9 193:11,16 203:11 213:19 219:13 221:2,7,10,22 222:11 222:13,19 223:10,22 224:9,19 226:13 227:10 229:12,16 253:7 260:13 261:6 268:13,19 269:5,11 271:4 297:9 298:8 302:14 <b>stated</b> 178:22 196:5 294:3 301:13,21 <b>statement</b> 88:4 126:20 127:17,20 128:2 129:18,22 130:4,6,7 130:10,16,19,21 131:2,6,8 139:19 179:3 181:22 190:2 190:11,18 203:14 226:21 227:7,18 229:1,9 230:3,13,21 231:6 250:13,20 251:5,11,19 256:9 263:14 266:6,15 267:1 268:7,15 269:1 269:9,16 270:5 272:22 273:14,21 274:4,7,8,13,16 275:12 277:12,15 278:7,14 280:13 282:4,9,11 285:22 286:8,16 288:22 293:12,21 296:14 298:13 305:1,8 306:12 310:6 313:9 <b>statements</b> 147:7 172:20 275:2,4 277:19 314:19 <b>states</b> 1:1 15:15 51:9,11 181:6 194:10,21 218:19 226:12 227:2 228:18 229:4 230:7,7 232:12 238:17 242:11 253:21 263:8 280:7 293:5 319:3 <b>statistics</b> 37:10,14,16 <b>stay</b> 140:20 <b>stearate</b> 227:15 229:22 230:2 <b>stearate-containing</b> 113:17 228:21 <b>stems</b> 313:5 <b>sterilize</b> 121:12 <b>steroid</b> 156:9 165:7,8 <b>steroids</b> 165:6 168:14 <b>stop</b> 291:9</p>	<p><b>storage</b> 114:15 214:5 230:10 235:5,18 <b>story</b> 59:15 83:5,5 275:1 <b>STP</b> 11:15 <b>straight</b> 79:16 <b>straightforward</b> 109:2 109:5,7 199:18 <b>strange</b> 66:14 <b>Street</b> 4:5 16:5 <b>stress</b> 312:13 <b>strict</b> 102:19 103:14 268:3 <b>strike</b> 104:16 117:9 119:13 148:15 161:2 176:14 186:5 202:4 203:19 221:8 247:2 <b>string</b> 42:3 <b>struck</b> 273:12 <b>structural</b> 7:4 9:12 14:11 159:2 280:8 293:7,15 294:9,12 296:7 297:1 302:19 303:13 <b>structurally</b> 77:14 <b>structure</b> 75:22 76:2 77:4,10,21 78:8,12 79:5,20 82:11 156:18 158:3,15 170:7,11,13 171:5,21,22 172:8 183:10,22 260:10,11 260:15,16 261:2,8,9 282:19 289:7 290:4 303:3 <b>structures</b> 10:5 80:2 157:18,21 184:9 185:11 266:3,11,18 282:1,13 288:20 290:7,10 291:2 294:3 309:6,12,19 310:2 <b>struggling</b> 101:1 103:13 105:7 122:2 <b>student</b> 55:14 287:7 <b>students</b> 55:22 60:15 60:22 78:21 89:11,15 89:19,21 <b>studies</b> 8:11 82:13,16 163:4 255:15 271:8 280:8 281:12 <b>study</b> 50:13 293:6 <b>studying</b> 59:3,8 <b>subheading</b> 213:14 <b>subject</b> 44:19 138:10 <b>subjected</b> 118:22 <b>submit</b> 163:5 <b>Subscribed</b> 319:9 <b>subsequently</b> 286:22</p>	<p><b>substances</b> 191:1,6 <b>substantially</b> 124:21 226:16 <b>subtle</b> 184:11 <b>sub-classes</b> 157:16 <b>successful</b> 161:10 273:8 273:11,17 274:10,15 <b>successfully</b> 272:16 <b>sucrose</b> 296:15 <b>sufficient</b> 43:19 132:4 132:19 133:6 212:18 212:22 230:12 231:17 <b>sufficiently</b> 260:9,14 261:7,20 <b>sugar</b> 296:18,19 301:14 <b>suggest</b> 122:17 123:3 171:9 243:4 <b>suggests</b> 179:3 <b>suitable</b> 110:4 111:17 112:6 187:19 264:5 <b>sulfite</b> 217:11,16 218:2 <b>summarize</b> 271:17 <b>summarized</b> 271:1 <b>summer</b> 55:15 <b>Super</b> 262:6 <b>supplement</b> 312:17 <b>support</b> 130:22 143:3 231:4,22 <b>supported</b> 314:16 <b>supporting</b> 130:8 <b>supposed</b> 100:8 <b>sure</b> 19:19 34:5 59:7 81:16 105:18 115:15 126:1 141:11,15 149:19 154:6 193:15 221:17 236:9 244:21 306:20 317:7 <b>surface</b> 12:9 74:15 82:13 283:22 <b>Surfaces</b> 14:15 <b>surfactant</b> 7:7,19,20 10:11 11:4,15 13:8 31:12 33:11,17 34:2 34:17 35:11 36:4,9,13 36:15 59:21 60:4 61:10 62:14 72:10,12 72:19 73:12 74:21,22 75:14,14,22 76:3 77:8 77:10,19,20 78:6,8 79:2,4 83:18 84:11 85:2,7,11,22 86:12 87:13,22 88:7,9,17 151:7 155:20 166:13 166:17 167:6 170:7 171:4 227:13 229:14 229:19 260:10,15,17 261:8,10 266:18,20</p>
---	--	---	---	---

<p>286:3,7 288:18 289:6 290:3 291:18 292:3 296:1,4 298:9 300:11 300:21 301:5,19,20 302:7,12,15,18,20,22 303:10,13,15,20 304:21 310:2 <b>surfactants</b> 9:6,14,16 12:11 13:14 52:11,16 61:1,8 62:16 64:3,6,8 65:16,16 66:8,18,20 67:2,5 68:21 74:8,16 74:18 75:1,11,18 76:21 77:4 80:2 81:10,12 82:1,9,10,20 82:22 84:5,20 86:6 166:11,18 167:3 169:21 255:20,22 256:3,5,6 263:9,17 264:4 265:22 280:9 281:16 282:1,12 286:14 289:13,15 293:6,15 294:12,19 296:8 297:1,6 299:16 299:20 300:2 301:15 306:9,11 307:2,4,10 307:11,14 308:1 309:6,11,18 310:4,7 310:16 311:4,5 313:4 <b>surfactant-based</b> 71:4 <b>Surfactant/Water</b> 265:21 <b>surrounding</b> 21:17,19 <b>suspect</b> 146:16 <b>suspected</b> 218:12 <b>suspension</b> 140:13,14 <b>swear</b> 16:20 <b>sworn</b> 17:1 319:9 <b>syndrome</b> 28:18 <b>synonym</b> 185:22 194:11,22 199:13 202:6 <b>synonymous</b> 44:4,6 179:4,10 182:6,8 <b>synonyms</b> 192:21 193:8 193:11,16 199:7 201:3 <b>synthesis</b> 74:20 <b>synthesize</b> 84:11 85:1 <b>synthesized</b> 74:22 81:13 82:2,21 85:12 <b>Synthetic</b> 7:20 9:5 12:10 <b>syrups</b> 258:9 <b>system</b> 7:9 33:11,17 34:3,17 35:11 36:4,9 36:15 61:15 63:8,19</p>	<p>214:3 261:4 285:21 286:7 309:9,14,21 310:10,20 <b>systems</b> 8:10 10:11 11:4 14:19 50:14 58:21 59:3,8,17 62:17 65:10,17 163:15 217:10,17 218:1 256:20 258:10,14,22 286:3 291:18 292:3 <b>S-O-L-U-B-I-L-I-S-E</b> 31:15</p> <hr/> <p style="text-align: center;"><b>T</b></p> <p><b>T</b> 5:6 6:1 7:1 8:1 9:1 10:1 11:1 12:1 13:1 14:1 <b>tab</b> 193:7 <b>Table</b> 113:8,9,12 116:1 118:20 119:2,5 214:13 215:19 240:18 240:22 241:3 291:14 292:1 <b>Tables</b> 118:16 <b>tablet</b> 233:12 <b>tablets</b> 233:13 258:9 <b>tabs</b> 192:6 <b>take</b> 17:20 19:4 22:16 54:18 55:5 58:5 62:18 63:13,22 65:19 66:6 68:9 69:15 73:22 80:11 81:7 88:21 90:3 96:15 97:14 102:11 103:6 106:20 108:2,4,7 110:11 116:1,19 118:15 123:20 125:2 126:9 127:1 128:5,21 131:9 132:10 133:22 138:6 141:17 142:12 142:19 146:22 147:22 152:20 153:11 155:11 166:9 171:16 172:11 175:14 177:2 178:16 179:11,20 185:12 186:16 189:8,14 190:21,22 191:22 192:12 195:3,19 196:6 198:22 200:15 201:7 202:9,18 206:20 207:16 208:15 209:8 213:4 214:11 216:8 217:6 218:15 219:10 223:7 225:6 226:9 227:1,9 228:15 229:11 230:5,15 234:13 236:2,15</p>	<p>239:19 240:14 245:12 245:16 249:19 250:8 252:5,18,21 253:17 254:4,5 260:5,10,14 261:7,19 263:6 271:2 272:11 273:6,16 276:21 277:14,21 280:6 281:11 283:16 288:15 291:13,13 292:1 293:3 295:19 298:7 299:12 300:6 302:13 308:8 309:4 310:3 313:1 <b>taken</b> 2:2 15:18 68:17 234:8 274:1 275:2 <b>takes</b> 235:2 236:16 258:5 <b>talk</b> 130:4 145:2 149:21 150:2 152:13 157:16 316:8 317:16 <b>talked</b> 166:10 222:16 242:18 <b>talking</b> 21:11 35:7 71:14 78:3 83:10 170:12 181:11,14,16 181:19 182:11,13 187:15 199:16 258:18 261:1 275:1 296:15 296:18 311:2,4 <b>tape</b> 80:15,18 81:2 136:8,13,19 204:22 205:6 254:16,20 255:4 316:10 318:18 <b>taught</b> 89:11,15,21 106:18 <b>teach</b> 89:8,10 113:22 114:21 115:9,16 116:4 219:18 253:3 256:4 <b>teacher</b> 24:21 <b>teaches</b> 116:22 185:3 221:1 <b>teaching</b> 89:5 101:18 185:7 <b>teachings</b> 101:9,14,22 102:7 106:13 107:6 107:12,14,20 108:13 109:8,16 111:19 220:4,19 <b>team</b> 267:20 278:18 279:4 <b>technique</b> 241:11 <b>techniques</b> 42:13 74:14 86:19 <b>technologies</b> 275:9,15 <b>technology</b> 8:13 138:12 138:20 139:6,8</p>	<p>149:10 <b>Telephone</b> 3:9,20 4:8 <b>telephones</b> 15:6 <b>tell</b> 17:13 22:3 34:19 83:5 116:13,19 218:5 219:11 239:10 245:16 291:15 <b>telling</b> 103:4 105:12 220:3 223:17 <b>tells</b> 223:1 <b>temperature</b> 50:2 76:11,19 219:3,4,6,15 256:20 257:2 272:3 306:10 307:12,13,20 308:7 309:8,13,20 310:9,18 <b>temperatures</b> 216:5 218:21 219:20,20 220:7,8,22,22 307:6 <b>ten</b> 58:16 59:20 60:3 <b>tend</b> 215:13 <b>tenfold</b> 256:1 <b>tension</b> 74:15 82:14 <b>term</b> 34:9,10,10 46:4,5 74:17 75:4 89:15,22 96:2,8 153:13 176:1 178:4,6,10,11,13,15 199:20 201:16 206:15 207:13 208:19 212:17 212:21 216:17,20 221:3,3,22 222:1,4,7 222:11,12,17,19 231:16 232:4 234:1 234:16 236:4,10,10 237:2,3,12 238:22 239:11 <b>terms</b> 20:5,6 90:6 92:8 92:13 93:2,10,20 94:9 94:13 134:20 137:7 150:19 155:1 175:20 176:14 179:6 245:3 <b>test</b> 38:13,16 50:3 108:5,18 109:2,5,6,8 110:2,3,5,8 111:2 113:12 118:22 120:15 120:16,17 133:11 227:4,20 249:20 250:1 253:9,22 294:18 <b>tested</b> 227:11 230:11 250:18 251:9 291:11 <b>testified</b> 17:2 69:17,21 70:2 142:16 249:7 <b>testify</b> 18:4 <b>testimony</b> 47:7,10 123:7 200:17,20 248:21 249:13 261:12</p>	<p>319:3 <b>testing</b> 36:17,20 37:4,7 39:10,19 40:6,14,21 41:2,4,8,12,17 214:19 215:2,7,20 219:14,19 220:6,21 251:18 253:4 268:19 <b>tests</b> 38:9 39:16 41:5,13 41:21 42:1,5,6,8,9,16 68:7 80:9 86:10 110:7,9 111:17 112:5 112:20,21 120:14,14 133:14,21 228:9 <b>tetraborate</b> 179:1 <b>tetrasodium</b> 89:13 102:16 103:3,11 104:2,19 105:5,15,16 105:21,21 172:19 173:20 174:1,12,16 175:5 176:8,8,16,17 176:20,21 177:7,8,17 177:17 178:5,7,10,14 179:16 182:16,21 186:3 190:3,12,19 191:5 196:3,9,15,19 197:2,14,19 203:15 <b>text</b> 58:12 <b>thank</b> 16:19 19:21 32:14 106:22 115:7 157:20 195:15 267:18 312:3 318:13,14 <b>theory</b> 173:5,5 216:1 <b>therapeutic</b> 224:6,16 <b>thereof</b> 124:17,17 129:11 <b>thermodynamic</b> 289:19 <b>thermodynamics</b> 258:6 <b>thing</b> 59:12 61:21 82:6 166:8 181:13 184:3 265:3 317:18 <b>things</b> 49:21 83:11 121:13 156:7 173:8 184:19 211:9 266:8 <b>think</b> 21:9 22:14,22 24:15 54:12 56:15 62:14 76:14,18 82:11 100:1 112:2 116:20 116:21 117:7 127:18 128:3 134:3 139:1,4 141:16 151:20 161:1 163:14,20 174:7,8,9 178:7 181:18 184:7,7 185:7,8,9 187:15 188:3,3,21 200:18 201:1 207:15 223:20 236:14 246:5 254:16</p>
--	---	--	---	---

<p>260:20 261:14 272:4 272:10 275:2 282:8 290:16,17 293:20 294:2 301:9 311:7 312:15 317:4 <b>thiosulfate</b> 217:12 <b>third</b> 187:14,15 193:8 263:7 273:7 <b>Thomas</b> 4:15 16:3 <b>thoroughly</b> 285:21 <b>thought</b> 112:13 115:20 121:7 137:16,18 143:11 147:15 314:10 <b>three</b> 60:21 136:19 205:1 218:18 253:15 301:1 <b>three-dimensional</b> 260:16 261:9 <b>threshold</b> 221:8,11 223:11 224:1,20 <b>time</b> 15:21 17:12 32:12 38:14 41:19 42:12 55:19 56:3,12 73:13 80:14,16,22 103:21 116:19 132:10 136:9 136:10,11,17 137:5 139:3 148:3 150:16 151:4,9 162:8 177:2 198:21 204:9,10,14 204:20 205:5 214:5 219:1,10 234:13 236:18 240:21 254:18 255:2,14 260:21 261:18 267:13 276:12 286:15 287:9,14,15 287:18 305:5 314:14 314:18 316:14,18 318:16 <b>times</b> 3:16 15:19 17:11 138:9 243:11 250:18 <b>time-consuming</b> 262:1 <b>title</b> 213:14 241:3 <b>today</b> 15:11,22 16:1 17:15 18:5 29:11 106:2 166:11 235:9 242:18 243:13 247:12 258:20 270:22 313:15 315:14,22 <b>today's</b> 17:13 314:8 <b>told</b> 40:5,8,13 42:4 89:18 100:5 273:4 <b>top</b> 141:18,20 153:1 183:3,19 194:4,16 195:21 197:11 276:21 <b>total</b> 55:2 73:18 <b>totally</b> 111:4 225:21,22 <b>touch</b> 148:10,12</p>	<p><b>toxic</b> 43:9 <b>toxicity</b> 269:12,20 270:10,17 <b>toxicological</b> 13:13 164:17 165:2,11 224:6,17 278:12 <b>toxicology</b> 164:22 <b>traditional</b> 289:17 <b>transcript</b> 317:1 319:1 319:2 <b>transferred</b> 303:9 <b>translates</b> 274:21 <b>treat</b> 197:4 198:1 <b>treated</b> 27:18 <b>treating</b> 49:3 155:20 <b>treatment</b> 277:3 <b>trial</b> 37:1,2,3 47:7 <b>trials</b> 268:2 <b>tried</b> 71:19 314:4 <b>triglycerides</b> 65:15,15 <b>trisodium</b> 172:19 197:8 <b>trivial</b> 260:20 <b>true</b> 172:20 226:21 227:7,18 229:1,9 230:3,13,21 231:6 250:13,20 251:5,11 251:19 263:14,16 264:6 266:6,15 267:1 268:7,15 269:1,9,16 272:22 273:14,21 274:4,13 275:12,14 276:5 277:12,19 278:7,14 280:13 285:22 286:8,21,22 288:22 293:12 298:13 305:1,8 306:12 309:11,18 310:6,7,15 313:9 <b>truthfully</b> 17:16 18:5 <b>try</b> 24:7 68:5 102:11 104:16 106:19 117:9 119:14 161:3,9 175:3 176:15 186:6 195:11 202:4 203:19 221:9 247:2,21 249:22 <b>trying</b> 35:20 84:5 139:19 149:20 174:7 174:9 185:1 286:5 <b>turn</b> 15:6 18:19 81:6 94:21 97:9 98:5 106:7,7,18 107:11 112:22 114:4 137:1 180:5,10 193:22 203:5 205:12 206:9 206:19 212:5 233:4 238:11 255:10 258:1 265:19 268:11 285:16</p>	<p>304:18 306:6 <b>Tween</b> 263:11,12,20,20 <b>Tweens</b> 263:11,19 <b>twice</b> 122:22 <b>two</b> 22:14,17 45:10 49:18,22 50:1,2,14 60:21 68:13,15,20 70:16,16,18 80:1 81:2 81:20 87:11,20 88:15 122:21 136:13 141:5 156:19 166:21 172:15 173:9 177:10 178:19 183:9,13,15 187:19 198:11,17 202:17 216:10 294:5 299:15 315:17,18 <b>tyloxapol</b> 28:10 29:1,4 29:7,12 30:10,20,22 31:4 32:18 33:10,16 33:21 34:3,16,20 35:1 35:11,22 47:17,20 53:3 61:4,7,9,12,15 61:16 64:11 67:10 69:2 126:17 128:14 128:18 129:12 155:19 166:11,12,16 167:6,8 167:12 168:4,8,12,19 169:2,5,13 170:5,15 171:2,7,11,12,14 227:16,17 229:6,8,15 229:20,20,21 289:3 289:22 <b>tyloxapol-containing</b> 113:16 228:19 <b>type</b> 61:21 73:17 87:8 87:13,22 88:9 120:1,5 127:8 128:15 129:12 140:17 163:11 211:14 213:7 219:2 227:12 259:7 285:20 301:19 302:12 303:5,6 <b>types</b> 31:2 44:10 119:21 138:13 139:14 139:20 140:4 141:6 225:13,15 <b>typical</b> 151:9 <b>typically</b> 82:12 173:7 198:14 <b>typographic</b> 198:15 243:12 <b>typographical</b> 198:6,8 198:12 200:21 202:10 202:13 242:18 243:1 243:6</p>	<p><b>UK</b> 17:10 27:10 28:1,4 47:6,12 61:14,16,21 69:22 <b>ultimate</b> 41:6 86:12 268:4 <b>Um</b> 199:5 <b>Um-mm</b> 60:20 118:17 179:7 185:17 191:2 199:3 <b>unambiguously</b> 170:3 <b>uncertain</b> 40:2 <b>unchanged</b> 44:12 <b>unclear</b> 38:5 39:3 78:1 222:12 <b>undergoing</b> 216:13 <b>understand</b> 17:21 69:14 70:8,9,12 85:17 90:16,22 91:6,12,19 92:1 93:15 95:22 97:19 98:14 99:14 101:2 104:8,11 118:9 118:11,14 120:9 121:3 122:8 124:7 137:3 138:4,10 147:2 147:7 150:11 152:17 153:1,12 154:22 155:1 180:7 189:12 192:10 195:17 203:2 212:8 220:6,20 222:3 232:17 238:3 239:7 247:21 252:8 271:20 289:9 293:20 <b>understanding</b> 21:1,6 22:5 34:7 37:14 39:15 44:18,20 45:4 48:7,11,15 79:12 84:8 96:3,5,20 97:5 99:4 103:19 104:7 114:2 137:11,15,17,20 138:6,19 139:1,5,7 144:18 147:12,17,22 148:3,5,17 149:4,11 149:15 150:6,13 153:5 156:10,14,20 163:10,14,21 164:5 164:10,16 165:1,10 165:21 166:5 169:1 169:20 210:6,14 260:8 303:4 <b>understood</b> 18:1 147:3 285:21 299:22 <b>undertaken</b> 30:15 <b>Undoubtedly</b> 29:2,21 <b>unfamiliar</b> 86:11 <b>unfortunate</b> 198:16 <b>unfortunately</b> 198:20 200:22 202:16 299:19</p>	<p><b>unit</b> 295:22 301:12 <b>United</b> 1:1 15:15 51:9 51:11 232:12 <b>unpredictable</b> 307:15 308:1 <b>unrelated</b> 297:7 <b>unstable</b> 42:21 69:13 218:13 225:21 <b>unsure</b> 84:18 <b>unusual</b> 165:7 261:5 <b>upheld</b> 73:9 <b>upper</b> 169:10 <b>usage</b> 214:6 309:5 <b>use</b> 8:16 10:12 23:13 31:1,4 32:9,15,18 34:11 41:7 43:16,18 44:12,12 50:2 58:22 59:21 61:4,10,12,14 61:19 62:16 64:11,18 67:10,15 68:4 69:2,6 73:5,19 74:3,7,17 82:18 83:14 85:16,19 85:22 86:1,12,18 87:1 96:8 100:11,14,16,16 100:20 101:10,15 106:19 107:12,15,22 108:18 109:17 110:1 110:4 111:12,15,18 111:20 112:7 120:4,9 121:3,19 122:3,3,4,6 141:9 170:10 178:4,6 178:10,11,13,15 180:15,20 206:15 207:13 208:19 215:16 216:7,7,11 218:9 221:5 234:1,16 238:22 241:14 268:4 269:21 270:14,14 286:5 296:6 299:21 300:3 <b>useful</b> 95:10 314:10 <b>uses</b> 84:6 199:20,22 201:15,19 <b>USP</b> 242:13 250:10,15 251:3,8,14 <b>usual</b> 255:18 <b>usually</b> 180:21 181:6 181:22 218:22 <b>U.S</b> 6:16,17 37:18 38:1 38:10,17 45:13,14,15 90:6,11,15,18,21 91:2 91:5,8,11,14,18 111:6 145:8 178:21 232:16 237:18 238:1 242:12 243:5 253:9,13</p>
<b>U</b>				
<p><b>uh</b> 111:6</p>				
<b>V</b>				



<p><b>vacations</b> 55:15  <b>Vadas</b> 212:7 213:2,4,11                  213:19 214:12,18                  215:1,6,19 216:9                  217:15 218:16 219:13                  219:18 220:4,19                  221:2,7,10,22 222:11                  222:19 223:10,22                  224:9,18,19  <b>vague</b> 19:13 20:11,19                  21:8,22 22:8 24:2                  26:1,10,14,21 27:2,8                  30:6,21 31:6 33:3,12                  33:18,19 34:18 35:12                  36:5,10 37:1,12,20                  38:4,22 39:9,13,21                  41:10 44:3,14 45:1,22                  46:8,12,20 50:7 52:5                  52:20 53:16 54:3,11                  57:11,12,17 58:18                  59:5 61:6 62:4 64:4,5                  64:13,20 65:5,6 67:3                  67:17 68:2 71:1,8,12                  72:6 73:2 75:20 77:1                  77:11,12,22 78:1,9                  79:6,11 80:6 82:3                  83:2,21 84:3 85:6,6                  85:14 86:4 87:4,15                  88:1,19 92:14 93:12                  93:21 94:11 95:3,14                  96:11 97:18 98:2,3,12                  98:19 99:17 100:13                  100:22 102:17 103:12                  104:3 105:6 106:16                  107:10,18 109:3,20                  110:18 111:14 112:1                  112:12 115:1,12,18                  115:21 116:11,20                  117:7 118:8 120:12                  120:20 121:6,22                  125:20 126:6 129:20                  132:7,21 133:7,17                  134:16 135:4,11,20                  138:1 139:16 140:6                  144:11,16 146:6,13                  147:20 148:13,20                  149:7,18 150:14                  151:1 154:3,10,20                  156:12,13 157:13                  158:4,6 159:8,15                  161:7,8,22 164:1,2,8                  164:13,18 165:4                  166:1,4 167:11,17                  168:21 169:15 170:8                  171:6 174:13,17,18                  174:20 175:6 176:9                  177:18 178:1 179:17</p>	<p>182:4 184:17 188:20                  189:7 191:12 197:6                  198:3 209:1 210:17                  211:13 215:9,22                  217:3 218:11 221:4                  221:15 222:2 223:15                  224:11 227:22 228:5                  228:11 235:12 237:4                  243:9 244:9 245:9                  246:2,17 247:8 250:5                  252:1 256:7 258:17                  259:3 261:11 268:8                  269:2,18 270:1                  271:12 273:1,22                  274:5 275:18 276:6                  278:8 282:3,7,14,15                  284:4,13 286:1,9,10                  289:8,12 290:5                  291:20 292:5 293:18                  294:15,20 296:11                  297:4 300:4 301:7                  302:10 303:1 305:2                  306:13 307:16 308:2                  308:4 309:15,22                  310:1,12,21 313:10  <b>vaguely</b> 159:18  <b>vagueness</b> 80:8  <b>valid</b> 73:1,12  <b>value</b> 241:8  <b>values</b> 113:10  <b>vaporization</b> 113:11                  117:19,22  <b>variation</b> 280:8  <b>variations</b> 9:13 227:12  <b>varied</b> 87:14,22 88:18                  262:5  <b>variety</b> 31:2 32:7 42:13                  110:21 160:20 168:16                  266:3 270:7 288:19                  291:18 292:2 313:4  <b>various</b> 59:3,8 171:13                  184:12 214:18 278:18                  313:6 314:15  <b>vary</b> 77:5,6 82:9  <b>vast</b> 66:17  <b>Vecchio</b> 4:15 16:3  <b>Vehicles</b> 8:6 11:6 12:5  <b>versa</b> 266:14  <b>Versene</b> 185:15  <b>versus</b> 15:13 46:10,10  <b>vesicle</b> 241:4  <b>vesicles</b> 7:19,21 11:5,15                  81:20 168:19 240:20                  241:8 260:12,21                  293:8  <b>Vesicular</b> 7:5  <b>vice</b> 266:14</p>	<p><b>Vicks</b> 55:16,17  <b>video</b> 15:8 16:4  <b>Videographer</b> 4:15                  15:2 16:19 80:16,22                  136:11,17 204:20                  205:4 254:18 255:2                  316:9,14,18 318:16  <b>videotaped</b> 2:1 80:19                  81:3 136:14,20 205:1                  205:7 254:21 255:5                  318:19  <b>view</b> 84:2 137:7 148:5                  163:2,8  <b>viewed</b> 312:15  <b>viscometric</b> 86:19  <b>viscosity</b> 74:15 82:14                  86:18 169:9  <b>viscous</b> 140:20,21  <b>vita</b> 19:6 8 23:6 54:18                  58:9 63:4 65:20 66:3                  66:22 68:10,12 89:3                  205:21 206:4 240:6                  240:12 257:21 259:14                  260:1 262:14 263:2                  265:14 279:15 280:4                  280:22 281:9 283:5                  283:14 285:2,14                  288:4,13 292:14                  293:1 295:8,17                  297:18 298:5 299:8                  304:7,16 305:17                  306:4 309:2 311:16                  312:12  <b>vitro</b> 235:16 274:21  <b>volume</b> 6:14 12:13                  208:7 229:6,7  <b>vs</b> 1:8</p> <p style="text-align: center;"><b>W</b></p> <p><b>wait</b> 195:10  <b>waived</b> 318:3,7  <b>want</b> 35:17 42:21 44:11                  59:18 75:3 81:14                  83:5 84:11,19 85:1,8                  85:10,16 86:18 96:16                  97:3 106:8 122:14                  123:1,14,21 152:20                  160:11 162:18 185:13                  187:17 193:6 231:9                  239:14 255:8 256:10                  256:12,19 312:13                  317:17  <b>wanted</b> 85:22 86:1,14                  86:17,22 160:6                  161:15 162:4  <b>wants</b> 160:19  <b>warranted</b> 219:7,16</p>	<p><b>Washington</b> 3:6 16:6  <b>wasn't</b> 130:5 198:7                  243:15 317:7  <b>water</b> 33:11,17 34:17                  34:20,22 35:18,20,21                  36:13,14 75:15 86:6                  86:14 100:7 157:1                  159:11,22 160:1                  165:14 272:19,20                  273:19 286:12 288:18                  288:21 299:17 313:4  <b>water-based</b> 33:11,17                  34:2,6,7,9 35:3,8,18                  36:3  <b>water-soluble</b> 33:1,8                  189:22 276:10 286:6  <b>way</b> 22:10 25:10 33:7                  35:14 43:1,4 57:14                  58:22 66:20 76:8                  83:7 84:1,21 104:20                  106:17 120:16 122:7                  128:4,16,16 162:7                  174:5 182:15 199:21                  201:20 233:14 234:11                  286:16 290:1 303:2                  310:15  <b>ways</b> 96:5 161:5,9                  174:6 204:11 250:17                  270:17 276:8  <b>weeks</b> 41:22 113:14                  114:16 119:7 230:10  <b>weight</b> 229:5,7 302:18  <b>weighted</b> 220:16  <b>Wellington</b> 17:10  <b>well-established</b>                  289:15 298:8  <b>well-known</b> 31:14                  172:22 173:7 209:20  <b>well-rated</b> 63:18  <b>went</b> 70:1 278:22 279:2  <b>we're</b> 136:7 187:15                  235:9 254:17 258:18                  258:19 265:1,1,2                  286:19 296:17 311:1                  311:4 317:10  <b>we've</b> 84:9 108:20                  110:6 162:11 166:10                  170:9  <b>whispering</b> 15:5  <b>wide</b> 148:7,11 266:2                  288:19 291:17 292:2                  309:5  <b>widely</b> 263:8,17  <b>wider</b> 142:17  <b>widespread</b> 299:21                  300:3  <b>Williams</b> 146:20</p>	<p><b>witness</b> 5:2 16:21 19:22                  20:5,12 21:9 22:9                  26:22 27:3,9 33:4,13                  33:19 34:19 36:6,11                  37:13,21 38:5 39:1,14                  39:22 40:18 41:11                  44:4 45:2 46:1,21                  49:17 50:8 52:6                  53:17 54:4,12 57:12                  57:18 59:6,11 61:7                  62:5 64:5,14,21 65:6                  67:4,18 68:3 71:2,9                  71:13 72:7 73:3                  75:21 77:12 78:1,11                  79:8 80:7 82:5 83:4                  83:22 84:4,17 85:6,15                  86:5 87:6,16 88:2,20                  92:15 93:13,22 94:12                  95:4,15 97:19 98:3,13                  98:21 99:18 100:14                  101:1 102:18 103:13                  105:7 106:17 107:11                  107:19 109:4,22                  110:19 111:15 112:2                  112:13 115:2,13,19                  118:9 120:13 121:7                  122:2 123:18 125:21                  126:8 127:15 129:21                  132:9,22 133:8                  134:20 135:13 138:2                  139:17 140:7 144:12                  144:17 145:16 146:1                  146:8,15 148:21                  149:8,19 150:15                  151:2 154:12,21                  156:13 157:15 158:6                  158:21 159:10,17                  160:15 161:8 162:2                  163:1 164:2,9,14,19                  165:5 166:2,5 167:18                  168:22 169:16 170:9                  171:7 174:14,20                  175:8,11 176:10                  177:19 178:2 179:18                  181:11 182:5 184:18                  188:21 191:13 197:7                  198:4 200:21 209:2                  210:18 211:14 215:10                  216:1 217:4 218:12                  220:1,11 221:5,16                  222:3 223:1,16                  224:12 228:2,6,13                  234:6 235:13 236:7                  236:14 237:6 239:5                  239:14,21 243:10                  245:10 246:3 247:9                  248:14,22 249:6,14</p>
---	--	---	---	--

250:6 252:2,17 256:8	<b>Y</b>	08:11:53 16:1	08:15:02 19:3	08:18:00 21:22
258:18 259:4 260:20	<b>Yamashita</b> 6:12 207:3	08:11:57 16:2	08:15:03 19:4	08:18:02 22:1
264:2,11 271:19	208:5,11	08:12:00 16:3	08:15:13 19:5	08:18:06 22:2
274:1,6 275:21 276:7	<b>yeah</b> 79:15 88:13	08:12:04 16:4	08:15:16 19:6	08:18:09 22:3
276:19 278:9,16	120:22 128:8 150:9	08:12:06 16:5	08:15:18 19:7	08:18:11 22:4
282:4,8,15 284:5,15	159:17 175:2,2,11	08:12:12 16:6	08:15:19 19:8	08:18:13 22:5
285:6 286:2,10 289:9	183:18,21 184:3	08:12:17 16:7	08:15:22 19:9	08:18:17 22:6
289:13 290:6 291:21	204:16 248:7 264:2	08:12:19 16:8	08:15:23 19:10	08:18:20 22:7,8
292:6 293:19 294:16	286:10 307:21 310:13	08:12:20 16:9	08:15:24 19:11	08:18:36 22:9
294:22 297:5 300:5	317:5	08:12:21 16:10,11	08:15:26 19:12	08:18:38 22:10
301:9 302:11 303:2	<b>year</b> 32:22 56:6,19	08:12:25 16:12	08:15:27 19:13	08:18:42 22:11
305:4 306:14 307:18	262:3	08:12:27 16:13	08:15:30 19:14,15	08:18:47 22:12
308:4 309:16 310:1	<b>years</b> 25:19 32:17	08:12:31 16:14,15	08:15:32 19:16	08:18:54 22:13
310:13 311:1 313:11	58:16 59:20 60:3	08:12:33 16:16	08:15:35 19:17	08:18:56 22:14
313:20	69:18 94:17 121:18	08:12:36 16:17	08:15:39 19:18	08:19:01 22:15
<b>Wood</b> 5:15	299:18 318:15	08:12:38 16:18	08:15:40 19:19	08:19:02 22:16
<b>word</b> 65:9 90:2 94:1	<b>Yep</b> 74:16 186:1	08:12:42 16:19	08:15:41 19:20	08:19:05 22:17
108:17 122:3	240:19	08:12:43 16:20	08:15:42 19:21	08:19:11 22:18
<b>wording</b> 93:6	<b>yesterday</b> 315:15	08:12:45 16:21	08:15:43 19:22	08:19:13 22:19,20
<b>words</b> 99:10 147:5	<b>York</b> 1:18,18 2:4,4 3:5	08:12:57 17:4,5	08:15:44 20:1,2	08:19:16 22:21
176:1,19 177:6	3:16,18,18 15:19,20	08:13:01 17:6	08:15:46 20:3	08:19:19 22:22
184:18 185:1 243:5	15:21	08:13:02 17:7	08:15:47 20:4	08:19:20 23:1
<b>work</b> 22:13 52:2,17	<b>Z</b>	08:13:04 17:8,9	08:15:49 20:5	08:19:21 23:2
53:1,13,22 55:6 57:2	<b>zwitterionic</b> 81:10	08:13:08 17:10	08:15:54 20:6	08:19:22 23:3
65:7 68:5,19 159:1	167:4 293:22 310:5	08:13:11 17:11	08:15:56 20:7	08:19:26 23:4
255:12 261:15 287:8	<b>Z-E</b> 31:15	08:13:14 17:12	08:15:58 20:8,9	08:19:28 23:5
314:16	<b>0</b>	08:13:16 17:13	08:16:01 20:10,11	08:19:31 23:6,7
<b>worked</b> 50:4 55:10,14	0 167:21,22	08:13:18 17:14	08:16:06 20:12	08:19:37 23:8
55:15 56:3,21 57:18	0.02 227:16 229:5,15	08:13:20 17:15	08:16:10 20:13	08:19:39 23:9
<b>working</b> 42:17 55:16	229:19,22	08:13:23 17:16	08:16:12 20:14	08:19:40 23:10
56:5 138:11 146:2	0.03 229:21	08:13:25 17:17	08:16:15 20:15	08:19:42 23:11
165:6	0.05 229:20 230:1	08:13:26 17:18	08:16:17 20:16	08:19:44 23:12
<b>works</b> 61:16	0.15 227:14,14,15	08:13:29 17:19	08:16:19 20:17	08:19:48 23:13
<b>worth</b> 270:9	229:7	08:13:31 17:20	08:16:20 20:18,19	08:19:52 23:14
<b>wouldn't</b> 99:2 105:9	08:10:15 15:2	08:13:34 17:21	08:16:21 20:20	08:19:57 23:15
111:15 198:9,11	08:10:16 15:3	08:13:36 17:22	08:16:23 20:21	08:19:58 23:16
199:18 249:17	08:10:20 15:4	08:13:38 18:1	08:16:35 20:22	08:19:59 23:17,18
<b>wrapped</b> 254:17	08:10:22 15:5	08:13:40 18:2	08:16:36 21:1	08:20:01 23:19
<b>write</b> 52:9,12 230:17	08:10:25 15:6	08:13:42 18:3,4	08:16:44 21:2,3	08:20:02 23:20
240:20 242:11 250:10	08:10:29 15:7	08:13:45 18:5	08:16:48 21:4	08:20:03 23:21
250:15,22 251:7,13	08:10:32 15:8	08:13:46 18:6	08:16:49 21:5	08:20:04 23:22 24:1
265:22 266:9,17	08:10:34 15:9	08:13:49 18:7	08:16:51 21:6	08:20:06 24:2
268:1 272:15 278:10	08:10:36 15:10	08:13:50 18:8	08:16:53 21:7	08:20:12 24:3
285:19 286:4	08:10:38 15:11	08:13:52 18:9	08:16:56 21:8	08:20:15 24:4
<b>writing</b> 200:3	08:10:42 15:12	08:13:53 18:10	08:17:06 21:9	08:20:20 24:5
<b>written</b> 52:7,15 104:20	08:10:48 15:13	08:13:55 18:11	08:17:08 21:10	08:20:24 24:6
132:12 137:18,19	08:10:52 15:14	08:13:59 18:12	08:17:12 21:11	08:20:27 24:7
278:18,19 286:11	08:11:00 15:15	08:14:30 18:13	08:17:15 21:12	08:20:31 24:8
287:10 314:5,5	08:11:13 15:16	08:14:31 18:14	08:17:17 21:13	08:20:33 24:9
<b>wrong</b> 134:3 220:2	08:11:23 15:17,18	08:14:33 18:15,16	08:17:19 21:14	08:20:59 24:10
264:18 265:3 287:6	08:11:25 15:19	08:14:37 18:17	08:17:27 21:15	08:21:02 24:11
<b>wrote</b> 286:21	08:11:30 15:20	08:14:45 18:18	08:17:30 21:16	08:21:09 24:12
<b>X</b>	08:11:33 15:21	08:14:46 18:19	08:17:36 21:17	08:21:12 24:13
<b>X</b> 1:2,14 5:1,6 6:1 7:1	08:11:44 15:22	08:14:54 18:20	08:17:43 21:18	08:21:15 24:14
8:1 9:1 10:1 11:1		08:14:57 18:21	08:17:47 21:19	08:21:18 24:15
12:1 13:1 14:1 319:7		08:14:58 18:22 19:1	08:17:50 21:20	08:21:23 24:16
		08:15:00 19:2	08:17:56 21:21	08:21:25 24:17

08:21:27 24:18	08:24:48 27:14	08:27:40 30:9	08:31:07 33:8	08:33:51 36:3
08:21:32 24:19	08:24:53 27:15	08:27:42 30:10	08:31:12 33:9	08:33:53 36:4
08:21:40 24:20	08:24:56 27:16	08:27:45 30:11,12	08:31:13 33:10	08:33:55 36:5
08:21:48 24:21	08:24:58 27:17	08:27:47 30:13	08:31:16 33:11	08:34:00 36:6
08:21:54 24:22	08:24:59 27:18	08:27:52 30:14	08:31:19 33:12	08:34:04 36:7
08:22:00 25:1	08:25:02 27:19	08:27:55 30:15	08:31:23 33:13	08:34:06 36:8
08:22:02 25:2	08:25:06 27:20,21	08:27:59 30:16	08:31:25 33:14,15	08:34:09 36:9
08:22:06 25:3	08:25:11 27:22	08:28:00 30:17	08:31:27 33:16	08:34:11 36:10
08:22:10 25:4	08:25:17 28:1	08:28:01 30:18	08:31:30 33:17	08:34:13 36:11
08:22:14 25:5	08:25:21 28:2	08:28:04 30:19	08:31:34 33:18	08:34:15 36:12
08:22:22 25:6	08:25:22 28:3	08:28:07 30:20	08:31:37 33:19	08:34:16 36:13
08:22:37 25:7	08:25:24 28:4	08:28:11 30:21	08:31:43 33:20	08:34:18 36:14
08:22:40 25:8	08:25:26 28:5	08:28:16 30:22	08:31:45 33:21	08:34:21 36:15
08:22:44 25:9	08:25:27 28:6	08:28:18 31:1	08:31:49 33:22	08:34:24 36:16
08:22:45 25:10	08:25:30 28:7	08:28:20 31:2	08:31:52 34:1,2	08:34:26 36:17
08:22:47 25:11	08:25:32 28:8	08:28:24 31:3	08:31:56 34:3	08:34:33 36:18
08:22:48 25:12	08:25:33 28:9	08:28:25 31:4	08:31:57 34:4	08:34:35 36:19
08:22:49 25:13	08:25:35 28:10	08:28:28 31:5	08:31:59 34:5	08:34:36 36:20
08:22:51 25:14,15	08:25:38 28:11	08:28:30 31:6	08:32:00 34:6	08:34:39 36:21
08:22:53 25:16	08:25:39 28:12	08:28:31 31:7	08:32:01 34:7	08:34:47 36:22
08:22:55 25:17	08:25:40 28:13	08:28:32 31:8	08:32:03 34:8	08:34:54 37:1
08:22:58 25:18,19	08:25:42 28:14	08:28:35 31:9	08:32:06 34:9	08:34:58 37:2
08:23:10 25:20	08:25:45 28:15	08:28:40 31:10	08:32:09 34:10	08:35:00 37:3
08:23:12 25:21,22	08:25:50 28:16	08:28:42 31:11	08:32:12 34:11	08:35:02 37:4
08:23:18 26:1	08:25:52 28:17	08:28:45 31:12	08:32:13 34:12	08:35:05 37:5
08:23:19 26:2	08:25:59 28:18	08:28:51 31:13	08:32:15 34:13	08:35:06 37:6,7
08:23:23 26:3	08:26:03 28:19	08:28:53 31:14	08:32:17 34:14	08:35:09 37:8
08:23:28 26:4	08:26:06 28:20	08:29:05 31:15	08:32:24 34:15	08:35:10 37:9,10
08:23:29 26:5	08:26:08 28:21	08:29:07 31:16	08:32:25 34:16	08:35:12 37:11
08:23:31 26:6	08:26:11 28:22	08:29:09 31:17	08:32:28 34:17	08:35:15 37:12
08:23:33 26:7,8	08:26:16 29:1,2	08:29:26 31:18	08:32:31 34:18	08:35:21 37:13
08:23:36 26:9	08:26:17 29:3	08:29:29 31:19,20	08:32:32 34:19	08:35:23 37:14
08:23:40 26:10	08:26:19 29:4	08:29:31 31:21	08:32:34 34:20	08:35:24 37:15
08:23:41 26:11	08:26:28 29:5	08:29:35 31:22	08:32:37 34:21,22	08:35:26 37:16
08:23:44 26:12	08:26:32 29:6,7	08:29:37 32:1	08:32:39 35:1	08:35:30 37:17
08:23:45 26:13	08:26:36 29:8	08:29:40 32:2	08:32:42 35:2	08:35:31 37:18
08:23:52 26:14	08:26:37 29:9	08:29:45 32:3,4,5	08:32:45 35:3	08:35:35 37:19
08:23:54 26:15	08:26:40 29:10	08:29:48 32:6	08:32:49 35:4	08:35:39 37:20
08:23:57 26:16	08:26:41 29:11	08:29:53 32:7	08:32:51 35:5	08:35:42 37:21
08:24:01 26:17	08:26:43 29:12	08:29:58 32:8,9	08:32:53 35:6,7	08:35:48 37:22
08:24:06 26:18,19	08:26:46 29:13	08:30:02 32:10	08:32:56 35:8	08:35:49 38:1
08:24:09 26:20	08:26:52 29:14	08:30:03 32:11	08:32:58 35:9	08:35:52 38:2
08:24:11 26:21	08:26:53 29:15	08:30:08 32:12	08:33:00 35:10	08:35:56 38:3
08:24:12 26:22	08:26:59 29:16	08:30:14 32:13,14	08:33:03 35:11	08:35:57 38:4
08:24:13 27:1	08:27:02 29:17,18	08:30:16 32:15	08:33:06 35:12	08:35:58 38:5
08:24:17 27:2	08:27:04 29:19	08:30:19 32:16	08:33:09 35:13	08:35:59 38:6
08:24:19 27:3	08:27:11 29:20	08:30:22 32:17	08:33:12 35:14	08:36:02 38:7
08:24:25 27:4	08:27:12 29:21	08:30:37 32:18	08:33:15 35:15	08:36:05 38:8
08:24:27 27:5	08:27:14 29:22	08:30:39 32:19	08:33:16 35:16	08:36:06 38:9
08:24:29 27:6	08:27:15 30:1	08:30:42 32:20	08:33:17 35:17	08:36:09 38:10
08:24:31 27:7	08:27:17 30:2	08:30:45 32:21	08:33:25 35:18	08:36:13 38:11
08:24:34 27:8	08:27:19 30:3	08:30:47 32:22	08:33:28 35:19	08:36:15 38:12
08:24:37 27:9	08:27:21 30:4	08:30:52 33:1	08:33:31 35:20	08:36:16 38:13
08:24:39 27:10	08:27:25 30:5	08:31:00 33:2,3	08:33:42 35:21	08:36:19 38:14
08:24:42 27:11	08:27:27 30:6	08:31:02 33:4,5	08:33:45 35:22	08:36:23 38:15
08:24:43 27:12	08:27:28 30:7	08:31:04 33:6	08:33:48 36:1	08:36:25 38:16
08:24:47 27:13	08:27:38 30:8	08:31:05 33:7	08:33:50 36:2	08:36:28 38:17

08:36:31 38:18	08:39:58 41:12	08:43:49 44:5,6	08:47:25 47:1	08:50:22 49:19
08:36:34 38:19	08:40:04 41:13	08:43:51 44:7	08:47:29 47:2	08:50:23 49:20
08:36:38 38:20	08:40:07 41:14	08:43:57 44:8	08:47:32 47:3	08:50:25 49:21
08:36:42 38:21	08:40:10 41:15	08:44:03 44:9	08:47:33 47:4	08:50:32 49:22
08:36:44 38:22	08:40:13 41:16,17	08:44:12 44:10	08:47:34 47:5	08:50:38 50:1
08:36:48 39:1	08:40:15 41:18	08:44:17 44:11	08:47:37 47:6	08:50:46 50:2
08:36:51 39:2	08:40:19 41:19	08:44:24 44:12	08:47:40 47:7	08:50:55 50:3
08:36:54 39:3	08:40:23 41:20	08:44:34 44:13	08:47:49 47:8,9	08:51:00 50:4
08:36:58 39:4	08:40:33 41:21	08:44:37 44:14	08:47:50 47:10	08:51:04 50:5
08:36:59 39:5	08:40:36 41:22	08:44:38 44:15	08:47:53 47:11	08:51:07 50:6
08:37:02 39:6	08:40:37 42:1	08:44:41 44:16	08:47:54 47:12	08:51:11 50:7
08:37:07 39:7,8	08:40:43 42:2	08:44:43 44:17,18	08:47:57 47:13	08:51:15 50:8
08:37:08 39:9	08:40:51 42:3	08:44:47 44:19	08:48:02 47:14	08:51:18 50:9
08:37:09 39:10	08:40:54 42:4	08:44:50 44:20	08:48:08 47:15	08:51:20 50:10
08:37:12 39:11	08:40:56 42:5,6	08:44:52 44:21	08:48:14 47:16	08:51:32 50:11
08:37:17 39:12,13	08:40:58 42:7	08:44:54 44:22	08:48:21 47:17	08:51:48 50:12
08:37:18 39:14	08:40:59 42:8	08:44:57 45:1	08:48:23 47:18	08:51:49 50:13
08:37:21 39:15	08:41:06 42:9	08:45:00 45:2	08:48:29 47:19,20	08:51:53 50:14
08:37:26 39:16	08:41:09 42:10	08:45:02 45:3	08:48:31 47:21,22	08:51:58 50:15
08:37:28 39:17,18	08:41:18 42:11	08:45:06 45:4	08:48:34 48:1	08:52:01 50:16
08:37:31 39:19	08:41:22 42:12	08:45:13 45:5	08:48:39 48:2	08:52:04 50:17
08:37:34 39:20	08:41:26 42:13	08:45:15 45:6	08:48:43 48:3	08:52:07 50:18
08:37:38 39:21	08:41:30 42:14	08:45:18 45:7,8	08:48:45 48:4	08:52:10 50:19
08:37:52 39:22	08:41:36 42:15	08:45:21 45:9	08:48:47 48:5	08:52:13 50:20,21
08:37:54 40:1	08:41:40 42:16	08:45:28 45:10	08:48:48 48:6	08:52:16 50:22
08:38:00 40:2	08:41:44 42:17	08:45:33 45:11	08:48:51 48:7	08:52:18 51:1
08:38:06 40:3	08:41:48 42:18	08:45:37 45:12,13	08:48:52 48:8,9	08:52:22 51:2
08:38:09 40:4	08:41:53 42:19	08:45:42 45:14	08:48:56 48:10	08:52:30 51:3
08:38:10 40:5	08:41:56 42:20	08:45:44 45:15	08:48:58 48:11,12	08:52:33 51:4
08:38:12 40:6	08:41:59 42:21	08:45:47 45:16	08:49:00 48:13	08:52:35 51:5
08:38:15 40:7	08:42:02 42:22	08:45:48 45:17	08:49:04 48:14	08:52:39 51:6
08:38:18 40:8	08:42:04 43:1	08:45:49 45:18	08:49:06 48:15	08:52:42 51:7
08:38:20 40:9	08:42:06 43:2	08:45:52 45:19	08:49:09 48:16	08:52:43 51:8
08:38:22 40:10	08:42:09 43:3	08:45:55 45:20	08:49:14 48:17	08:52:45 51:9
08:38:26 40:11	08:42:12 43:4	08:46:00 45:21	08:49:17 48:18	08:52:49 51:10,11
08:38:32 40:12	08:42:14 43:5	08:46:06 45:22	08:49:19 48:19	08:52:51 51:12
08:38:35 40:13	08:42:16 43:6	08:46:19 46:1	08:49:23 48:20	08:52:54 51:13
08:38:37 40:14	08:42:17 43:7	08:46:21 46:2	08:49:26 48:21	08:52:55 51:14
08:38:40 40:15	08:42:20 43:8	08:46:23 46:3	08:49:29 48:22	08:52:56 51:15
08:38:44 40:16	08:42:24 43:9	08:46:28 46:4	08:49:33 49:1	08:52:59 51:16,17
08:38:45 40:17	08:42:29 43:10	08:46:30 46:5	08:49:37 49:2	08:53:00 51:18
08:38:50 40:18	08:42:31 43:11	08:46:34 46:6	08:49:39 49:3	08:53:02 51:19
08:38:53 40:19	08:42:33 43:12	08:46:35 46:7	08:49:43 49:4	08:53:06 51:20
08:39:01 40:20	08:42:39 43:13	08:46:36 46:8,9	08:49:47 49:5	08:53:08 51:21
08:39:06 40:21	08:42:42 43:14	08:46:44 46:10	08:49:49 49:6	08:53:10 51:22
08:39:11 40:22	08:42:44 43:15	08:46:49 46:11	08:49:51 49:7	08:53:13 52:1
08:39:20 41:1	08:42:47 43:16	08:46:52 46:12	08:49:52 49:8	08:53:14 52:2
08:39:22 41:2	08:42:53 43:17	08:46:55 46:13	08:49:53 49:9	08:53:16 52:3
08:39:25 41:3	08:42:59 43:18	08:46:58 46:14	08:50:01 49:10	08:53:21 52:4
08:39:28 41:4	08:43:05 43:19	08:47:00 46:15	08:50:03 49:11	08:53:24 52:5
08:39:39 41:5	08:43:14 43:20	08:47:02 46:16	08:50:06 49:12	08:53:25 52:6
08:39:42 41:6	08:43:20 43:21	08:47:05 46:17	08:50:10 49:13	08:53:27 52:7
08:39:47 41:7	08:43:30 43:22	08:47:08 46:18	08:50:12 49:14	08:53:30 52:8
08:39:48 41:8	08:43:32 44:1	08:47:11 46:19	08:50:13 49:15	08:53:33 52:9
08:39:50 41:9	08:43:37 44:2	08:47:13 46:20	08:50:14 49:16	08:53:36 52:10,11
08:39:52 41:10	08:43:39 44:3	08:47:22 46:21	08:50:16 49:17	08:53:40 52:12
08:39:56 41:11	08:43:41 44:4	08:47:24 46:22	08:50:18 49:18	08:53:42 52:13

08:53:46 52:14	08:56:53 55:10	09:00:51 58:4	09:04:08 60:21	09:07:57 63:15,16
08:53:52 52:15	08:56:57 55:11	09:00:52 58:5	09:04:13 60:22	09:08:05 63:17
08:53:56 52:16	08:56:58 55:12,13	09:00:57 58:6	09:04:17 61:1	09:08:08 63:18
08:53:57 52:17	08:57:01 55:14	09:01:01 58:7	09:04:21 61:2	09:08:10 63:19
08:53:59 52:18	08:57:06 55:15	09:01:07 58:8	09:04:23 61:3	09:08:12 63:20
08:54:03 52:19	08:57:10 55:16	09:01:10 58:9	09:04:25 61:4	09:08:16 63:21
08:54:04 52:20	08:57:15 55:17	09:01:11 58:10	09:04:28 61:5	09:08:17 63:22
08:54:06 52:21	08:57:18 55:18	09:01:14 58:11	09:04:30 61:6	09:08:20 64:1
08:54:10 52:22	08:57:22 55:19	09:01:20 58:12	09:04:33 61:7	09:08:21 64:2
08:54:11 53:1	08:57:32 55:20	09:01:24 58:13	09:04:39 61:8	09:08:25 64:3
08:54:13 53:2	08:57:36 55:21	09:01:30 58:14	09:04:43 61:9	09:08:28 64:4
08:54:16 53:3	08:57:42 55:22	09:01:32 58:15	09:04:46 61:10	09:08:31 64:5
08:54:20 53:4	08:57:45 56:1	09:01:33 58:16	09:04:48 61:11	09:08:34 64:6
08:54:23 53:5	08:57:49 56:2	09:01:36 58:17	09:04:50 61:12	09:08:36 64:7
08:54:26 53:6	08:57:51 56:3	09:01:39 58:18	09:04:54 61:13,14	09:08:40 64:8
08:54:28 53:7,8	08:57:53 56:4	09:01:41 58:19	09:04:57 61:15	09:08:43 64:9
08:54:30 53:9	08:58:01 56:5	09:01:49 58:20	09:05:00 61:16	09:08:45 64:10
08:54:31 53:10	08:58:11 56:6	09:01:53 58:21	09:05:04 61:17	09:08:48 64:11
08:54:37 53:11,12	08:58:14 56:7	09:01:58 58:22	09:05:06 61:18	09:08:50 64:12
08:54:40 53:13	08:58:17 56:8	09:02:02 59:1	09:05:08 61:19	09:08:52 64:13
08:54:42 53:14	08:58:19 56:9	09:02:04 59:2	09:05:13 61:20	09:08:59 64:14
08:54:45 53:15	08:58:21 56:10	09:02:07 59:3	09:05:21 61:21	09:09:00 64:15
08:54:50 53:16	08:58:23 56:11	09:02:10 59:4	09:05:26 61:22	09:09:02 64:16
08:54:55 53:17	08:58:24 56:12	09:02:15 59:5	09:05:31 62:1	09:09:03 64:17
08:54:59 53:18	08:58:26 56:13	09:02:19 59:6	09:05:32 62:2	09:09:06 64:18
08:55:04 53:19	08:58:29 56:14	09:02:20 59:7	09:05:34 62:3	09:09:09 64:19
08:55:08 53:20	08:58:50 56:15	09:02:22 59:8	09:05:39 62:4,5	09:09:10 64:20
08:55:11 53:21	08:59:14 56:16	09:02:27 59:9	09:05:40 62:6	09:09:12 64:21
08:55:13 53:22	08:59:17 56:17	09:02:29 59:10	09:05:42 62:7	09:09:19 64:22
08:55:15 54:1	08:59:22 56:18	09:02:30 59:11	09:05:51 62:8	09:09:21 65:1,2
08:55:19 54:2	08:59:26 56:19	09:02:32 59:12,13	09:05:58 62:9	09:09:23 65:3
08:55:26 54:3	08:59:28 56:20	09:02:35 59:14	09:05:59 62:10	09:09:26 65:4
08:55:32 54:4	08:59:30 56:21	09:02:37 59:15,16	09:06:02 62:11	09:09:27 65:5
08:55:34 54:5	08:59:35 56:22	09:02:38 59:17	09:06:05 62:12	09:09:29 65:6
08:55:38 54:6	08:59:38 57:1	09:02:41 59:18	09:06:13 62:13	09:09:39 65:7
08:55:42 54:7	08:59:51 57:2	09:02:43 59:19	09:06:18 62:14	09:09:46 65:8
08:55:46 54:8,9	08:59:54 57:3	09:02:47 59:20	09:06:23 62:15	09:09:52 65:9
08:55:49 54:10	08:59:56 57:4	09:02:50 59:21	09:06:27 62:16	09:09:56 65:10
08:55:52 54:11	08:59:58 57:5	09:02:54 59:22	09:06:31 62:17	09:09:57 65:11
08:55:57 54:12	09:00:00 57:6	09:02:55 60:1	09:06:32 62:18	09:09:59 65:12
08:56:01 54:13	09:00:02 57:7	09:02:56 60:2	09:06:35 62:19	09:10:02 65:13
08:56:05 54:14	09:00:04 57:8	09:02:58 60:3	09:06:36 62:20	09:10:07 65:14
08:56:08 54:15	09:00:05 57:9	09:03:04 60:4	09:06:39 62:21	09:10:15 65:15
08:56:11 54:16	09:00:09 57:10	09:03:08 60:5	09:06:46 62:22	09:10:19 65:16
08:56:13 54:17	09:00:11 57:11	09:03:09 60:6	09:06:47 63:1	09:10:22 65:17
08:56:14 54:18	09:00:14 57:12	09:03:11 60:7	09:06:48 63:2,3	09:10:27 65:18
08:56:19 54:19	09:00:23 57:13	09:03:12 60:8	09:06:51 63:4	09:10:30 65:19
08:56:23 54:20	09:00:24 57:14	09:03:31 60:9	09:07:01 63:5	09:10:35 65:20
08:56:27 54:21	09:00:27 57:15	09:03:34 60:10	09:07:06 63:6	09:10:40 65:21
08:56:33 54:22	09:00:30 57:16	09:03:38 60:11	09:07:27 63:7	09:10:42 65:22
08:56:34 55:1	09:00:32 57:17	09:03:42 60:12	09:07:31 63:8	09:10:43 66:1,2
08:56:38 55:2	09:00:35 57:18	09:03:45 60:13	09:07:34 63:9	09:10:46 66:3
08:56:40 55:3	09:00:38 57:19	09:03:49 60:14	09:07:36 63:10	09:10:48 66:4
08:56:41 55:4,5	09:00:44 57:20	09:03:56 60:15	09:07:40 63:11	09:10:49 66:5
08:56:44 55:6	09:00:47 57:21,22	09:04:03 60:16	09:07:49 63:12	09:10:50 66:6
08:56:48 55:7	09:00:49 58:1,2	09:04:04 60:17,18	09:07:51 63:13	09:10:58 66:7
08:56:51 55:8,9	09:00:50 58:3	09:04:07 60:19,20	09:07:55 63:14	09:11:01 66:8

09:11:04 66:9	09:15:05 68:22	09:18:06 71:15	09:21:34 74:14	09:25:30 77:10
09:11:05 66:10	09:15:06 69:1	09:18:09 71:16	09:21:38 74:15	09:25:33 77:11
09:11:31 66:11	09:15:07 69:2	09:18:14 71:17	09:21:44 74:16	09:25:34 77:12
09:11:33 66:12	09:15:10 69:3	09:18:18 71:18	09:21:51 74:17	09:25:37 77:13
09:11:35 66:13	09:15:14 69:4	09:18:24 71:19	09:21:55 74:18	09:25:41 77:14
09:11:43 66:14	09:15:15 69:5	09:18:27 71:20	09:21:56 74:19,20	09:25:44 77:15
09:11:48 66:15	09:15:17 69:6	09:18:30 71:21	09:21:58 74:21	09:25:52 77:16
09:12:23 66:16	09:15:20 69:7	09:18:34 71:22 72:1	09:22:00 74:22	09:25:54 77:17
09:12:25 66:17	09:15:21 69:8	09:18:36 72:2	09:22:03 75:1	09:25:57 77:18
09:12:30 66:18	09:15:22 69:9	09:18:39 72:3	09:22:06 75:2	09:25:59 77:19
09:12:35 66:19	09:15:24 69:10	09:18:42 72:4	09:22:09 75:3	09:26:02 77:20
09:12:39 66:20	09:15:28 69:11	09:18:44 72:5	09:22:15 75:4	09:26:05 77:21
09:12:42 66:21	09:15:35 69:12	09:18:47 72:6	09:22:21 75:5,6,7	09:26:07 77:22
09:12:45 66:22	09:15:38 69:13	09:18:50 72:7	09:22:22 75:8	09:26:09 78:1
09:12:48 67:1	09:15:42 69:14	09:18:54 72:8	09:22:23 75:9	09:26:23 78:2
09:12:51 67:2	09:15:45 69:15	09:18:56 72:9	09:22:25 75:10	09:26:28 78:3
09:12:59 67:3	09:15:48 69:16	09:19:00 72:10,11	09:22:27 75:11	09:26:32 78:4
09:13:01 67:4	09:15:59 69:17	09:19:04 72:12	09:22:31 75:12	09:26:34 78:5
09:13:10 67:5	09:16:07 69:18	09:19:06 72:13	09:22:37 75:13	09:26:37 78:6
09:13:14 67:6	09:16:09 69:19	09:19:08 72:14,15	09:22:41 75:14	09:26:40 78:7
09:13:17 67:7	09:16:10 69:20	09:19:10 72:16	09:22:45 75:15	09:26:43 78:8
09:13:20 67:8	09:16:11 69:21	09:19:12 72:17	09:22:46 75:16	09:26:47 78:9
09:13:23 67:9	09:16:15 69:22	09:19:13 72:18	09:22:53 75:17	09:26:48 78:10,11
09:13:26 67:10	09:16:17 70:1	09:19:15 72:19	09:22:55 75:18	09:26:51 78:12
09:13:28 67:11	09:16:22 70:2	09:19:20 72:20,21	09:22:59 75:19	09:26:53 78:13
09:13:29 67:12	09:16:26 70:3	09:19:22 72:22	09:23:05 75:20	09:26:59 78:14
09:13:31 67:13	09:16:29 70:4	09:19:30 73:1	09:23:07 75:21	09:27:04 78:15
09:13:33 67:14	09:16:32 70:5	09:19:33 73:2	09:23:09 75:22	09:27:07 78:16
09:13:38 67:15	09:16:33 70:6	09:19:36 73:3	09:23:12 76:1,2	09:27:09 78:17,18
09:13:41 67:16	09:16:36 70:7	09:19:39 73:4	09:23:15 76:3	09:27:13 78:19
09:13:45 67:17	09:16:40 70:8	09:19:45 73:5	09:23:22 76:4	09:27:16 78:20
09:13:47 67:18	09:16:42 70:9	09:19:51 73:6	09:23:30 76:5	09:27:58 78:21
09:13:48 67:19	09:16:45 70:10	09:19:58 73:7	09:23:35 76:6	09:28:00 78:22
09:13:51 67:20	09:16:49 70:11	09:20:01 73:8	09:23:37 76:7	09:28:01 79:1
09:13:52 67:21	09:16:50 70:12	09:20:04 73:9	09:23:42 76:8	09:28:05 79:2
09:13:54 67:22	09:16:53 70:13,14	09:20:05 73:10	09:23:46 76:9	09:28:08 79:3
09:13:57 68:1	09:16:57 70:15,16	09:20:08 73:11	09:23:51 76:10	09:28:10 79:4
09:13:59 68:2	09:16:59 70:17	09:20:13 73:12	09:23:55 76:11	09:28:13 79:5
09:14:05 68:3	09:17:00 70:18	09:20:18 73:13	09:24:05 76:12	09:28:16 79:6
09:14:07 68:4	09:17:02 70:19	09:20:25 73:14	09:24:10 76:13	09:28:18 79:7,8
09:14:11 68:5	09:17:11 70:20	09:20:31 73:15	09:24:15 76:14	09:28:21 79:9
09:14:14 68:6	09:17:14 70:21	09:20:39 73:16	09:24:17 76:15	09:28:22 79:10
09:14:18 68:7	09:17:19 70:22	09:20:40 73:17	09:24:22 76:16	09:28:26 79:11
09:14:20 68:8	09:17:24 71:1	09:20:45 73:18	09:24:27 76:17	09:28:30 79:12
09:14:26 68:9	09:17:27 71:2	09:20:51 73:19	09:24:35 76:18	09:28:33 79:13
09:14:33 68:10	09:17:33 71:3	09:20:57 73:20	09:24:39 76:19	09:28:38 79:14
09:14:35 68:11	09:17:38 71:4	09:20:58 73:21	09:24:48 76:20	09:28:44 79:15
09:14:40 68:12	09:17:41 71:5	09:21:04 73:22	09:24:49 76:21	09:28:49 79:16
09:14:42 68:13	09:17:42 71:6	09:21:08 74:1	09:24:53 76:22	09:28:53 79:17
09:14:44 68:14	09:17:43 71:7	09:21:10 74:2,3	09:24:56 77:1	09:28:59 79:18
09:14:45 68:15	09:17:49 71:8	09:21:15 74:4	09:24:59 77:2	09:29:02 79:19
09:14:47 68:16	09:17:50 71:9	09:21:19 74:5,6,7	09:25:02 77:3	09:29:07 79:20
09:14:49 68:17	09:17:52 71:10	09:21:24 74:8	09:25:06 77:4	09:29:09 79:21
09:14:54 68:18	09:17:54 71:11	09:21:26 74:9,10	09:25:14 77:5	09:29:11 79:22
09:14:57 68:19	09:17:56 71:12	09:21:27 74:11	09:25:20 77:6,7	09:29:13 80:1
09:14:59 68:20	09:17:58 71:13	09:21:29 74:12	09:25:22 77:8	09:29:18 80:2
09:15:03 68:21	09:18:01 71:14	09:21:30 74:13	09:25:26 77:9	09:29:21 80:3

09:29:24 80:4	09:48:22 82:18	09:51:56 85:15	09:55:49 88:7	09:58:46 91:6
09:29:27 80:5	09:48:24 82:19	09:51:58 85:16	09:55:53 88:8	09:58:49 91:7
09:29:31 80:6	09:48:27 82:20	09:52:02 85:17	09:55:54 88:9	09:58:50 91:8
09:29:32 80:7	09:48:31 82:21	09:52:06 85:18	09:55:56 88:10,11	09:58:55 91:9
09:29:34 80:8	09:48:34 82:22	09:52:08 85:19	09:55:57 88:12,13	09:58:57 91:10
09:29:38 80:9	09:48:39 83:1,2	09:52:11 85:20	09:56:00 88:14	09:58:58 91:11
09:29:41 80:10	09:48:42 83:3	09:52:14 85:21	09:56:02 88:15	09:59:03 91:12
09:29:42 80:11	09:48:44 83:4	09:52:17 85:22	09:56:05 88:16	09:59:07 91:13,14
09:29:47 80:12	09:48:46 83:5	09:52:21 86:1	09:56:09 88:17	09:59:09 91:15
09:29:49 80:13	09:48:48 83:6	09:52:24 86:2	09:56:13 88:18	09:59:14 91:16
09:29:50 80:14	09:48:51 83:7	09:52:26 86:3	09:56:15 88:19	09:59:15 91:17,18
09:29:53 80:15	09:49:01 83:8	09:52:28 86:4	09:56:19 88:20	09:59:21 91:19
09:29:57 80:16	09:49:09 83:9	09:52:29 86:5	09:56:23 88:21	09:59:24 91:20
09:29:59 80:17	09:49:14 83:10	09:52:32 86:6	09:56:27 88:22	09:59:25 91:21
09:30:09 80:18	09:49:18 83:11	09:52:38 86:7	09:56:31 89:1	09:59:32 91:22
09:30:12 80:19	09:49:21 83:12	09:52:42 86:8	09:56:32 89:2	09:59:36 92:1
09:30:15 80:20	09:49:25 83:13	09:52:44 86:9	09:56:36 89:3	09:59:37 92:2
09:30:18 80:21	09:49:29 83:14	09:52:49 86:10	09:56:38 89:4	09:59:38 92:3
09:45:18 80:22	09:49:33 83:15	09:52:56 86:11	09:56:41 89:5,6	09:59:40 92:4
09:45:33 81:1	09:49:35 83:16	09:53:00 86:12	09:56:42 89:7,8	09:59:42 92:5
09:45:45 81:2	09:49:38 83:17	09:53:07 86:13	09:56:45 89:9	09:59:43 92:6
09:45:48 81:3	09:49:41 83:18	09:53:09 86:14	09:56:46 89:10	09:59:45 92:7
09:45:50 81:4	09:49:43 83:19	09:53:22 86:15	09:56:48 89:11	09:59:48 92:8
09:45:52 81:5,6	09:49:45 83:20	09:53:33 86:16	09:56:50 89:12	09:59:50 92:9
09:45:55 81:7	09:49:46 83:21	09:53:42 86:17	09:56:55 89:13	09:59:51 92:10,11
09:46:00 81:8	09:49:51 83:22	09:53:46 86:18	09:57:02 89:14	09:59:54 92:12
09:46:05 81:9	09:49:56 84:1	09:53:50 86:19	09:57:03 89:15	09:59:57 92:13
09:46:09 81:10	09:49:59 84:2	09:53:54 86:20	09:57:06 89:16	09:59:58 92:14
09:46:11 81:11	09:50:04 84:3	09:53:57 86:21	09:57:08 89:17	
09:46:13 81:12	09:50:08 84:4	09:54:00 86:22	09:57:11 89:18	<b>I</b>
09:46:17 81:13	09:50:10 84:5	09:54:04 87:1	09:57:16 89:19	1 5:10 9:10 18:9,10,14
09:46:27 81:14	09:50:13 84:6	09:54:09 87:2	09:57:20 89:20	18:16 90:4 97:15,16
09:46:32 81:15	09:50:20 84:7	09:54:11 87:3	09:57:22 89:21	97:22 106:9,15 107:2
09:46:33 81:16	09:50:22 84:8	09:54:14 87:4	09:57:25 89:22	107:2,8,16 108:1,20
09:46:35 81:17	09:50:26 84:9	09:54:15 87:5	09:57:28 90:1	112:14 113:4,5,8,9,12
09:46:39 81:18	09:50:29 84:10	09:54:21 87:6	09:57:30 90:2	113:21 114:20 115:8
09:46:44 81:19	09:50:32 84:11	09:54:24 87:7	09:57:35 90:3	115:15 117:8,10
09:46:49 81:20	09:50:37 84:12,13	09:54:28 87:8	09:57:37 90:4	118:1,16,20 119:16
09:47:00 81:21	09:50:39 84:14,15,16	09:54:32 87:9,10	09:57:46 90:5	120:10 121:4,20
09:47:07 81:22	09:50:43 84:17	09:54:54 87:11	09:57:48 90:6	122:10,15 123:3,15
09:47:09 82:1	09:50:50 84:18	09:54:58 87:12	09:57:53 90:7	155:16 227:3,11,13
09:47:13 82:2	09:50:56 84:19	09:55:01 87:13	09:57:55 90:8,9	227:20 228:8,18
09:47:16 82:3	09:51:00 84:20	09:55:04 87:14	09:57:56 90:10	229:4 230:20 231:2
09:47:21 82:4	09:51:03 84:21	09:55:09 87:15	09:58:01 90:11	235:14 279:13 280:3
09:47:25 82:5	09:51:05 84:22	09:55:10 87:16	09:58:04 90:12	1.2 267:22
09:47:29 82:6	09:51:07 85:1	09:55:11 87:17	09:58:08 90:13,14	1/10 251:3,16
09:47:32 82:7	09:51:11 85:2	09:55:12 87:18	09:58:09 90:15	1/1000 251:2
09:47:36 82:8	09:51:21 85:3,4	09:55:13 87:19	09:58:13 90:16	1:14-CV-00667 15:15
09:47:42 82:9	09:51:22 85:5,6	09:55:16 87:20	09:58:16 90:17,18	1:14-cv-00667-JBS-...
09:47:46 82:10	09:51:26 85:7	09:55:19 87:21	09:58:21 90:19	1:6
09:47:50 82:11	09:51:29 85:8	09:55:22 87:22	09:58:23 90:20	1:14-cv-04149-JBS-...
09:47:54 82:12	09:51:31 85:9	09:55:25 88:1	09:58:24 90:21	1:6
09:47:58 82:13	09:51:34 85:10	09:55:29 88:2	09:58:29 90:22	1:14-cv-05144-JBS-...
09:48:04 82:14	09:51:37 85:11	09:55:31 88:3	09:58:32 91:1,2	1:7
09:48:10 82:15	09:51:41 85:12	09:55:34 88:4	09:58:38 91:3	1:14-cv-06893-JBS-...
09:48:15 82:16	09:51:43 85:13	09:55:44 88:5	09:58:40 91:4	1:12
09:48:18 82:17	09:51:45 85:14	09:55:46 88:6	09:58:41 91:5	1:15-cv-00335-JBS-...

1:7	10:02:11 95:2	10:05:43 97:19	10:09:50 100:14	10:13:30 103:9
1:15-cv-03240-JBS-...	10:02:13 95:3	10:05:45 97:20	10:09:52 100:15,16	10:13:33 103:10
1:13	10:02:23 95:4	10:05:46 97:21	10:10:00 100:17	10:13:37 103:11
1:27 205:3,5	10:02:25 95:5	10:05:48 97:22	10:10:04 100:18	10:13:40 103:12
10 8:10 58:6,8 62:10,11	10:02:28 95:6	10:05:52 98:1	10:10:05 100:19	10:13:43 103:13
65:15 81:7 238:11,14	10:02:30 95:7,8	10:05:56 98:2,3	10:10:07 100:20	10:13:45 103:14
238:16 239:1 246:8	10:02:33 95:9	10:05:59 98:4	10:10:10 100:21	10:13:49 103:15
260:5 264:10,15	10:02:42 95:10	10:06:01 98:5	10:10:28 100:22 101:1	10:13:57 103:16
265:2,8,10,12,17	10:02:47 95:11,12	10:06:24 98:6,7	10:10:30 101:2	10:14:02 103:17
10:00:06 92:15	10:02:50 95:13	10:06:25 98:8	10:10:36 101:3	10:14:05 103:18
10:00:08 92:16	10:02:52 95:14	10:06:29 98:9	10:10:38 101:4	10:14:08 103:19
10:00:12 92:17	10:02:54 95:15	10:06:34 98:10	10:10:44 101:5	10:14:09 103:20
10:00:15 92:18	10:02:56 95:16	10:06:38 98:11	10:10:47 101:6	10:14:11 103:21
10:00:16 92:19,20	10:02:58 95:17	10:06:42 98:12	10:10:50 101:7	10:14:12 103:22
10:00:18 92:21	10:02:59 95:18	10:06:45 98:13	10:10:52 101:8	10:14:15 104:1
10:00:20 92:22	10:03:00 95:19	10:06:48 98:14	10:10:53 101:9	10:14:18 104:2
10:00:22 93:1	10:03:02 95:20	10:06:51 98:15,16	10:10:59 101:10	10:14:21 104:3
10:00:24 93:2	10:03:03 95:21	10:06:54 98:17	10:11:01 101:11	10:14:23 104:4,5
10:00:27 93:3	10:03:10 95:22	10:06:57 98:18	10:11:04 101:12	10:14:27 104:6
10:00:28 93:4	10:03:16 96:1	10:07:01 98:19	10:11:07 101:13	10:14:29 104:7
10:00:29 93:5	10:03:21 96:2	10:07:02 98:20	10:11:09 101:14	10:14:33 104:8
10:00:33 93:6	10:03:25 96:3	10:07:10 98:21	10:11:12 101:15	10:14:36 104:9
10:00:36 93:7	10:03:28 96:4	10:07:14 98:22	10:11:14 101:16	10:14:42 104:10,11
10:00:37 93:8	10:03:30 96:5	10:07:18 99:1	10:11:18 101:17	10:14:44 104:12
10:00:39 93:9	10:03:32 96:6	10:07:21 99:2	10:11:22 101:18	10:14:51 104:13
10:00:43 93:10	10:03:33 96:7	10:07:24 99:3	10:11:30 101:19	10:14:52 104:14
10:00:45 93:11	10:03:35 96:8	10:07:28 99:4	10:11:39 101:20	10:14:54 104:15
10:00:47 93:12	10:03:36 96:9	10:07:30 99:5	10:11:43 101:21,22	10:14:57 104:16
10:00:48 93:13	10:03:37 96:10	10:07:32 99:6	10:11:46 102:1	10:14:59 104:17
10:00:52 93:14	10:03:39 96:11,12	10:07:36 99:7	10:11:50 102:2	10:15:01 104:18
10:00:55 93:15	10:03:43 96:13	10:07:43 99:8	10:11:53 102:3	10:15:04 104:19
10:00:56 93:16	10:03:46 96:14	10:07:46 99:9	10:11:55 102:4	10:15:06 104:20
10:00:58 93:17,18	10:03:47 96:15	10:07:49 99:10	10:12:00 102:5	10:15:09 104:21
10:01:01 93:19	10:03:55 96:16	10:07:51 99:11	10:12:06 102:6	10:15:11 104:22
10:01:04 93:20	10:03:58 96:17	10:07:52 99:12,13	10:12:07 102:7	10:15:13 105:1
10:01:06 93:21	10:04:04 96:18	10:07:56 99:14	10:12:10 102:8	10:15:14 105:2
10:01:09 93:22	10:04:18 96:19,20	10:07:58 99:15	10:12:12 102:9	10:15:15 105:3
10:01:12 94:1	10:04:20 96:21	10:08:02 99:16	10:12:15 102:10	10:15:18 105:4
10:01:16 94:2,3	10:04:22 96:22	10:08:30 99:17	10:12:23 102:11	10:15:22 105:5
10:01:19 94:4	10:04:28 97:1	10:08:34 99:18	10:12:31 102:12	10:15:26 105:6
10:01:22 94:5	10:04:31 97:2	10:08:38 99:19	10:12:34 102:13	10:15:31 105:7
10:01:23 94:6	10:04:34 97:3	10:08:44 99:20	10:12:36 102:14	10:15:35 105:8
10:01:26 94:7	10:04:36 97:4	10:08:47 99:21	10:12:39 102:15	10:15:38 105:9
10:01:29 94:8,9	10:04:37 97:5	10:08:49 99:22	10:12:44 102:16	10:15:42 105:10
10:01:31 94:10	10:04:38 97:6	10:08:50 100:1	10:12:46 102:17	10:15:45 105:11
10:01:33 94:11	10:04:41 97:7	10:08:53 100:2	10:12:56 102:18	10:15:49 105:12
10:01:38 94:12	10:04:45 97:8	10:08:55 100:3	10:12:58 102:19	10:15:51 105:13
10:01:40 94:13	10:04:47 97:9	10:09:03 100:4	10:13:02 102:20	10:15:52 105:14
10:01:44 94:14	10:04:51 97:10	10:09:09 100:5	10:13:05 102:21,22	10:15:54 105:15
10:01:47 94:15	10:04:56 97:11	10:09:14 100:6	10:13:08 103:1	10:16:00 105:16
10:01:48 94:16	10:04:58 97:12	10:09:27 100:7	10:13:11 103:2	10:16:02 105:17
10:01:53 94:17	10:05:00 97:13	10:09:32 100:8	10:13:14 103:3	10:16:04 105:18,19
10:01:55 94:18	10:05:06 97:14	10:09:38 100:9	10:13:16 103:4	10:16:06 105:20
10:01:58 94:19	10:05:11 97:15	10:09:41 100:10	10:13:19 103:5	10:16:09 105:21
10:02:00 94:20	10:05:22 97:16	10:09:43 100:11	10:13:22 103:6	10:16:14 105:22
10:02:05 94:21	10:05:25 97:17	10:09:46 100:12	10:13:26 103:7	10:16:15 106:1
10:02:09 94:22 95:1	10:05:27 97:18	10:09:49 100:13	10:13:29 103:8	10:16:17 106:2



10:16:32 06:4	10:20:47 108:21	10:24:34 111:14	10:28:44 114:6	10:34:20 116:22
10:16:44 06:5	10:20:50 108:22	10:24:39 111:15	10:28:53 114:7	10:34:26 117:1
10:16:46 06:6	10:21:02 109:1	10:24:44 111:16	10:28:57 114:8	10:34:31 117:2
10:16:48 06:7	10:21:08 109:2	10:24:47 111:17	10:29:01 114:9	10:34:35 117:3
10:16:52 06:8	10:21:11 109:3	10:24:50 111:18	10:29:05 114:10	10:34:40 117:4
10:16:56 06:9	10:21:15 109:4	10:24:52 111:19	10:29:11 114:11	10:34:44 117:5
10:17:03 06:10	10:21:17 109:5	10:24:56 111:20	10:29:14 114:12	10:34:48 117:6
10:17:04 06:11	10:21:20 109:6,7	10:24:58 111:21	10:29:17 114:13	10:34:53 117:7
10:17:10 06:12	10:21:22 109:8	10:25:01 111:22	10:29:20 114:14	10:34:56 117:8
10:17:11 06:13	10:21:24 109:9	10:25:04 112:1	10:29:23 114:15	10:34:59 117:9
10:17:14 06:14	10:21:25 109:10	10:25:21 112:2	10:29:27 114:16	10:35:01 117:10
10:17:16 06:15	10:21:30 109:11	10:25:23 112:3	10:29:28 114:17	10:35:05 117:11
10:17:21 06:16	10:21:36 109:12	10:25:29 112:4	10:29:29 114:18	10:35:07 117:12
10:17:52 06:17	10:21:40 109:13	10:25:32 112:5	10:29:31 114:19,20	10:35:15 117:13
10:17:54 06:18	10:21:46 109:14	10:25:39 112:6	10:29:35 114:21	10:35:18 117:14
10:18:00 06:19	10:21:49 109:15	10:25:42 112:7	10:29:38 114:22	10:35:20 117:15
10:18:05 06:20	10:21:51 109:16	10:25:45 112:8	10:29:43 115:1	10:35:24 117:16
10:18:10 06:21	10:21:54 109:17	10:25:48 112:9	10:29:46 115:2	10:35:48 117:17
10:18:15 06:22 107:1	10:21:56 109:18	10:25:51 112:10	10:29:48 115:3,4	10:35:54 117:18
10:18:18 07:2	10:22:00 109:19	10:25:53 112:11	10:29:50 115:5,6	10:36:03 117:19
10:18:25 07:3	10:22:06 109:20	10:25:57 112:12	10:29:51 115:7	10:36:08 117:20
10:18:28 07:4,5	10:22:09 109:21	10:26:05 112:13	10:29:52 115:8	10:36:09 117:21
10:18:30 07:6	10:22:10 109:22	10:26:07 112:14	10:29:54 115:9	10:36:12 117:22
10:18:33 07:7	10:22:26 110:1	10:26:11 112:15	10:29:59 115:10	10:36:17 118:1
10:18:35 07:8	10:22:29 110:2	10:26:15 112:16	10:30:03 115:11	10:36:19 118:2
10:18:39 07:9	10:22:33 110:3	10:26:20 112:17	10:30:09 115:12	10:36:37 118:3
10:18:40 07:10	10:22:35 110:4	10:26:23 112:18	10:31:23 115:13	10:36:38 118:4
10:18:48 07:11	10:22:38 110:5	10:26:25 112:19	10:31:24 115:14	10:36:41 118:5
10:18:49 07:12	10:22:42 110:6	10:26:28 112:20	10:31:26 115:15	10:36:43 118:6
10:18:53 07:13,14	10:22:47 110:7	10:26:31 112:21	10:31:29 115:16	10:36:46 118:7
10:18:56 07:15	10:22:52 110:8	10:26:38 112:22	10:31:33 115:17	10:36:47 118:8
10:18:59 07:16	10:22:58 110:9	10:26:42 113:1	10:31:38 115:18	10:36:53 118:9
10:19:02 07:17	10:23:01 110:10,11	10:26:43 113:2	10:31:43 115:19	10:36:54 118:10
10:19:05 07:18	10:23:05 110:12	10:26:56 113:3	10:31:51 115:20	10:36:55 118:11
10:19:13 07:19	10:23:10 110:13	10:27:01 113:4	10:31:52 115:21	10:36:59 118:12
10:19:15 07:20	10:23:19 110:14	10:27:10 113:5	10:31:59 115:22	10:37:03 118:13
10:19:18 07:21	10:23:20 110:15	10:27:12 113:6,7	10:32:06 116:1	10:37:06 118:14
10:19:21 07:22	10:23:23 110:16	10:27:13 113:8	10:32:11 116:2	10:37:07 118:15
10:19:24 08:1	10:23:26 110:17	10:27:17 113:9	10:32:16 116:3	10:37:17 118:16
10:19:30 08:2	10:23:30 110:18	10:27:21 113:10	10:32:19 116:4	10:37:20 118:17
10:19:38 08:3	10:23:36 110:19	10:27:24 113:11	10:32:23 116:5	10:37:21 118:18
10:19:42 08:4	10:23:39 110:20	10:27:27 113:12	10:32:34 116:6	10:37:24 118:19
10:19:54 08:5	10:23:41 110:21	10:27:31 113:13	10:32:36 116:7	10:37:29 118:20
10:20:00 08:6,7	10:23:46 110:22	10:27:36 113:14	10:32:39 116:8	10:37:32 118:21
10:20:05 08:8	10:23:50 111:1	10:27:45 113:15	10:32:41 116:9	10:37:35 118:22 119:1
10:20:09 08:9	10:23:52 111:2	10:27:47 113:16	10:32:45 116:10	10:37:39 119:2
10:20:13 08:10	10:23:54 111:3	10:27:51 113:17	10:32:51 116:11	10:37:43 119:3
10:20:15 08:11	10:23:57 111:4	10:27:56 113:18	10:32:58 116:12	10:37:46 119:4
10:20:17 08:12	10:24:02 111:5	10:27:59 113:19	10:33:27 116:13	10:37:50 119:5
10:20:18 08:13	10:24:05 111:6	10:28:00 113:20	10:33:29 116:14	10:37:54 119:6
10:20:20 08:14	10:24:10 111:7	10:28:01 113:21	10:33:30 116:15	10:37:57 119:7
10:20:23 08:15	10:24:16 111:8	10:28:04 113:22	10:33:31 116:16	10:38:01 119:8
10:20:26 08:16	10:24:18 111:9	10:28:07 114:1	10:33:32 116:17	10:38:07 119:9
10:20:32 08:17	10:24:21 111:10	10:28:12 114:2	10:33:36 116:18	10:38:09 119:10
10:20:34 08:18	10:24:23 111:11	10:28:18 114:3	10:33:37 116:19	10:38:10 119:11
10:20:38 08:19	10:24:25 111:12	10:28:23 114:4	10:34:11 116:20	10:38:12 119:12,13
10:20:43 08:20	10:24:29 111:13	10:28:40 114:5	10:34:15 116:21	10:38:14 119:14,15

10:38:17 119:16	10:41:40 122:13	10:44:47 125:8	10:49:20 127:22	10:53:42 130:18
10:38:21 119:17	10:41:42 122:14	10:44:48 125:9	10:49:24 128:1	10:53:44 130:19
10:38:24 119:18	10:41:44 122:15	10:44:52 125:10	10:49:27 128:2	10:53:47 130:20
10:38:25 119:19	10:41:48 122:16	10:44:55 125:11	10:49:34 128:3	10:53:48 130:21
10:38:29 119:20	10:41:49 122:17	10:44:59 125:12	10:49:36 128:4	10:53:51 130:22
10:38:36 119:21	10:41:52 122:18	10:45:04 125:13	10:49:39 128:5	10:53:53 131:1
10:38:38 119:22	10:41:58 122:19	10:45:05 125:14	10:49:44 128:6	10:53:55 131:2
10:38:42 120:1	10:42:03 122:20,21	10:45:06 125:15	10:49:52 128:7,8	10:54:00 131:3
10:38:47 120:2	10:42:06 122:22	10:45:07 125:16	10:49:56 128:9	10:54:04 131:4
10:38:52 120:3	10:42:09 123:1	10:45:10 125:17	10:49:58 128:10	10:54:05 131:5
10:38:54 120:4	10:42:11 123:2	10:45:13 125:18	10:49:59 128:11	10:54:07 131:6
10:38:58 120:5	10:42:14 123:3	10:45:15 125:19	10:50:01 128:12	10:54:09 131:7
10:38:59 120:6	10:42:17 123:4	10:45:20 125:20	10:50:10 128:13	10:54:13 131:8,9
10:39:01 120:7,8	10:42:20 123:5	10:45:24 125:21	10:50:11 128:14	10:54:17 131:10
10:39:04 120:9	10:42:23 123:6	10:45:26 125:22 126:1	10:50:16 128:15	10:54:30 131:11
10:39:06 120:10	10:42:24 123:7	10:45:28 126:2	10:50:18 128:16	10:54:33 131:12
10:39:11 120:11	10:42:27 123:8	10:45:30 126:3	10:50:22 128:17	10:54:35 131:13
10:39:16 120:12	10:42:29 123:9	10:45:33 126:4	10:50:23 128:18	10:54:39 131:14
10:39:19 120:13	10:42:32 123:10	10:45:36 126:5	10:50:30 128:19,20	10:54:41 131:15
10:39:20 120:14	10:42:35 123:11	10:45:41 126:6	10:50:31 128:21	10:54:44 131:16
10:39:26 120:15	10:42:38 123:12	10:45:43 126:7	10:50:34 128:22	10:54:48 131:17
10:39:32 120:16	10:42:39 123:13	10:45:55 126:8	10:50:47 129:1	10:54:51 131:18
10:39:36 120:17	10:42:42 123:14	10:45:58 126:9	10:50:48 129:2	10:54:52 131:19
10:39:40 120:18	10:42:44 123:15	10:46:10 126:10	10:50:50 129:3	10:54:55 131:20
10:39:45 120:19	10:42:50 123:16	10:46:13 126:11	10:50:52 129:4	10:54:56 131:21
10:39:49 120:20,21,22	10:42:51 123:17	10:46:15 126:12	10:50:53 129:5,6	10:54:59 131:22
10:39:51 121:1,2	10:42:52 123:18	10:46:43 126:13	10:50:58 129:7	10:55:09 132:1
10:39:53 121:3	10:42:57 123:19	10:46:44 126:14	10:51:02 129:8	10:55:12 132:2
10:39:56 121:4	10:42:59 123:20	10:46:47 126:15	10:51:04 129:9	10:55:17 132:3
10:40:00 121:5,6	10:43:03 123:21	10:46:50 126:16	10:51:09 129:10	10:55:22 132:4
10:40:01 121:7	10:43:18 123:22	10:46:52 126:17	10:51:13 129:11	10:55:25 132:5
10:40:05 121:8	10:43:19 124:1	10:47:01 126:18	10:51:17 129:12	10:55:31 132:6,7
10:40:14 121:9	10:43:22 124:2	10:47:02 126:19	10:51:21 129:13	10:55:47 132:8
10:40:20 121:10	10:43:25 124:3,4	10:47:05 126:20	10:51:25 129:14	10:55:48 132:9
10:40:28 121:11	10:43:31 124:5	10:47:06 126:21	10:51:26 129:15	10:55:55 132:10
10:40:31 121:12	10:43:42 124:6	10:47:10 126:22	10:51:27 129:16,17	10:55:58 132:11
10:40:33 121:13	10:43:43 124:7	10:47:13 127:1	10:51:29 129:18	10:56:37 132:12
10:40:40 121:14	10:43:45 124:8	10:47:19 127:2	10:51:30 129:19	10:56:42 132:13
10:40:42 121:15	10:43:52 124:9	10:47:31 127:3	10:51:37 129:20	10:56:46 132:14
10:40:47 121:16	10:43:55 124:10,11	10:47:49 127:4	10:51:38 129:21	10:56:50 132:15
10:40:48 121:17	10:43:57 124:12	10:47:50 127:5	10:51:40 129:22	10:56:55 132:16,17
10:40:50 121:18	10:43:59 124:13	10:47:54 127:6	10:51:42 130:1	10:56:56 132:18
10:40:54 121:19	10:44:01 124:14	10:47:58 127:7	10:51:44 130:2	10:56:58 132:19
10:40:57 121:20	10:44:04 124:15	10:48:02 127:8	10:51:45 130:3	10:57:01 132:20
10:41:01 121:21,22	10:44:07 124:16	10:48:08 127:9	10:51:49 130:4	10:57:05 132:21
10:41:03 122:1	10:44:11 124:17	10:48:11 127:10	10:51:52 130:5	10:57:07 132:22
10:41:06 122:2	10:44:13 124:18	10:48:15 127:11	10:51:57 130:6	10:57:15 133:1
10:41:09 122:3	10:44:17 124:19	10:48:19 127:12	10:52:00 130:7	10:57:18 133:2
10:41:13 122:4	10:44:21 124:20	10:48:21 127:13	10:52:04 130:8,9	10:57:20 133:3
10:41:19 122:5	10:44:23 124:21	10:48:23 127:14	10:52:06 130:10	10:57:22 133:4
10:41:22 122:6	10:44:26 124:22	10:48:24 127:15	10:52:11 130:11	10:57:25 133:5
10:41:23 122:7	10:44:27 125:1,2	10:48:25 127:16	10:53:26 130:12	10:57:29 133:6
10:41:25 122:8	10:44:32 125:3	10:48:28 127:17	10:53:30 130:13	10:57:32 133:7
10:41:27 122:9	10:44:37 125:4	10:48:29 127:18	10:53:32 130:14	10:57:36 133:8
10:41:31 122:10	10:44:41 125:5	10:49:07 127:19	10:53:35 130:15	10:57:54 133:9
10:41:36 122:11	10:44:42 125:6	10:49:09 127:20	10:53:38 130:16	10:57:58 133:10
10:41:39 122:12	10:44:44 125:7	10:49:16 127:21	10:53:41 130:17	10:58:01 133:11

10:58:04 133:12	11:00:46 135:15	11:22:06 138:7	11:25:24 141:3	11:28:07 143:18
10:58:08 133:13	11:00:48 135:16	11:22:10 138:8	11:25:26 141:4	11:28:10 143:19
10:58:12 133:14	11:00:51 135:17	11:22:12 138:9	11:25:31 141:5	11:28:11 143:20
10:58:17 133:15	11:00:53 135:18	11:22:15 138:10	11:25:34 141:6	11:28:12 143:21
10:58:26 133:16	11:00:54 135:19	11:22:17 138:11	11:25:39 141:7	11:28:14 143:22
10:58:28 133:17	11:00:56 135:20	11:22:20 138:12	11:25:41 141:8	11:28:16 144:1
10:58:35 133:18	11:00:58 135:21	11:22:23 138:13	11:25:44 141:9	11:28:19 144:2
10:58:38 133:19	11:01:02 135:22	11:22:25 138:14	11:25:47 141:10	11:28:21 144:3
10:58:41 133:20	11:01:04 136:1	11:22:28 138:15	11:25:50 141:11	11:28:22 144:4
10:58:44 133:21	11:01:09 136:2	11:22:31 138:16	11:25:53 141:12	11:28:24 144:5
10:58:47 133:22	11:01:13 136:3	11:22:33 138:17,18	11:25:56 141:13	11:28:26 144:6
10:58:50 134:1	11:01:15 136:4	11:22:34 138:19	11:25:57 141:14	11:28:28 144:7
10:59:04 134:2	11:01:17 136:5	11:22:36 138:20	11:26:01 141:15	11:28:38 144:8
10:59:07 134:3	11:01:19 136:6	11:22:38 138:21	11:26:03 141:16	11:28:41 144:9
10:59:09 134:4,5	11:01:22 136:7	11:22:49 138:22	11:26:05 141:17	11:28:42 144:10
10:59:10 134:6,7	11:01:23 136:8	11:22:52 139:1	11:26:09 141:18	11:28:44 144:11
10:59:14 134:8,9	11:01:26 136:9	11:22:55 139:2	11:26:13 141:19	11:29:01 144:12
10:59:17 134:10	11:01:27 136:10	11:23:00 139:3	11:26:16 141:20	11:29:03 144:13,14
10:59:20 134:11	11:01:31 136:11	11:23:01 139:4	11:26:18 141:21	11:29:06 144:15
10:59:34 134:12	11:01:36 136:12	11:23:04 139:5	11:26:20 141:22	11:29:08 144:16
10:59:35 134:13	11:01:45 136:13	11:23:06 139:6	11:26:23 142:1,2	11:29:10 144:17
10:59:37 134:14	11:01:48 136:14	11:23:09 139:7	11:26:24 142:3	11:29:13 144:18
10:59:40 134:15	11:01:51 136:15	11:23:12 139:8	11:26:26 142:4	11:29:17 144:19
10:59:42 134:16	11:01:53 136:16	11:23:13 139:9	11:26:28 142:5	11:29:22 144:20
10:59:44 134:17	11:02 136:12,16	11:23:15 139:10	11:26:32 142:6	11:29:29 144:21
10:59:45 134:18	11:19:18 136:17	11:23:22 139:11	11:26:34 142:7	11:29:32 144:22
10:59:50 134:19	11:19:58 136:18	11:23:25 139:12	11:26:35 142:8	11:29:36 145:1
100,000 60:13	11:20:05 136:19	11:23:31 139:13,14	11:26:37 142:9	11:29:39 145:2
10018 15:21	11:20:08 136:20	11:23:33 139:15	11:26:41 142:10	11:29:43 145:3
10018-1405 2:4 3:18	11:20:11 136:21	11:23:38 139:16	11:26:47 142:11	11:29:47 145:4
102 14:22 66:13 311:14 312:11	11:20:13 136:22 137:1	11:23:40 139:17	11:26:52 142:12	11:29:52 145:5
1049-1070 8:13	11:20:16 137:2	11:23:41 139:18	11:26:57 142:13	11:29:55 145:6
1054 265:19	11:20:21 137:3	11:23:43 139:19	11:26:58 142:14	11:29:59 145:7
108 66:11,21	11:20:23 137:4	11:23:46 139:20	11:27:01 142:15	11:30:01 145:8
11 8:15 60:17 65:16 97:14 172:11 175:15 178:16 267:6,7,11,19 272:12	11:20:25 137:5	11:23:49 139:21	11:27:04 142:16	11:30:04 145:9
11.1 258:3	11:20:28 137:6	11:23:51 139:22	11:27:05 142:17	11:30:05 145:10
11:00:01 134:20	11:20:31 137:7	11:23:53 140:1,2	11:27:07 142:18	11:30:06 145:11
11:00:03 134:21	11:20:34 137:8,9	11:23:56 140:3,4	11:27:08 142:19	11:30:08 145:12
11:00:06 134:22	11:20:35 137:10,11	11:24:00 140:5	11:27:12 142:20	11:30:11 145:13
11:00:08 135:1	11:20:37 137:12	11:24:04 140:6	11:27:14 142:21	11:30:12 145:14
11:00:10 135:2	11:20:40 137:13	11:24:07 140:7	11:27:15 142:22	11:30:14 145:15,16
11:00:13 135:3	11:20:43 137:14	11:24:10 140:8	11:27:23 143:1	11:30:16 145:17
11:00:16 135:4	11:20:44 137:15	11:24:15 140:9	11:27:24 143:2,3	11:30:17 145:18
11:00:18 135:5	11:20:52 137:16	11:24:18 140:10	11:27:27 143:4	11:30:19 145:19
11:00:20 135:6	11:21 136:16,18	11:24:25 140:11	11:27:30 143:5	11:30:22 145:20
11:00:21 135:7	11:21:14 137:17	11:24:30 140:12	11:27:33 143:6	11:30:24 145:21
11:00:24 135:8	11:21:17 137:18	11:24:34 140:13	11:27:34 143:7	11:30:25 145:22
11:00:27 135:9	11:21:21 137:19	11:24:37 140:14	11:27:36 143:8	11:30:29 146:1
11:00:30 135:10	11:21:23 137:20	11:24:42 140:15	11:27:38 143:9	11:30:32 146:2
11:00:33 135:11	11:21:25 137:21	11:24:47 140:16	11:27:41 143:10	11:30:35 146:3
11:00:35 135:12	11:21:28 137:22	11:24:49 140:17	11:27:45 143:11	11:30:37 146:4
11:00:40 135:13	11:21:30 138:1	11:24:52 140:18	11:27:50 143:12	11:30:40 146:5
11:00:43 135:14	11:21:39 138:2	11:24:56 140:19	11:27:56 143:13	11:30:43 146:6
	11:21:50 138:3	11:25:03 140:20	11:27:58 143:14	11:30:45 146:7
	11:21:54 138:4	11:25:08 140:21	11:28:01 143:15	11:30:47 146:8
	11:21:57 138:5	11:25:13 140:22 141:1	11:28:03 143:16	11:30:50 146:9
	11:21:59 138:6	11:25:16 141:2	11:28:05 143:17	11:30:53 146:10

11:30:54 146:11	11:33:50 149:6	11:37:26 151:21	11:39:59 154:16	11:43:01 157:12
11:30:55 146:12	11:33:53 149:7	11:37:28 151:22	11:40:01 154:17	11:43:05 157:13
11:30:58 146:13	11:34:00 149:8	11:37:30 152:1	11:40:03 154:18	11:43:07 157:14
11:31:00 146:14	11:34:02 149:9	11:37:32 152:2	11:40:06 154:19	11:43:08 157:15
11:31:01 146:15	11:34:04 149:10	11:37:36 152:3	11:40:08 154:20	11:43:10 157:16
11:31:04 146:16	11:34:06 149:11	11:37:38 152:4	11:40:10 154:21	11:43:15 157:17
11:31:07 146:17	11:34:08 149:12	11:37:40 152:5,6	11:40:13 154:22	11:43:21 157:18
11:31:10 146:18	11:34:09 149:13	11:37:41 152:7	11:40:15 155:1	11:43:25 157:19
11:31:14 146:19	11:34:16 149:14	11:37:43 152:8	11:40:19 155:2	11:43:27 157:20
11:31:15 146:20	11:34:18 149:15	11:37:45 152:9	11:40:22 155:3	11:43:30 157:21
11:31:19 146:21,22	11:34:21 149:16	11:37:48 152:10	11:40:24 155:4	11:43:32 157:22
11:31:25 147:1	11:34:24 149:17	11:37:50 152:11	11:40:26 155:5	11:43:34 158:1
11:31:28 147:2	11:34:25 149:18	11:37:52 152:12	11:40:29 155:6	11:43:38 158:2
11:31:30 147:3	11:34:54 149:19	11:37:54 152:13	11:40:31 155:7	11:43:41 158:3
11:31:34 147:4	11:34:58 149:20	11:37:58 152:14	11:40:32 155:8	11:43:42 158:4
11:31:37 147:5	11:35:01 149:21	11:37:59 152:15,16	11:40:35 155:9	11:43:43 158:5
11:31:40 147:6	11:35:03 149:22	11:38:00 152:17	11:40:37 155:10,11	11:43:46 158:6
11:31:44 147:7	11:35:07 150:1	11:38:02 152:18	11:40:40 155:12	11:43:50 158:7
11:31:46 147:8	11:35:10 150:2	11:38:05 152:19,20	11:40:42 155:13	11:43:53 158:8
11:31:48 147:9	11:35:13 150:3	11:38:11 152:21	11:40:43 155:14	11:44:00 158:9
11:31:49 147:10,11	11:35:15 150:4,5	11:38:13 152:22	11:40:46 155:15	11:44:03 158:10
11:31:50 147:12	11:35:18 150:6	11:38:16 153:1	11:40:49 155:16	11:44:08 158:11,12
11:31:53 147:13	11:35:19 150:7	11:38:19 153:2	11:40:53 155:17	11:44:10 158:13
11:31:55 147:14	11:35:21 150:8	11:38:23 153:3	11:40:59 155:18,19	11:44:13 158:14
11:31:56 147:15	11:35:24 150:9,10	11:38:26 153:4	11:41:07 155:20	11:44:15 158:15
11:31:59 147:16	11:35:26 150:11	11:38:31 153:5	11:41:10 155:21	11:44:17 158:16
11:32:01 147:17	11:35:28 150:12	11:38:34 153:6	11:41:12 155:22	11:44:19 158:17
11:32:04 147:18	11:35:30 150:13	11:38:36 153:7	11:41:13 156:1	11:44:23 158:18
11:32:07 147:19	11:35:32 150:14	11:38:39 153:8	11:41:14 156:2,3	11:44:25 158:19
11:32:09 147:20	11:35:35 150:15	11:38:40 153:9	11:41:17 156:4	11:44:27 158:20
11:32:10 147:21	11:35:37 150:16	11:38:43 153:10	11:41:22 156:5	11:44:32 158:21
11:32:14 147:22	11:35:40 150:17	11:38:44 153:11	11:41:26 156:6	11:44:41 158:22
11:32:19 148:1	11:35:44 150:18	11:38:50 153:12	11:41:30 156:7	11:44:44 159:1
11:32:23 148:2	11:35:47 150:19	11:38:53 153:13	11:41:35 156:8	11:44:48 159:2
11:32:26 148:3	11:35:52 150:20	11:38:56 153:14	11:41:39 156:9	11:44:53 159:3
11:32:33 148:4	11:35:53 150:21	11:38:59 153:15	11:41:42 156:10	11:44:55 159:4
11:32:35 148:5	11:35:57 150:22	11:39:01 153:16	11:41:44 156:11	11:44:59 159:5
11:32:39 148:6	11:36:01 151:1	11:39:05 153:17	11:41:48 156:12	11:45:01 159:6
11:32:42 148:7	11:36:15 151:2	11:39:08 153:18,19	11:41:50 156:13	11:45:05 159:7
11:32:46 148:8	11:36:17 151:3	11:39:09 153:20	11:41:58 156:14	11:45:06 159:8
11:32:50 148:9	11:36:19 151:4	11:39:10 153:21	11:42:02 156:15,16	11:45:08 159:9
11:32:51 148:10	11:36:22 151:5	11:39:13 153:22	11:42:04 156:17	11:45:11 159:10
11:33:04 148:11	11:36:30 151:6	11:39:17 154:1	11:42:06 156:18	11:45:13 159:11
11:33:08 148:12	11:36:33 151:7	11:39:19 154:2	11:42:11 156:19	11:45:17 159:12
11:33:11 148:13	11:36:39 151:8	11:39:22 154:3	11:42:16 156:20	11:45:19 159:13
11:33:14 148:14,15	11:36:43 151:9	11:39:25 154:4	11:42:18 156:21	11:45:23 159:14
11:33:18 148:16,17	11:36:54 151:10	11:39:28 154:5	11:42:20 156:22	11:45:26 159:15
11:33:21 148:18	11:36:57 151:11	11:39:37 154:6	11:42:23 157:1	11:45:28 159:16
11:33:24 148:19	11:37:02 151:12	11:39:39 154:7	11:42:29 157:2	11:45:29 159:17
11:33:27 148:20	11:37:04 151:13	11:39:41 154:8	11:42:35 157:3	11:45:32 159:18
11:33:34 148:21	11:37:05 151:14	11:39:44 154:9	11:42:39 157:4	11:45:37 159:19
11:33:36 148:22	11:37:07 151:15	11:39:45 154:10	11:42:42 157:5	11:45:40 159:20
11:33:40 149:1	11:37:08 151:16	11:39:46 154:11	11:42:47 157:6,7	11:45:46 159:21
11:33:42 149:2	11:37:10 151:17	11:39:48 154:12	11:42:52 157:8	11:45:50 159:22
11:33:43 149:3	11:37:13 151:18	11:39:49 154:13	11:42:53 157:9	11:45:54 160:1
11:33:46 149:4	11:37:15 151:19	11:39:51 154:14	11:42:55 157:10	11:45:56 160:2
11:33:48 149:5	11:37:23 151:20	11:39:55 154:15	11:42:58 157:11	11:45:59 160:3

11:46:03 160:4	11:49:32 162:19	11:52:08 165:11	11:55:23 168:5	11:58:28 171:1
11:46:07 160:5	11:49:35 162:20	11:52:12 165:12	11:55:25 168:6,7	11:58:30 171:2
11:46:11 160:6	11:49:36 162:21	11:52:13 165:13	11:55:28 168:8	11:58:33 171:3
11:46:16 160:7	11:49:39 162:22	11:52:14 165:14	11:55:32 168:9	11:58:35 171:4
11:46:20 160:8	11:49:42 163:1	11:52:19 165:15	11:55:35 168:10	11:58:38 171:5
11:46:24 160:9,10	11:49:47 163:2	11:52:21 165:16	11:55:38 168:11	11:58:39 171:6
11:46:26 160:11	11:49:52 163:3	11:52:23 165:17	11:55:44 168:12,13	11:58:42 171:7
11:46:29 160:12	11:49:55 163:4	11:52:26 165:18	11:55:46 168:14	11:58:44 171:8
11:46:31 160:13	11:49:58 163:5	11:52:27 165:19	11:55:52 168:15	11:58:48 171:9
11:46:33 160:14	11:50:01 163:6	11:52:28 165:20,21	11:55:55 168:16	11:58:52 171:10
11:46:37 160:15	11:50:03 163:7	11:52:30 165:22	11:55:58 168:17	11:58:56 171:11
11:46:43 160:16	11:50:05 163:8	11:52:35 166:1	11:56:00 168:18	11:58:58 171:12
11:46:45 160:17	11:50:07 163:9	11:52:40 166:2	11:56:01 168:19	11:59:04 171:13
11:46:48 160:18	11:50:10 163:10	11:52:42 166:3	11:56:06 168:20	11:59:07 171:14
11:46:52 160:19	11:50:15 163:11	11:52:53 166:4	11:56:07 168:21	11:59:10 171:15
11:46:55 160:20	11:50:20 163:12	11:52:54 166:5	11:56:12 168:22	11:59:12 171:16
11:46:59 160:21	11:50:23 163:13	11:52:55 166:6	11:56:14 169:1	11:59:16 171:17
11:47:02 160:22	11:50:31 163:14	11:53:02 166:7	11:56:15 169:2	11:59:19 171:18,19
11:47:04 161:1	11:50:33 163:15	11:53:05 166:8	11:56:18 169:3	11:59:23 171:20
11:47:08 161:2	11:50:35 163:16	11:53:07 166:9	11:56:19 169:4	11:59:27 171:21
11:47:12 161:3	11:50:38 163:17	11:53:14 166:10	11:56:21 169:5	11:59:30 171:22 172:1
11:47:13 161:4	11:50:42 163:18	11:53:20 166:11	11:56:25 169:6	11:59:31 172:2,3
11:47:16 161:5	11:50:43 163:19	11:53:24 166:12	11:56:29 169:7	11:59:32 172:4
11:47:19 161:6	11:50:47 163:20	11:53:27 166:13	11:56:31 169:8	11:59:36 172:5
11:47:21 161:7	11:50:49 163:21	11:53:29 166:14	11:56:36 169:9	11:59:37 172:6
11:47:24 161:8	11:50:51 163:22	11:53:30 166:15,16	11:56:40 169:10	11:59:39 172:7
11:47:29 161:9	11:50:56 164:1	11:53:34 166:17	11:56:45 169:11	11:59:42 172:8
11:47:32 161:10	11:50:57 164:2	11:53:36 166:18	11:56:53 169:12	11:59:45 172:9
11:47:42 161:11	11:50:58 164:3	11:53:42 166:19	11:56:58 169:13	11:59:46 172:10
11:47:44 161:12	11:51:00 164:4	11:53:49 166:20	11:57:02 169:14	11:59:48 172:11
11:47:46 161:13	11:51:01 164:5	11:53:54 166:21	11:57:04 169:15,16	11:59:52 172:12,13
11:47:56 161:14	11:51:03 164:6	11:54:00 166:22	11:57:08 169:17	11:59:53 172:14
11:47:58 161:15	11:51:06 164:7	11:54:08 167:1	11:57:10 169:18	11:59:56 172:15
11:48:02 161:16	11:51:09 164:8	11:54:12 167:2	11:57:13 169:19	117 67:5
11:48:07 161:17	11:51:10 164:9	11:54:16 167:3	11:57:16 169:20	12 8:18 9:4 11:11 60:19
11:48:08 161:18	11:51:11 164:10	11:54:22 167:4	11:57:20 169:21	63:22 88:22 107:1
11:48:10 161:19	11:51:12 164:11	11:54:24 167:5	11:57:27 169:22	127:2 179:20 186:17
11:48:13 161:20	11:51:15 164:12	11:54:26 167:6	11:57:35 170:1	267:8,15 279:11,12
11:48:16 161:21	11:51:18 164:13	11:54:31 167:7	11:57:38 170:2	279:18,22 280:2
11:48:19 161:22	11:51:19 164:14	11:54:32 167:8	11:57:41 170:3	288:2,11
11:48:22 162:1	11:51:20 164:15	11:54:36 167:9,10	11:57:43 170:4	12:00:00 172:16
11:48:27 162:2	11:51:21 164:16	11:54:37 167:11	11:57:45 170:5	12:00:03 172:17
11:48:29 162:3	11:51:22 164:17	11:54:38 167:12	11:57:48 170:6	12:00:06 172:18
11:48:31 162:4	11:51:28 164:18	11:54:42 167:13	11:57:51 170:7	12:00:10 172:19
11:48:41 162:5	11:51:34 164:19	11:54:45 167:14	11:57:55 170:8	12:00:15 172:20
11:48:46 162:6	11:51:36 164:20	11:54:48 167:15	11:57:57 170:9	12:00:23 172:21
11:48:48 162:7	11:51:39 164:21	11:54:50 167:16	11:58:01 170:10	12:00:24 172:22
11:48:54 162:8	11:51:42 164:22	11:54:54 167:17	11:58:06 170:11	12:00:29 173:1,2
11:49:00 162:9	11:51:43 165:1	11:54:56 167:18	11:58:12 170:12	12:00:34 173:3
11:49:08 162:10	11:51:45 165:2	11:54:58 167:19	11:58:14 170:13	12:00:36 173:4
11:49:11 162:11	11:51:47 165:3	11:55:02 167:20	11:58:16 170:14	12:00:42 173:5
11:49:16 162:12	11:51:50 165:4	11:55:04 167:21	11:58:18 170:15,16	12:00:48 173:6
11:49:17 162:13	11:51:53 165:5	11:55:09 167:22	11:58:20 170:17	12:00:53 173:7
11:49:20 162:14	11:51:55 165:6	11:55:12 168:1	11:58:21 170:18	12:00:56 173:8
11:49:21 162:15	11:52:00 165:7	11:55:16 168:2	11:58:23 170:19	12:01:00 173:9
11:49:24 162:16,17	11:52:03 165:8	11:55:18 168:3	11:58:26 170:20,21	12:01:01 173:10
11:49:29 162:18	11:52:06 165:9,10	11:55:20 168:4	11:58:27 170:22	12:01:08 173:11

12:01:10 173:12	12:04:12 176:6	12:08:36 178:21	12:11:40 181:19	12:14:23 184:17
12:01:14 173:13	12:04:15 176:7	12:08:39 178:22	12:11:43 181:20	12:14:24 184:18
12:01:15 173:14	12:04:20 176:8	12:08:44 179:1	12:11:50 181:21	12:14:26 184:19
12:01:20 173:15	12:04:24 176:9	12:08:47 179:2	12:11:52 181:22	12:14:32 184:20
12:01:23 173:16	12:04:26 176:10	12:08:51 179:3	12:11:53 182:1	12:14:34 184:21
12:01:27 173:17	12:04:29 176:11	12:08:54 179:4	12:11:57 182:2	12:14:36 184:22
12:01:28 173:18	12:04:34 176:12	12:08:56 179:5	12:12:00 182:3	12:14:37 185:1
12:01:30 173:19	12:04:36 176:13	12:08:59 179:6,7	12:12:01 182:4	12:14:39 185:2
12:01:33 173:20	12:04:38 176:14	12:09:00 179:8	12:12:03 182:5	12:14:41 185:3,4
12:01:37 173:21	12:04:40 176:15	12:09:02 179:9	12:12:05 182:6	12:14:45 185:5
12:01:40 173:22	12:04:41 176:16	12:09:05 179:10	12:12:08 182:7	12:14:48 185:6
12:01:41 174:1	12:04:44 176:17	12:09:11 179:11	12:12:09 182:8	12:14:49 185:7
12:01:44 174:2	12:04:47 176:18	12:09:14 179:12	12:12:11 182:9	12:14:51 185:8
12:01:48 174:3	12:04:49 176:19	12:09:15 179:13	12:12:13 182:10	12:14:52 185:9
12:01:53 174:4	12:04:52 176:20	12:09:18 179:14	12:12:15 182:11	12:14:56 185:10
12:01:55 174:5	12:04:56 176:21	12:09:21 179:15	12:12:17 182:12	12:15:00 185:11,12
12:01:58 174:6	12:04:59 176:22	12:09:25 179:16	12:12:20 182:13	12:15:04 185:13
12:01:59 174:7	12:05:03 177:1	12:09:28 179:17	12:12:24 182:14	12:15:07 185:14,15
12:02:02 174:8	12:05:06 177:2	12:09:32 179:18	12:12:29 182:15	12:15:11 185:16
12:02:06 174:9	12:05:11 177:3	12:09:34 179:19	12:12:32 182:16	12:15:12 185:17,18
12:02:08 174:10	12:05:14 177:4	12:09:36 179:20	12:12:36 182:17	12:15:15 185:19,20,21
12:02:09 174:11	12:05:17 177:5,6	12:09:40 179:21	12:12:38 182:18	12:15:20 185:22
12:02:12 174:12	12:05:21 177:7	12:09:44 179:22	12:12:42 182:19,20	12:15:27 186:1,2
12:02:17 174:13	12:05:26 177:8	12:09:48 180:1	12:12:45 182:21	12:15:32 186:3
12:02:18 174:14	12:05:29 177:9	12:09:49 180:2,3	12:12:48 182:22	12:15:36 186:4
12:02:19 174:15	12:07:01 177:10	12:09:50 180:4	12:12:50 183:1	12:15:39 186:5
12:02:21 174:16,17	12:07:04 177:11	12:09:54 180:5	12:12:53 183:2	12:15:42 186:6,7
12:02:25 174:18	12:07:06 177:12	12:10:00 180:6	12:12:57 183:3	12:15:46 186:8
12:02:26 174:19,20	12:07:09 177:13	12:10:03 180:7	12:13:00 183:4	12:15:47 186:9,10
12:02:27 174:21	12:07:12 177:14	12:10:06 180:8,9	12:13:04 183:5	12:15:50 186:11
12:02:30 174:22	12:07:14 177:15	12:10:07 180:10	12:13:05 183:6	12:15:52 186:12
12:02:31 175:1	12:07:17 177:16	12:10:11 180:11	12:13:06 183:7	12:15:55 186:13
12:02:32 175:2	12:07:23 177:17	12:10:17 180:12	12:13:07 183:8	12:15:56 186:14
12:02:36 175:3	12:07:26 177:18	12:10:24 180:13	12:13:09 183:9	12:15:59 186:15
12:02:37 175:4	12:07:27 177:19	12:10:27 180:14,15	12:13:12 183:10	12:16:00 186:16
12:02:41 175:5	12:07:30 177:20	12:10:40 180:16	12:13:16 183:11	12:16:03 186:17
12:02:45 175:6	12:07:35 177:21	12:10:44 180:17	12:13:17 183:12	12:16:09 186:18
12:02:46 175:7	12:07:37 177:22	12:10:51 180:18	12:13:19 183:13	12:16:20 186:19
12:02:47 175:8	12:07:42 178:1	12:10:52 180:19	12:13:24 183:14,15	12:16:23 186:20
12:02:49 175:9	12:07:45 178:2	12:10:53 180:20	12:13:28 183:16	12:16:26 186:21
12:02:52 175:10	12:07:48 178:3	12:11:02 180:21	12:13:31 183:22	12:16:27 186:22 187:1
12:02:53 175:11	12:07:49 178:4	12:11:06 180:22	12:13:33 184:1	12:16:29 187:2
12:03:02 175:12	12:07:52 178:5	12:11:09 181:1	12:13:35 184:2	12:16:32 187:3
12:03:04 175:13	12:07:53 178:6	12:11:13 181:2	12:13:39 184:3	12:16:35 187:4
12:03:15 175:14	12:07:56 178:7	12:11:14 181:3,4	12:13:41 184:4	12:16:38 187:5
12:03:44 175:15	12:07:58 178:8	12:11:15 181:5	12:13:44 184:5	12:16:41 187:6
12:03:47 175:16	12:07:59 178:9	12:11:20 181:6	12:13:48 184:6	12:16:42 187:7
12:03:48 175:17	12:08:02 178:10	12:11:21 181:7	12:13:51 184:7	12:16:43 187:8,9
12:03:50 175:18	12:08:07 178:11	12:11:24 181:8	12:13:57 184:8	12:16:47 187:10
12:03:54 175:19	12:08:12 178:12	12:11:25 181:9	12:14:00 184:9	12:16:50 187:11
12:03:56 175:20	12:08:14 178:13	12:11:26 181:10	12:14:03 184:10	12:16:52 187:12
12:03:59 175:21	12:08:17 178:14	12:11:27 181:11	12:14:07 184:11	12:16:54 187:13
12:04:02 175:22	12:08:19 178:15	12:11:29 181:12	12:14:10 184:12	12:16:58 187:14
12:04:05 176:1	12:08:23 178:16	12:11:32 181:13	12:14:11 184:13	12:17:03 187:15
12:04:07 176:2	12:08:27 178:17	12:11:34 181:14	12:14:14 184:14	12:17:06 187:16
12:04:08 176:3,4	12:08:29 178:18,19	12:11:36 181:15,16	12:14:17 184:15	12:17:09 187:17
12:04:09 176:5	12:08:33 178:20	12:11:38 181:17,18	12:14:21 184:16	12:17:12 187:18

12:17:16 187:19	12:20:12 190:12	12:23:11 193:5	12:26:41 196:6	12:30:13 199:5,6
12:17:20 187:20	12:20:17 190:13	12:23:16 193:6	12:26:44 196:7	12:30:15 199:7
12:17:31 187:21	12:20:23 190:14	12:23:18 193:7	12:26:50 196:8	12:30:21 199:8
12:17:32 187:22	12:20:24 190:15	12:23:28 193:8	12:26:51 196:9	12:30:22 199:9
12:17:37 188:1	12:20:26 190:16	12:23:34 193:9	12:26:57 196:10	12:30:25 199:10
12:17:39 188:2	12:20:29 190:17	12:23:37 193:10	12:26:58 196:11	12:30:28 199:11,12
12:17:40 188:3	12:20:33 190:18	12:23:39 193:11	12:26:59 196:12	12:30:30 199:13
12:17:43 188:4	12:20:36 190:19	12:23:43 193:12	12:27:01 196:13	12:30:35 199:14
12:17:48 188:5	12:20:39 190:20	12:23:56 193:13	12:27:03 196:14	12:30:38 199:15
12:17:52 188:6	12:20:42 190:21	12:23:58 193:14,15	12:27:06 196:15	12:30:41 199:16
12:17:55 188:7	12:20:47 190:22	12:23:59 193:16	12:27:10 196:16	12:30:44 199:17
12:17:57 188:8	12:20:55 191:1	12:24:03 193:17	12:27:13 196:17	12:30:47 199:18
12:17:59 188:9	12:20:57 191:2	12:24:23 193:18	12:27:14 196:18	12:30:51 199:19
12:18:02 188:10	12:20:59 191:3	12:24:24 193:19	12:27:19 196:19	12:31:00 199:20
12:18:04 188:11,12	12:21:03 191:4	12:24:28 193:20	12:27:25 196:20	12:31:02 199:21
12:18:05 188:13	12:21:05 191:5	12:24:30 193:21,22	12:27:32 196:21,22	12:31:06 199:22
12:18:07 188:14,15	12:21:11 191:6	12:24:33 194:1	12:27:33 197:1,2	12:31:09 200:1
12:18:08 188:16	12:21:16 191:7	12:24:39 194:2	12:27:37 197:3	12:31:13 200:2
12:18:18 188:17	12:21:17 191:8	12:24:40 194:3	12:27:42 197:4	12:31:34 200:3
12:18:21 188:18	12:21:21 191:9	12:24:43 194:4	12:27:46 197:5	12:31:37 200:4
12:18:23 188:19	12:21:22 191:10	12:24:44 194:5	12:27:49 197:6	12:31:41 200:5
12:18:27 188:20	12:21:27 191:11	12:24:45 194:6	12:27:51 197:7	12:31:46 200:6
12:18:29 188:21	12:21:31 191:12	12:24:47 194:7,8	12:27:58 197:8	12:31:48 200:7
12:18:31 188:22	12:21:33 191:13	12:24:49 194:9,10	12:28:06 197:9	12:31:51 200:8
12:18:35 189:1	12:21:35 191:14	12:24:52 194:11,12	12:28:07 197:10	12:31:55 200:9
12:18:37 189:2	12:21:39 191:15	12:24:55 194:13	12:28:09 197:11	12:31:57 200:10
12:18:39 189:3	12:21:41 191:16	12:24:56 194:14	12:28:13 197:12	12:32:00 200:11
12:18:42 189:4	12:21:44 191:17	12:24:57 194:15	12:28:16 197:13,14	12:32:06 200:12
12:18:43 189:5	12:21:47 191:18	12:24:58 194:16	12:28:21 197:15,16	12:32:13 200:13
12:18:45 189:6	12:21:54 191:19	12:25:02 194:17	12:28:22 197:17,18,19	12:32:18 200:14
12:18:47 189:7	12:21:56 191:20	12:25:05 194:18,19	12:28:40 197:20	12:32:24 200:15
12:18:48 189:8	12:22:00 191:21,22	12:25:06 194:20	12:28:42 197:21,22	12:32:29 200:16
12:18:51 189:9	12:22:03 192:1	12:25:08 194:21	12:28:45 198:1	12:32:31 200:17
12:18:56 189:10	12:22:08 192:2	12:25:13 194:22	12:28:50 198:2	12:32:33 200:18,19
12:18:59 189:11	12:22:14 192:3	12:25:15 195:1	12:28:52 198:3	12:32:35 200:20,21
12:19:02 189:12	12:22:16 192:4	12:25:16 195:2,3	12:28:53 198:4	12:32:37 200:22 201:1
12:19:03 189:13	12:22:18 192:5	12:25:19 195:4	12:28:56 198:5	12:32:41 201:2
12:19:05 189:14	12:22:19 192:6	12:25:31 195:5	12:28:58 198:6	12:32:42 201:3
12:19:09 189:15	12:22:29 192:7	12:25:34 195:6,7	12:29:01 198:7	12:32:46 201:4
12:19:15 189:16	12:22:30 192:8	12:25:36 195:8,9	12:29:03 198:8	12:32:48 201:5
12:19:19 189:17	12:22:31 192:9	12:25:38 195:10	12:29:06 198:9	12:32:50 201:6
12:19:21 189:18	12:22:33 192:10	12:25:42 195:11	12:29:10 198:10	12:32:52 201:7
12:19:25 189:19	12:22:35 192:11	12:25:43 195:12	12:29:13 198:11	12:32:53 201:8
12:19:29 189:20	12:22:36 192:12	12:25:45 195:13	12:29:15 198:12	12:32:55 201:9
12:19:33 189:21	12:22:40 192:13	12:25:47 195:14,15	12:29:18 198:13,14	12:32:58 201:10,11
12:19:36 189:22	12:22:44 192:14	12:25:52 195:16	12:29:20 198:15	12:33:00 201:12
12:19:41 190:1	12:22:48 192:15	12:25:53 195:17	12:29:22 198:16	12:33:02 201:13
12:19:44 190:2	12:22:49 192:16	12:25:55 195:18	12:29:29 198:17	12:33:03 201:14
12:19:46 190:3	12:22:55 192:17	12:26:03 195:19	12:29:35 198:18	12:33:11 201:15
12:19:51 190:4	12:22:57 192:18	12:26:14 195:20	12:29:39 198:19	12:33:16 201:16
12:19:52 190:5	12:22:58 192:19	12:26:20 195:21	12:29:43 198:20	12:33:18 201:17
12:19:53 190:6	12:22:59 192:20	12:26:23 195:22	12:29:46 198:21	12:33:19 201:18
12:19:56 190:7	12:23:03 192:21	12:26:27 196:1	12:29:48 198:22	12:33:24 201:19
12:20:00 190:8	12:23:06 192:22 193:1	12:26:29 196:2	12:29:50 199:1	12:33:28 201:20
12:20:04 190:9	193:2	12:26:32 196:3	12:29:53 199:2	12:33:32 201:21
12:20:08 190:10	12:23:07 193:3	12:26:36 196:4	12:29:54 199:3	12:33:35 201:22
12:20:10 190:11	12:23:10 193:4	12:26:39 196:5	12:30:05 199:4	12:33:39 202:1

12:33:46 202:2	12:36:39 205:1	13:29:05 207:15	13:32:50 210:15	13:39:43 213:7
12:33:48 202:3	12:36:42 205:2	13:29:07 207:16	13:32:53 210:16	13:39:51 213:8
12:33:52 202:4	12:36:44 205:3	13:29:09 207:17	13:32:55 210:17	13:39:53 213:9
12:33:55 202:5	12:37 204:21 205:3	13:29:19 207:18	13:32:59 210:18	13:39:54 213:10
12:33:57 202:6	120 8:17	13:29:20 207:19	13:33:04 210:19	13:39:55 213:11
12:34:02 202:7	125-171 8:8	13:29:22 207:20,21	13:33:08 210:20	13:40:00 213:12
12:34:04 202:8	13 9:12 98:8 106:21	13:29:24 207:22	13:33:10 210:21	13:40:05 213:13,14
12:34:07 202:9	195:4 202:18 243:18	13:29:27 208:1	13:33:12 210:22	13:40:09 213:15
12:34:10 202:10	267:22 280:18,19	13:29:30 208:2	13:33:16 211:1	13:40:11 213:16
12:34:13 202:11	281:2,5,7	13:29:34 208:3	13:33:21 211:2	13:40:13 213:17
12:34:17 202:12,13	13:25:53 205:4	13:29:37 208:4	13:33:31 211:3	13:40:27 213:18
12:34:20 202:14	13:25:55 205:5	13:29:40 208:5	13:33:32 211:4	13:40:28 213:19
12:34:22 202:15,16	13:26:05 205:6	13:29:45 208:6	13:33:35 211:5,6	13:40:31 213:20
12:34:25 202:17	13:26:07 205:7	13:29:48 208:7	13:33:36 211:7	13:40:34 213:21
12:34:27 202:18	13:26:10 205:8	13:30:13 208:8,9	13:33:41 211:8	13:40:36 213:22
12:34:32 202:19	13:26:12 205:9,10	13:30:14 208:10,11	13:33:44 211:9	13:40:40 214:1
12:34:44 202:20	13:26:13 205:11	13:30:18 208:12	13:33:45 211:10	13:40:44 214:2
12:34:47 202:21	13:26:14 205:12	13:30:21 208:13	13:33:48 211:11	13:40:48 214:3
12:34:48 202:22	13:26:17 205:13	13:30:22 208:14	13:33:51 211:12	13:40:51 214:4
12:34:49 203:1	13:26:22 205:14	13:30:23 208:15	13:33:52 211:13	13:40:54 214:5
12:34:52 203:2	13:26:27 205:15	13:30:30 208:16	13:33:54 211:14	13:40:57 214:6
12:34:55 203:3,4	13:26:29 205:16	13:30:34 208:17	13:33:56 211:15	13:41:00 214:7
12:34:56 203:5	13:26:31 205:17	13:30:41 208:18	13:33:58 211:16	13:41:01 214:8
12:35:02 203:6	13:26:32 205:18	13:30:42 208:19	13:34:00 211:17	13:41:04 214:9
12:35:06 203:7	13:26:34 205:19	13:30:47 208:20	13:34:05 211:18	13:41:08 214:10
12:35:14 203:8	13:26:40 205:20	13:30:50 208:21	13:34:10 211:19	13:41:09 214:11
12:35:18 203:9	13:26:41 205:21,22	13:30:54 208:22	13:34:14 211:20	13:41:11 214:12
12:35:19 203:10	13:27:04 206:1	13:30:56 209:1	13:34:18 211:21	13:41:16 214:13
12:35:20 203:11	13:27:05 206:2,3	13:31:03 209:2	13:34:19 211:22	13:41:19 214:14
12:35:22 203:12	13:27:09 206:4	13:31:05 209:3	13:34:21 212:1	13:41:22 214:15,16
12:35:27 203:13	13:27:12 206:5,6	13:31:08 209:4	13:34:22 212:2	13:41:23 214:17
12:35:28 203:14	13:27:16 206:7	13:31:12 209:5,6	13:34:25 212:3	13:41:24 214:18
12:35:32 203:15	13:27:17 206:8,9	13:31:15 209:7,8	13:34:30 212:4	13:41:27 214:19
12:35:33 203:16	13:27:26 206:10	13:31:18 209:9	13:34:34 212:5	13:41:29 214:20
12:35:34 203:17	13:27:30 206:11	13:31:23 209:10	13:34:39 212:6	13:41:32 214:21
12:35:36 203:18	13:27:36 206:12	13:31:25 209:11	13:34:50 212:7	13:41:33 214:22
12:35:39 203:19	13:27:37 206:13	13:31:26 209:12	13:34:53 212:8	13:41:37 215:1
12:35:42 203:20,21	13:27:51 206:14	13:31:33 209:13	13:34:55 212:9	13:41:39 215:2,3,4
12:35:45 203:22	13:27:52 206:15	13:31:38 209:14	13:34:56 212:10	13:41:50 215:5,6
12:35:46 204:1	13:27:57 206:16	13:31:40 209:15	13:35:00 212:11	13:41:51 215:7
12:35:47 204:2	13:27:59 206:17	13:31:42 209:16	13:35:04 212:12	13:41:54 215:8
12:35:49 204:3	13:28:00 206:18	13:31:43 209:17	13:35:18 212:13	13:41:57 215:9
12:35:51 204:4,5	13:28:03 206:19	13:31:47 209:18	13:38:42 212:14	13:42:00 215:10
12:35:53 204:6	13:28:08 206:20	13:31:50 209:19	13:38:43 212:15	13:42:07 215:11
12:35:55 204:7	13:28:14 206:21	13:31:53 209:20	13:38:47 212:16	13:42:09 215:12
12:36:01 204:8	13:28:17 206:22 207:1	13:31:56 209:21	13:38:50 212:17	13:42:12 215:13
12:36:02 204:9	13:28:19 207:2	13:31:59 209:22	13:38:54 212:18	13:42:15 215:14
12:36:06 204:10	13:28:26 207:3	13:32:00 210:1	13:38:58 212:19	13:42:18 215:15
12:36:09 204:11	13:28:31 207:4	13:32:03 210:2	13:38:59 212:20	13:42:21 215:16
12:36:11 204:12	13:28:34 207:5	13:32:06 210:3	13:39:01 212:21	13:42:24 215:17
12:36:12 204:13	13:28:39 207:6	13:32:09 210:4,5	13:39:04 212:22	13:42:26 215:18
12:36:13 204:14,15	13:28:43 207:7	13:32:13 210:6	13:39:07 213:1	13:42:30 215:19
12:36:17 204:16,17	13:28:49 207:8,9,10	13:32:15 210:7	13:39:11 213:2	13:42:35 215:20
12:36:18 204:18	13:28:54 207:11	13:32:18 210:8,9	13:39:21 213:3	13:42:38 215:21,22
12:36:21 204:19,20	13:28:57 207:12	13:32:44 210:10,11,12	13:39:25 213:4	13:42:40 216:1
12:36:24 204:21	13:28:58 207:13	210:13	13:39:29 213:5	13:42:45 216:2
12:36:32 204:22	13:29:01 207:14	13:32:47 210:14	13:39:32 213:6	13:42:49 216:3



13:42:54 216:4	13:46:08 218:22	13:49:00 221:14	13:52:29 224:9	13:57:15 227:3
13:42:56 216:5	13:46:11 219:1	13:49:02 221:15	13:52:31 224:10	13:57:19 227:4
13:43:00 216:6	13:46:17 219:2	13:49:22 221:16	13:52:33 224:11	13:57:26 227:5
13:43:04 216:7	13:46:20 219:3	13:49:23 221:17	13:54:00 224:12	13:57:28 227:6
13:43:05 216:8	13:46:24 219:4	13:49:25 221:18	13:54:04 224:13	13:57:30 227:7
13:43:10 216:9	13:46:27 219:5	13:49:30 221:19	13:54:10 224:14	13:57:33 227:8
13:43:22 216:10	13:46:30 219:6	13:49:33 221:20,21	13:54:14 224:15	13:57:34 227:9
13:43:25 216:11	13:46:34 219:7,8	13:49:34 221:22	13:54:18 224:16	13:57:38 227:10
13:43:28 216:12	13:46:38 219:9	13:49:38 222:1	13:54:21 224:17	13:57:47 227:11
13:43:32 216:13	13:46:41 219:10	13:49:45 222:2,3	13:54:25 224:18	13:57:49 227:12
13:43:35 216:14	13:46:44 219:11	13:49:48 222:4	13:54:29 224:19	13:57:53 227:13
13:43:38 216:15	13:46:57 219:12	13:49:50 222:5	13:54:32 224:20	13:57:58 227:14
13:43:39 216:16	13:46:58 219:13	13:49:53 222:6	13:54:34 224:21	13:58:03 227:15
13:43:41 216:17	13:47:01 219:14	13:49:57 222:7	13:54:37 224:22	13:58:10 227:16
13:43:44 216:18	13:47:04 219:15	13:50:22 222:8	13:54:40 225:1	13:58:14 227:17
13:43:51 216:19	13:47:06 219:16	13:50:25 222:9	13:54:43 225:2	13:58:16 227:18
13:43:53 216:20	13:47:08 219:17	13:50:28 222:10	13:54:46 225:3	13:58:20 227:19,20
13:43:56 216:21	13:47:12 219:18	13:50:29 222:11	13:54:52 225:4	13:58:23 227:21
13:43:58 216:22	13:47:14 219:19	13:50:33 222:12	13:54:57 225:5	13:58:26 227:22
13:44:00 217:1	13:47:18 219:20	13:50:38 222:13	13:55:01 225:6	13:58:29 228:1
13:44:03 217:2	13:47:22 219:21	13:50:41 222:14	13:55:04 225:7	13:58:33 228:2
13:44:08 217:3	13:47:23 219:22	13:50:44 222:15	13:55:10 225:8	13:58:35 228:3
13:44:10 217:4	13:47:24 220:1	13:50:47 222:16	13:55:15 225:9	13:58:37 228:4
13:44:12 217:5,6	13:47:29 220:2	13:50:50 222:17	13:55:18 225:10	13:58:40 228:5
13:44:17 217:7,8	13:47:32 220:3	13:50:53 222:18	13:55:30 225:11,12	13:58:44 228:6
13:44:18 217:9	13:47:35 220:4	13:50:55 222:19	13:55:33 225:13	13:58:46 228:7
13:44:21 217:10	13:47:37 220:5	13:50:57 222:20	13:55:40 225:14	13:58:48 228:8
13:44:25 217:11	13:47:39 220:6	13:51:02 222:21	13:55:44 225:15,16	13:58:51 228:9
13:44:30 217:12	13:47:42 220:7	13:51:04 222:22	13:55:46 225:17	13:58:54 228:10
13:44:36 217:13,14	13:47:45 220:8	13:51:05 223:1	13:55:55 225:18	13:58:55 228:11
13:44:37 217:15	13:47:48 220:9	13:51:07 223:2	13:56:00 225:19	13:58:56 228:12
13:44:39 217:16	13:47:49 220:10	13:51:13 223:3	13:56:03 225:20	13:59:00 228:13
13:44:43 217:17	13:47:50 220:11	13:51:15 223:4	13:56:07 225:21	13:59:01 228:14
13:44:48 217:18	13:47:54 220:12	13:51:20 223:5	13:56:12 225:22 226:1	13:59:04 228:15
13:44:51 217:19	13:48:00 220:13	13:51:23 223:6	13:56:15 226:2	13:59:09 228:16
13:44:53 217:20	13:48:04 220:14	13:51:25 223:7	13:56:17 226:3	13:59:13 228:17
13:44:58 217:21	13:48:07 220:15	13:51:30 223:8	13:56:18 226:4	13:59:17 228:18
13:44:59 217:22	13:48:10 220:16	13:51:33 223:9	13:56:19 226:5	13:59:20 228:19
13:45:01 218:1,2	13:48:13 220:17	13:51:35 223:10	13:56:21 226:6	13:59:24 228:20
13:45:05 218:3,4	13:48:15 220:18	13:51:38 223:11	13:56:25 226:7	13:59:27 228:21
13:45:08 218:5	13:48:17 220:19	13:51:41 223:12	13:56:27 226:8	13:59:29 228:22
13:45:11 218:6	13:48:20 220:20	13:51:46 223:13	13:56:28 226:9	13:59:32 229:1
13:45:14 218:7	13:48:22 220:21	13:51:48 223:14	13:56:32 226:10	13:59:34 229:2
13:45:15 218:8	13:48:25 220:22	13:51:50 223:15	13:56:36 226:11	13:59:35 229:3
13:45:18 218:9	13:48:27 221:1	13:51:53 223:16	13:56:37 226:12	13:59:37 229:4
13:45:23 218:10	13:48:29 221:2	13:51:55 223:17	13:56:40 226:13	13:59:40 229:5
13:45:27 218:11	13:48:32 221:3	13:51:58 223:18	13:56:45 226:14	13:59:44 229:6
13:45:31 218:12	13:48:36 221:4	13:52:02 223:19	13:56:49 226:15	13:59:47 229:7
13:45:34 218:13	13:48:40 221:5	13:52:05 223:20	13:56:52 226:16	13:59:51 229:8
13:45:39 218:14	13:48:41 221:6	13:52:09 223:21,22	13:56:54 226:17	13:59:52 229:9
13:45:40 218:15	13:48:43 221:7	13:52:12 224:1	13:56:57 226:18	13:59:53 229:10
13:45:46 218:16	13:48:45 221:8	13:52:15 224:2	13:56:58 226:19	13:59:54 229:11
13:45:50 218:17	13:48:49 221:9	13:52:17 224:3	13:56:59 226:20	13:59:57 229:12
13:45:53 218:18	13:48:50 221:10	13:52:20 224:4,5	13:57:00 226:21	131 91:6,21 110:11,17
13:45:58 218:19	13:48:51 221:11	13:52:23 224:6	13:57:03 226:22	111:13,19,22 112:8
13:46:01 218:20	13:48:54 221:12	13:52:26 224:7	13:57:06 227:1	112:11 242:5 243:6
13:46:04 218:21	13:48:58 221:13	13:52:28 224:8	13:57:12 227:2	247:15 248:9,17

249:2,20 250:2 251:22 254:4,10 137 263:6 14 8:9 10:4 108:7 110:13 192:1 212:12 251:15,17 262:13 263:1 268:11 271:2 283:1,2,7,10,12 14:00:02 229:13 14:00:05 229:14 14:00:08 229:15 14:00:21 229:16 14:00:25 229:17 14:00:29 229:18 14:00:33 229:19 14:00:39 229:20 14:00:47 229:21 14:00:52 229:22 14:00:59 230:1 14:01:05 230:2,3 14:01:07 230:4 14:01:08 230:5 14:01:12 230:6 14:01:16 230:7 14:01:20 230:8 14:01:24 230:9 14:01:28 230:10 14:01:33 230:11 14:01:35 230:12 14:01:38 230:13 14:01:42 230:14 14:01:46 230:15 14:01:50 230:16 14:01:54 230:17 14:01:57 230:18 14:02:01 230:19 14:02:04 230:20 14:02:06 230:21 14:02:12 230:22 14:02:14 231:1 14:02:17 231:2 14:02:20 231:3 14:02:23 231:4 14:02:26 231:5 14:02:27 231:6 14:02:29 231:7 14:02:30 231:8 14:02:36 231:9 14:02:41 231:10 14:02:44 231:11 14:02:45 231:12 14:04:33 231:13 14:04:34 231:14 14:04:38 231:15 14:04:41 231:16 14:04:45 231:17 14:04:48 231:18	14:04:51 231:19,20 14:04:54 231:21 14:04:58 231:22 14:05:05 232:1 14:05:07 232:2 14:05:08 232:3 14:05:12 232:4 14:05:14 232:5 14:05:18 232:6 14:05:21 232:7 14:05:24 232:8 14:05:26 232:9 14:05:29 232:10 14:05:31 232:11 14:05:33 232:12 14:05:59 232:13,14 14:06:01 232:15,16 14:06:08 232:17 14:06:11 232:18 14:06:12 232:19 14:06:15 232:20 14:06:19 232:21 14:06:20 232:22 233:1 14:06:23 233:2 14:06:24 233:3 14:06:25 233:4 14:06:31 233:5 14:06:39 233:6 14:06:42 233:7 14:06:47 233:8 14:06:51 233:9 14:06:56 233:10 14:07:02 233:11 14:07:07 233:12 14:07:10 233:13 14:07:15 233:14 14:07:17 233:15 14:07:18 233:16,17 14:07:22 233:18 14:07:25 233:19 14:07:26 233:20 14:07:29 233:21 14:07:30 233:22 234:1 14:07:33 234:2 14:07:37 234:3 14:07:38 234:4 14:07:40 234:5 14:07:42 234:6 14:07:44 234:7 14:07:47 234:8 14:07:52 234:9 14:07:55 234:10 14:07:57 234:11 14:08:00 234:12,13 14:08:02 234:14 14:08:03 234:15 14:13:48 234:16	14:13:53 234:17 14:13:58 234:18 14:13:59 234:19 14:14:01 234:20 14:14:05 234:21 14:14:08 234:22 14:14:13 235:1 14:14:18 235:2 14:14:21 235:3 14:14:27 235:4 14:14:31 235:5 14:14:39 235:6 14:14:42 235:7 14:14:46 235:8 14:14:51 235:9 14:14:53 235:10 14:14:56 235:11 14:14:57 235:12 14:15:08 235:13 14:15:12 235:14 14:15:15 235:15 14:15:19 235:16 14:15:29 235:17 14:15:34 235:18 14:15:38 235:19 14:15:43 235:20 14:15:46 235:21 14:15:51 235:22 14:15:53 236:1 14:15:54 236:2 14:15:59 236:3 14:16:03 236:4 14:16:07 236:5 14:16:08 236:6 14:16:11 236:7 14:16:13 236:8 14:16:14 236:9 14:16:18 236:10 14:16:21 236:11 14:16:23 236:12 14:16:24 236:13 14:16:50 236:14 14:16:53 236:15 14:17:00 236:16 14:17:03 236:17 14:17:06 236:18 14:17:09 236:19 14:17:11 236:20 14:17:13 236:21,22 14:17:14 237:1 14:17:18 237:2 14:17:20 237:3 14:17:23 237:4 14:17:30 237:5 14:17:31 237:6 14:17:35 237:7 14:17:37 237:8	14:17:39 237:9 14:17:40 237:10 14:17:43 237:11 14:17:46 237:12 14:17:49 237:13 14:18:04 237:14 14:18:05 237:15 14:18:07 237:16 14:18:08 237:17 14:18:10 237:18 14:18:14 237:19 14:18:45 237:20 14:18:46 237:21 14:18:47 237:22 238:1 14:18:52 238:2 14:19:00 238:3 14:19:02 238:4 14:19:03 238:5 14:19:07 238:6 14:19:10 238:7,8 14:19:13 238:9 14:19:14 238:10 14:19:16 238:11 14:19:32 238:12 14:19:51 238:13,14 14:19:53 238:15 14:20:21 238:16 14:20:26 238:17 14:20:29 238:18 14:20:32 238:19 14:20:33 238:20 14:20:34 238:21,22 14:20:38 239:1 14:20:41 239:2 14:20:44 239:3 14:20:45 239:4 14:20:48 239:5 14:20:50 239:6 14:20:54 239:7 14:20:55 239:8 14:20:57 239:9 14:21:02 239:10 14:21:05 239:11 14:21:08 239:12 14:21:12 239:13 14:21:14 239:14 14:21:16 239:15 14:21:18 239:16,17 14:21:20 239:18,19 14:21:21 239:20 14:21:26 239:21 14:21:49 239:22 14:21:52 240:1 14:21:55 240:2 14:21:56 240:3 14:21:57 240:4 14:22:01 240:5	14:22:03 240:6 14:22:16 240:7 14:22:17 240:8 14:22:44 240:9,10 14:22:47 240:11 14:22:52 240:12 14:22:54 240:13 14:22:55 240:14 14:23:16 240:15 14:24:15 240:16 14:24:16 240:17 14:24:19 240:18 14:24:20 240:19 14:24:21 240:20 14:24:25 240:21 14:24:29 240:22 14:24:31 241:1 14:24:32 241:2,3 14:24:37 241:4 14:24:40 241:5 14:24:41 241:6,7 14:24:45 241:8 14:24:49 241:9 14:24:51 241:10 14:24:54 241:11 14:24:58 241:12 14:25:14 241:13 14:25:20 241:14 14:25:24 241:15 14:25:30 241:16 14:25:39 241:17 14:25:43 241:18 14:25:48 241:19,20 14:25:54 241:21 14:25:55 241:22 14:25:57 242:1 14:26:01 242:2,3 14:26:10 242:4 14:26:13 242:5 14:26:17 242:6 14:26:21 242:7 14:26:22 242:8 14:26:23 242:9 14:26:24 242:10 14:26:27 242:11 14:26:29 242:12 14:26:33 242:13 14:26:36 242:14 14:26:39 242:15 14:26:43 242:16 14:26:44 242:17 14:26:45 242:18 14:26:47 242:19 14:26:48 242:20 14:26:49 242:21,22 14:26:52 243:1 14:26:54 243:2
---	---	--	---	---

14:26:55 243:3,4	14:30:57 245:19	14:34:20 248:12	14:37:55 251:7	14:41:54 254:1
14:26:58 243:5	14:31:01 245:20	14:34:21 248:13	14:37:57 251:8	14:41:57 254:2,3
14:27:01 243:6	14:31:03 245:21	14:34:29 248:14	14:38:01 251:9	14:41:58 254:4
14:27:05 243:7	14:31:08 245:22	14:34:34 248:15	14:38:04 251:10	14:42:03 254:5
14:27:10 243:8	14:31:11 246:1	14:34:39 248:16	14:38:05 251:11	14:42:12 254:6
14:27:13 243:9	14:31:13 246:2	14:34:41 248:17	14:38:06 251:12	14:42:24 254:7
14:27:22 243:10	14:31:27 246:3	14:34:45 248:18	14:38:07 251:13	14:42:30 254:8
14:28:03 243:11	14:31:31 246:4	14:34:48 248:19,20	14:38:09 251:14	14:42:33 254:9
14:28:05 243:12	14:31:39 246:5	14:34:49 248:21	14:38:13 251:15	14:42:36 254:10
14:28:09 243:13	14:31:41 246:6	14:34:53 248:22	14:38:18 251:16	14:43:02 254:11
14:28:11 243:14,15	14:31:44 246:7	14:34:56 249:1	14:38:21 251:17	14:42:41 254:12
14:28:14 243:16	14:31:47 246:8	14:34:59 249:2	14:38:25 251:18	14:42:43 254:13
14:28:17 243:17	14:31:50 246:9	14:35:03 249:3	14:38:26 251:19	14:42:52 254:14
14:28:21 243:18	14:31:51 246:10,11	14:35:06 249:4	14:38:27 251:20	14:42:53 254:15
14:28:24 243:19	14:31:53 246:12	14:35:07 249:5	14:38:30 251:21	14:42:54 254:16
14:28:38 243:20	14:31:56 246:13	14:35:08 249:6	14:38:34 251:22	14:42:57 254:17
14:28:41 243:21	14:32:00 246:14	14:35:09 249:7	14:38:40 252:1	14:43:00 254:18
14:28:49 243:22	14:32:04 246:15	14:35:14 249:8	14:38:49 252:2	14:43:02 254:19
14:28:50 244:1	14:32:08 246:16	14:35:18 249:9	14:38:52 252:3	14:43:11 254:20
14:28:53 244:2	14:32:11 246:17	14:35:21 249:10	14:38:56 252:4	14:43:15 254:21
14:28:57 244:3	14:32:13 246:18	14:35:24 249:11	14:38:57 252:5	14:43:18 254:22
14:29:01 244:4,5	14:32:17 246:19	14:35:25 249:12	14:39:06 252:6	14:43:20 255:1
14:29:05 244:6	14:32:18 246:20	14:35:26 249:13	14:39:39 252:7	14:58:44 255:2
14:29:08 244:7	14:32:20 246:21	14:35:28 249:14	14:39:42 252:8	14:59:22 255:3
14:29:12 244:8	14:32:24 246:22	14:35:29 249:15	14:39:43 252:9,10	14:59:28 255:4
14:29:14 244:9	14:32:28 247:1	14:35:35 249:16	14:39:46 252:11	14:59:32 255:5
14:29:16 244:10	14:32:32 247:2,3	14:35:39 249:17	14:39:47 252:12	14:59:35 255:6
14:29:17 244:11	14:32:37 247:4	14:35:53 249:18	14:39:48 252:13	14:59:36 255:7,8
14:29:22 244:12	14:32:41 247:5	14:35:56 249:19	14:39:50 252:14	14:59:39 255:9
14:29:29 244:13	14:32:44 247:6	14:35:59 249:20	14:39:54 252:15	14:59:43 255:10
14:29:31 244:14	14:32:49 247:7	14:36:24 249:21,22	14:39:56 252:16	14:59:47 255:11
14:29:34 244:15	14:32:54 247:8	14:36:31 250:1	14:39:58 252:17	14:59:50 255:12
14:29:35 244:16	14:32:57 247:9	14:36:35 250:2	14:39:59 252:18	14:59:58 255:13
14:29:39 244:17	14:33:03 247:10	14:36:42 250:3	14:40:05 252:19	14:59:59 255:14
14:29:42 244:18	14:33:04 247:11	14:36:46 250:4	14:40:11 252:20	147-172 5:17
14:29:48 244:19	14:33:07 247:12	14:36:49 250:5	14:40:13 252:21	15 8:14 10:11 65:12
14:29:51 244:20	14:33:10 247:13	14:36:53 250:6	14:40:17 252:22	168:1 209:10 211:1
14:29:52 244:21	14:33:13 247:14	14:36:55 250:7	14:40:20 253:1	264:15,19 265:13
14:29:57 244:22	14:33:16 247:15	14:36:56 250:8	14:40:55 253:2	284:20,21 285:4,10
14:30:00 245:1	14:33:18 247:16	14:37:01 250:9	14:40:56 253:3	285:12 286:17,18
14:30:04 245:2	14:33:20 247:17	14:37:16 250:10	14:40:59 253:4	287:19
14:30:08 245:3	14:33:23 247:18	14:37:19 250:11	14:41:02 253:5	15:00:02 255:15
14:30:11 245:4	14:33:27 247:19	14:37:21 250:12,13	14:41:07 253:6	15:00:06 255:16
14:30:14 245:5	14:33:33 247:20	14:37:22 250:14	14:41:10 253:7	15:00:09 255:17
14:30:18 245:6	14:33:37 247:21	14:37:23 250:15	14:41:12 253:8	15:00:13 255:18
14:30:22 245:7	14:33:39 248:1	14:37:25 250:16	14:41:16 253:9	15:00:16 255:19
14:30:24 245:8	14:33:41 248:2	14:37:28 250:17	14:41:20 253:10	15:00:22 255:20
14:30:27 245:9	14:33:43 248:3	14:37:32 250:18	14:41:23 253:11	15:00:28 255:21
14:30:30 245:10	14:33:46 248:4	14:37:35 250:19	14:41:24 253:12,13	15:00:32 255:22
14:30:37 245:11	14:33:52 248:5	14:37:37 250:20	14:41:27 253:14	15:00:37 256:1
14:30:39 245:12	14:33:56 248:6	14:37:38 250:21,22	14:41:31 253:15	15:00:42 256:2
14:30:43 245:13	14:33:59 248:7	14:37:40 251:1	14:41:36 253:16,17	15:00:45 256:3
14:30:46 245:14	14:34:08 248:8	14:37:43 251:2	14:41:39 253:18	15:00:49 256:4
14:30:48 245:15	14:34:10 248:9	14:37:48 251:3	14:41:44 253:19	15:00:52 256:5
14:30:49 245:16	14:34:12 248:10	14:37:52 251:4	14:41:45 253:20	15:00:55 256:6
14:30:53 245:17	14:34:16 248:11	14:37:53 251:5	14:41:47 253:21	15:00:59 256:7
14:30:56 245:18		14:37:54 251:6	14:41:50 253:22	15:01:03 256:8

15:01:06 256:9	15:04:34 259:3	15:07:58 261:19	15:11:48 264:16	15:15:12 267:15
15:01:09 256:10	15:04:36 259:4	15:08:04 261:20	15:11:51 264:17	15:15:13 267:16
15:01:12 256:11,12	15:04:38 259:5	15:08:08 261:21	15:11:52 264:18	15:15:14 267:17
15:01:15 256:13	15:04:42 259:6	15:08:10 261:22	15:11:54 264:19	15:15:15 267:18
15:01:19 256:14	15:04:46 259:7	15:08:15 262:1	15:11:57 264:20	15:15:17 267:19
15:01:24 256:15	15:04:48 259:8	15:08:19 262:2,3	15:12:00 264:21	15:15:20 267:20
15:01:28 256:16	15:05:01 259:9	15:08:23 262:4	15:12:02 264:22 265:1	15:15:23 267:21
15:01:31 256:17	15:05:02 259:10	15:08:28 262:5	15:12:12 265:2	15:15:28 267:22
15:01:32 256:18	15:05:03 259:11	15:08:31 262:6	15:12:17 265:3	15:15:38 268:1
15:01:35 256:19	15:05:04 259:12	15:08:33 262:7	15:12:27 265:4	15:15:43 268:2
15:01:38 256:20	15:05:06 259:13	15:08:36 262:8	15:12:28 265:5	15:15:47 268:3
15:01:42 256:21	15:05:09 259:14	15:09:00 262:9	15:12:30 265:6	15:15:50 268:4
15:01:45 256:22	15:05:31 259:15	15:09:01 262:10	15:12:31 265:7	15:15:54 268:5
15:01:48 257:1	15:05:32 259:16,17,18	15:09:02 262:11	15:12:33 265:8,9	15:15:58 268:6
15:01:50 257:2	15:05:35 259:19	15:09:03 262:12	15:12:42 265:10,11,12	15:16:01 268:7
15:01:57 257:3	15:05:36 259:20,21	15:09:05 262:13	15:12:45 265:13	15:16:03 268:8
15:02:04 257:4	15:05:39 259:22	15:09:09 262:14	15:12:49 265:14,15	15:16:04 268:9
15:02:07 257:5	15:05:42 260:1	15:09:32 262:15,16	15:12:50 265:16	15:16:05 268:10
15:02:10 257:6	15:05:43 260:2	15:09:33 262:17	15:13:00 265:17	15:16:06 268:11
15:02:21 257:7	15:05:44 260:3	15:09:34 262:18,19	15:13:02 265:18	15:16:12 268:12
15:02:23 257:8	15:05:48 260:4	15:09:37 262:20	15:13:05 265:19	15:16:15 268:13
15:02:24 257:9	15:05:49 260:5	15:09:38 262:21	15:13:18 265:20	15:16:18 268:14
15:02:26 257:10	15:05:53 260:6	15:09:39 262:22	15:13:23 265:21	15:16:20 268:15
15:02:28 257:11	15:05:58 260:7	15:09:41 263:1	15:13:28 265:22	15:16:22 268:16
15:02:31 257:12	15:06:01 260:8	15:09:45 263:2	15:13:30 266:1	15:16:23 268:17
15:02:51 257:13	15:06:04 260:9	15:09:46 263:3	15:13:34 266:2	15:16:26 268:18
15:02:52 257:14	15:06:07 260:10	15:09:47 263:4	15:13:38 266:3	15:16:28 268:19
15:02:53 257:15,16	15:06:11 260:11	15:09:50 263:5	15:13:41 266:4	15:16:33 268:20
15:03:00 257:17	15:06:15 260:12	15:09:52 263:6	15:13:46 266:5	15:16:36 268:21
15:03:01 257:18	15:06:17 260:13	15:09:59 263:7	15:13:48 266:6	15:16:38 268:22
15:03:02 257:19	15:06:19 260:14	15:10:05 263:8	15:13:51 266:7	15:16:41 269:1
15:03:04 257:20	15:06:22 260:15	15:10:08 263:9	15:13:54 266:8	15:16:44 269:2
15:03:09 257:21,22	15:06:26 260:16	15:10:12 263:10	15:13:56 266:9	15:16:45 269:3
15:03:10 258:1	15:06:28 260:17	15:10:18 263:11	15:13:58 266:10	15:16:47 269:4
15:03:13 258:2	15:06:29 260:18	15:10:23 263:12	15:14:02 266:11	15:16:48 269:5
15:03:18 258:3	15:06:30 260:19	15:10:28 263:13	15:14:05 266:12	15:16:50 269:6
15:03:26 258:4	15:06:32 260:20	15:10:29 263:14	15:14:08 266:13	15:16:55 269:7
15:03:30 258:5	15:06:35 260:21	15:10:34 263:15	15:14:13 266:14	15:16:58 269:8,9
15:03:34 258:6	15:06:40 260:22	15:10:35 263:16	15:14:15 266:15	15:16:59 269:10
15:03:39 258:7	15:06:44 261:1	15:10:38 263:17	15:14:16 266:16	15:17:00 269:11
15:03:43 258:8	15:06:47 261:2	15:10:43 263:18	15:14:17 266:17	15:17:02 269:12
15:03:46 258:9	15:06:49 261:3	15:10:47 263:19	15:14:19 266:18	15:17:05 269:13
15:03:49 258:10	15:06:53 261:4	15:10:50 263:20	15:14:21 266:19	15:17:09 269:14
15:03:53 258:11	15:06:57 261:5	15:10:51 263:21,22	15:14:25 266:20	15:17:12 269:15,16
15:03:57 258:12	15:06:58 261:6	15:10:52 264:1	15:14:28 266:21	15:17:14 269:17,18
15:04:00 258:13	15:07:01 261:7	15:10:53 264:2	15:14:31 266:22	15:17:15 269:19
15:04:03 258:14	15:07:04 261:8	15:10:55 264:3	15:14:32 267:1,2	15:17:18 269:20
15:04:07 258:15	15:07:07 261:9	15:10:59 264:4	15:14:33 267:3	15:17:21 269:21
15:04:10 258:16	15:07:11 261:10	15:11:02 264:5	15:14:41 267:4	15:17:24 269:22
15:04:11 258:17	15:07:13 261:11	15:11:05 264:6,7	15:14:43 267:5	15:17:27 270:1
15:04:13 258:18	15:07:25 261:12	15:11:31 264:8	15:14:45 267:6	15:17:28 270:2
15:04:15 258:19	15:07:27 261:13	15:11:33 264:9	15:14:46 267:7	15:17:30 270:3
15:04:19 258:20	15:07:30 261:14	15:11:34 264:10	15:14:48 267:8	15:17:32 270:4
15:04:22 258:21	15:07:35 261:15	15:11:36 264:11	15:14:51 267:9	15:17:36 270:5
15:04:26 258:22	15:07:40 261:16	15:11:39 264:12,13	15:15:08 267:10	15:17:37 270:6
15:04:29 259:1	15:07:45 261:17	15:11:40 264:14	15:15:09 267:11	15:17:39 270:7
15:04:32 259:2	15:07:53 261:18	15:11:42 264:15	15:15:10 267:12,13,14	15:17:45 270:8

15:17:49 270:9	15:20:57 273:2	15:23:36 275:17	15:26:41 278:12	15:29:59 281:14
15:17:54 270:10	15:20:59 273:3	15:23:39 275:18	15:26:46 278:13	15:30:00 281:15
15:17:58 270:11	15:21:02 273:4	15:23:40 275:19	15:26:47 278:14	15:30:06 281:16
15:18:01 270:12	15:21:09 273:5	15:23:41 275:20	15:26:49 278:15,16	15:30:13 281:17
15:18:03 270:13	15:21:15 273:6	15:23:44 275:21	15:26:52 278:17	15:30:17 281:18
15:18:07 270:14	15:21:22 273:7	15:23:47 275:22	15:26:54 278:18	15:30:20 281:19
15:18:14 270:15	15:21:24 273:8	15:23:52 276:1	15:26:58 278:19	15:30:23 281:20
15:18:21 270:16	15:21:26 273:9	15:23:55 276:2	15:27:01 278:20	15:30:24 281:21,22
15:18:26 270:17	15:21:30 273:10	15:23:59 276:3	15:27:04 278:21	15:30:27 282:1
15:18:31 270:18	15:21:31 273:11	15:24:02 276:4	15:27:05 278:22	15:30:31 282:2
15:18:33 270:19,20	15:21:33 273:12	15:24:03 276:5	15:27:08 279:1,2	15:30:34 282:3
15:18:35 270:21	15:21:37 273:13	15:24:07 276:6	15:27:14 279:3	15:30:36 282:4
15:18:38 270:22 271:1	15:21:40 273:14	15:24:09 276:7	15:27:16 279:4	15:30:37 282:5
15:18:41 271:2	15:21:41 273:15	15:24:13 276:8	15:27:17 279:5	15:30:39 282:6
15:18:44 271:3	15:21:42 273:16	15:24:16 276:9	15:27:19 279:6,7	15:30:41 282:7
15:18:48 271:4	15:21:45 273:17	15:24:29 276:10	15:27:20 279:8	15:30:45 282:8
15:18:49 271:5	15:21:49 273:18	15:24:32 276:11	15:27:46 279:9	15:30:48 282:9
15:18:52 271:6	15:21:52 273:19	15:24:40 276:12	15:27:47 279:10	15:30:50 282:10
15:18:55 271:7	15:21:55 273:20	15:24:41 276:13	15:27:49 279:11	15:30:53 282:11
15:18:58 271:8	15:21:56 273:21	15:24:44 276:14,15,16	15:27:51 279:12	15:30:57 282:12
15:19:02 271:9	15:21:58 273:22	15:24:45 276:17	15:27:55 279:13	15:30:58 282:13
15:19:05 271:10	15:22:00 274:1	15:24:47 276:18,19	15:27:59 279:14	15:31:02 282:14
15:19:08 271:11	15:22:03 274:2	15:24:48 276:20	15:28:01 279:15	15:31:03 282:15
15:19:10 271:12	15:22:04 274:3	15:24:49 276:21	15:28:14 279:16,17	15:31:06 282:16
15:19:12 271:13	15:22:05 274:4	15:24:53 276:22	15:28:15 279:18,19	15:31:08 282:17
15:19:14 271:14	15:22:07 274:5	15:25:00 277:1	15:28:16 279:20,21	15:31:13 282:18
15:19:15 271:15	15:22:08 274:6	15:25:04 277:2	15:28:19 279:22	15:31:15 282:19
15:19:17 271:16	15:22:10 274:7	15:25:09 277:3	15:28:20 280:1,2	15:31:16 282:20
15:19:18 271:17	15:22:15 274:8	15:25:11 277:4	15:28:22 280:3	15:31:32 282:21
15:19:22 271:18	15:22:20 274:9	15:25:14 277:5	15:28:26 280:4	15:31:33 282:22
15:19:27 271:19	15:22:22 274:10	15:25:17 277:6	15:28:27 280:5	15:31:34 283:1
15:19:31 271:20	15:22:25 274:11	15:25:18 277:7	15:28:28 280:6	15:31:35 283:2
15:19:32 271:21	15:22:28 274:12	15:25:20 277:8	15:28:32 280:7	15:31:37 283:3
15:19:41 271:22	15:22:29 274:13	15:25:24 277:9	15:28:35 280:8	15:31:41 283:4
15:19:44 272:1	15:22:30 274:14	15:25:26 277:10	15:28:38 280:9	15:31:44 283:5
15:19:48 272:2	15:22:33 274:15	15:25:29 277:11	15:28:42 280:10	15:32:09 283:6,7
15:19:50 272:3	15:22:37 274:16	15:25:32 277:12	15:28:46 280:11	15:32:10 283:8,9
15:19:53 272:4	15:22:39 274:17,18	15:25:35 277:13	15:28:49 280:12	15:32:13 283:10
15:19:58 272:5	15:22:41 274:19	15:25:36 277:14	15:28:51 280:13	15:32:15 283:11,12
15:20:02 272:6	15:22:44 274:20	15:25:51 277:15	15:28:52 280:14	15:32:18 283:13
15:20:04 272:7	15:22:48 274:21	15:25:53 277:16	15:28:53 280:15	15:32:22 283:14
15:20:07 272:8	15:22:52 274:22	15:25:56 277:17	15:29:05 280:16	15:32:23 283:15
15:20:10 272:9	15:22:54 275:1	15:25:59 277:18	15:29:07 280:17	15:32:24 283:16
15:20:12 272:10	15:22:57 275:2	15:26:02 277:19	15:29:09 280:18,19	15:32:26 283:17
15:20:15 272:11	15:23:00 275:3	15:26:04 277:20,21	15:29:11 280:20	15:32:27 283:18
15:20:18 272:12	15:23:04 275:4	15:26:10 277:22	15:29:14 280:21	15:32:29 283:19
15:20:27 272:13	15:23:06 275:5	15:26:13 278:1	15:29:16 280:22	15:32:33 283:20
15:20:30 272:14	15:23:08 275:6	15:26:17 278:2	15:29:35 281:1,2	15:32:37 283:21
15:20:34 272:15	15:23:11 275:7	15:26:19 278:3	15:29:36 281:3,4	15:32:40 283:22
15:20:36 272:16	15:23:14 275:8	15:26:22 278:4	15:29:39 281:5	15:32:44 284:1
15:20:38 272:17	15:23:17 275:9	15:26:25 278:5	15:29:40 281:6,7	15:32:47 284:2
15:20:41 272:18	15:23:21 275:10	15:26:28 278:6	15:29:42 281:8	15:32:49 284:3
15:20:46 272:19	15:23:23 275:11	15:26:30 278:7	15:29:46 281:9	15:32:53 284:4
15:20:48 272:20	15:23:24 275:12	15:26:31 278:8	15:29:47 281:10	15:32:55 284:5
15:20:51 272:21	15:23:25 275:13,14	15:26:35 278:9	15:29:48 281:11	15:32:58 284:6
15:20:53 272:22	15:23:29 275:15	15:26:36 278:10	15:29:51 281:12	15:33:02 284:7
15:20:55 273:1	15:23:32 275:16	15:26:38 278:11	15:29:53 281:13	15:33:06 284:8

15:33:11 284:9	15:36:41 287:7	15:40:06 290:2	15:43:44 292:21	15:47:43 295:14
15:33:13 284:10	15:36:45 287:8	15:40:10 290:3	15:43:47 292:22	15:47:44 295:15
15:33:16 284:11	15:36:48 287:9	15:40:13 290:4	15:43:51 293:1	15:47:47 295:16
15:33:20 284:12	15:36:51 287:10	15:40:14 290:5	15:43:52 293:2	15:47:50 295:17
15:33:22 284:13	15:36:55 287:11	15:40:16 290:6	15:43:53 293:3	15:47:51 295:18
15:33:23 284:14	15:36:59 287:12	15:40:18 290:7	15:44:02 293:4	15:47:52 295:19
15:33:26 284:15	15:37:02 287:13	15:40:21 290:8	15:44:06 293:5	15:47:58 295:20
15:33:29 284:16	15:37:05 287:14	15:40:22 290:9 291:1	15:44:17 293:6	15:48:02 295:21
15:33:32 284:17	15:37:06 287:15	15:40:24 290:10 291:2	15:44:20 293:7	15:48:04 295:22
15:33:42 284:18	15:37:07 287:16	291:3	15:44:22 293:8	15:48:08 296:1
15:33:43 284:19	15:37:09 287:17	15:40:25 290:11	15:44:26 293:9	15:48:12 296:2
15:33:45 284:20	15:37:11 287:18	15:40:31 290:12	15:44:30 293:10	15:48:15 296:3
15:33:46 284:21	15:37:13 287:19	15:40:39 290:13	15:44:34 293:11,12	15:48:20 296:4
15:33:48 284:22	15:37:29 287:20	15:40:44 290:14	15:44:36 293:13	15:48:22 296:5
15:33:53 285:1	15:37:30 287:21	15:40:50 290:15	15:44:40 293:14	15:48:26 296:6
15:33:54 285:2	15:37:32 287:22	15:40:53 290:16	15:44:43 293:15	15:48:30 296:7
15:34:31 285:3,4,5,6,7	15:37:33 288:1	15:40:54 290:17	15:44:46 293:16	15:48:33 296:8
15:34:32 285:8,9	15:37:36 288:2	15:40:57 290:18	15:44:49 293:17	15:48:37 296:9
15:34:40 285:10	15:37:41 288:3	15:40:58 290:19	15:44:51 293:18	15:48:40 296:10
15:34:41 285:11,12	15:37:42 288:4	15:41:00 290:20,21,22	15:44:54 293:19	15:48:41 296:11
15:34:44 285:13	15:38:14 288:5,6	15:41:16 291:4	15:45:14 293:20	15:48:42 296:12
15:34:47 285:14	15:38:15 288:7,8	15:41:19 291:5	15:45:18 293:21	15:48:44 296:13,14
15:34:48 285:15	15:38:31 288:9,10	15:41:24 291:6	15:45:19 293:22	15:48:47 296:15
15:34:49 285:16	15:38:32 288:11	15:41:28 291:7	15:45:24 294:1	15:48:58 296:16
15:34:52 285:17	15:38:35 288:12	15:41:31 291:8	15:45:27 294:2	15:49:04 296:17
15:34:58 285:18	15:38:37 288:13	15:41:40 291:9	15:45:30 294:3	15:49:09 296:18
15:35:00 285:19	15:38:38 288:14,15	15:41:43 291:10	15:45:35 294:4	15:49:14 296:19
15:35:03 285:20	15:38:43 288:16	15:41:46 291:11	15:45:38 294:5	15:49:18 296:20
15:35:07 285:21	15:38:46 288:17	15:41:49 291:12	15:45:42 294:6	15:49:20 296:21
15:35:09 285:22	15:38:49 288:18	15:41:50 291:13	15:45:45 294:7	15:49:23 296:22
15:35:10 286:1	15:38:52 288:19	15:41:55 291:14	15:45:51 294:8	15:49:27 297:1
15:35:13 286:2	15:38:57 288:20	15:42:01 291:15	15:45:55 294:9	15:49:30 297:2
15:35:15 286:3	15:39:00 288:21	15:42:10 291:16	15:45:57 294:10	15:49:33 297:3
15:35:19 286:4	15:39:02 288:22	15:42:11 291:17	15:45:59 294:11	15:49:34 297:4
15:35:21 286:5	15:39:03 289:1	15:42:14 291:18	15:46:03 294:12	15:49:35 297:5
15:35:24 286:6	15:39:04 289:2	15:42:18 291:19	15:46:07 294:13	15:49:37 297:6
15:35:29 286:7	15:39:06 289:3	15:42:22 291:20	15:46:10 294:14	15:49:42 297:7
15:35:31 286:8	15:39:10 289:4	15:42:26 291:21	15:46:12 294:15	15:49:45 297:8
15:35:33 286:9	15:39:12 289:5	15:42:27 291:22 292:1	15:46:14 294:16	15:49:48 297:9
15:35:34 286:10	15:39:15 289:6	15:42:31 292:2	15:46:18 294:17	15:49:50 297:10
15:35:37 286:11	15:39:18 289:7	15:42:34 292:3	15:46:20 294:18	15:49:52 297:11
15:35:39 286:12	15:39:21 289:8	15:42:37 292:4	15:46:22 294:19	15:50:16 297:12
15:35:40 286:13	15:39:22 289:9	15:42:41 292:5	15:46:24 294:20	15:50:18 297:13
15:35:43 286:14	15:39:23 289:10	15:42:43 292:6	15:46:25 294:21	15:50:20 297:14
15:35:45 286:15,16	15:39:24 289:11	15:42:44 292:7	15:46:27 294:22	15:50:21 297:15
15:35:48 286:17	15:39:28 289:12	15:42:57 292:8	15:46:28 295:1	15:50:23 297:16
15:35:50 286:18	15:39:31 289:13	15:42:58 292:9	15:46:44 295:2	15:50:27 297:17
15:35:53 286:19	15:39:33 289:14	15:43:00 292:10	15:46:46 295:3	15:50:28 297:18
15:35:55 286:20	15:39:37 289:15	15:43:01 292:11	15:46:47 295:4	15:50:53 297:19,20
15:35:57 286:21	15:39:39 289:16	15:43:04 292:12	15:46:48 295:5	15:50:54 297:21,22
15:36:01 286:22	15:39:47 289:17	15:43:08 292:13	15:46:50 295:6	15:50:57 298:1
15:36:04 287:1	15:39:51 289:18	15:43:10 292:14	15:46:54 295:7	15:50:59 298:2,3
15:36:09 287:2	15:39:54 289:19	15:43:35 292:15	15:46:55 295:8	15:51:02 298:4
15:36:10 287:3	15:39:56 289:20	15:43:36 292:16	15:47:18 295:9	15:51:06 298:5
15:36:12 287:4	15:39:57 289:21	15:43:37 292:17,18	15:47:19 295:10	15:51:07 298:6
15:36:19 287:5	15:39:59 289:22	15:43:41 292:19	15:47:20 295:11,12	15:51:08 298:7
15:36:38 287:6	15:40:03 290:1	15:43:43 292:20	15:47:42 295:13	15:51:11 298:8

15:51:14 298:9	15:54:37 301:7	15:57:40 304:5	16:00:35 306:12	16:03:58 309:9
15:51:17 298:10	15:54:42 301:8,9	15:57:43 304:6	16:00:37 306:13	16:04:02 309:10,11
15:51:20 298:11	15:54:44 301:10	15:57:45 304:7	16:00:39 306:14	16:04:06 309:12
15:51:24 298:12	15:54:46 301:11	15:58:09 304:8	16:00:41 306:15,16	16:04:09 309:13
15:51:25 298:13	15:54:52 301:12	15:58:10 304:9	16:00:45 306:17	16:04:11 309:14
15:51:26 298:14,15	15:54:56 301:13	15:58:11 304:10,11	16:00:47 306:18	16:04:14 309:15
15:51:33 298:16	15:55:00 301:14	15:58:14 304:12	16:00:48 306:19	16:04:16 309:16
15:51:34 298:17	15:55:03 301:15	15:58:15 304:13,14	16:01:02 306:20	16:04:18 309:17,18
15:51:37 298:18	15:55:11 301:16	15:58:18 304:15	16:01:04 306:21	16:04:21 309:19
15:51:38 298:19	15:55:13 301:17	15:58:21 304:16	16:01:07 306:22	16:04:24 309:20
15:51:39 298:20	15:55:15 301:18	15:58:22 304:17	16:01:09 307:1,2	16:04:27 309:21
15:51:42 298:21	15:55:18 301:19	15:58:23 304:18	16:01:12 307:3	16:04:31 309:22
15:52:08 298:22 299:1	15:55:21 301:20	15:58:30 304:19	16:01:14 307:4	16:04:33 310:1
15:52:09 299:2,3	15:55:26 301:21	15:58:35 304:20	16:01:17 307:5	16:04:37 310:2
15:52:13 299:4	15:55:27 301:22 302:1	15:58:38 304:21	16:01:20 307:6	16:04:41 310:3
15:52:14 299:5,6	15:55:29 302:2	15:58:41 304:22	16:01:21 307:7	16:04:46 310:4
15:52:17 299:7	15:55:33 302:3	15:58:44 305:1	16:01:23 307:8	16:04:54 310:5
15:52:20 299:8	15:55:35 302:4	15:58:46 305:2	16:01:26 307:9	16:05:12 310:6
15:52:21 299:9	15:55:39 302:5	15:58:47 305:3	16:01:30 307:10	16:05:14 310:7
15:52:22 299:10	15:55:40 302:6	15:58:50 305:4	16:01:35 307:11	16:05:19 310:8
15:52:26 299:11	15:55:43 302:7	15:58:52 305:5	16:01:36 307:12	16:05:22 310:9
15:52:27 299:12	15:55:47 302:8,9	15:58:57 305:6	16:01:46 307:13	16:05:25 310:10
15:52:30 299:13,14	15:55:49 302:10,11	15:58:58 305:7	16:01:50 307:14	16:05:27 310:11,12
15:52:31 299:15	15:55:51 302:12	15:59:01 305:8	16:01:54 307:15	16:05:29 310:13
15:52:35 299:16	15:55:53 302:13	15:59:02 305:9	16:01:57 307:16	16:05:30 310:14
15:52:37 299:17	15:55:58 302:14	15:59:03 305:10	16:01:58 307:17	16:05:31 310:15
15:52:40 299:18	15:56:01 302:15	15:59:15 305:11	16:02:00 307:18	16:05:33 310:16
15:52:43 299:19	15:56:04 302:16	15:59:17 305:12	16:02:01 307:19	16:05:36 310:17
15:52:46 299:20	15:56:07 302:17	15:59:19 305:13	16:02:02 307:20,21	16:05:39 310:18
15:52:50 299:21	15:56:10 302:18	15:59:20 305:14	16:02:04 307:22	16:05:42 310:19
15:52:53 299:22	15:56:13 302:19	15:59:22 305:15	16:02:06 308:1	16:05:46 310:20
15:52:56 300:1	15:56:16 302:20	15:59:27 305:16	16:02:09 308:2	16:05:47 310:21
15:52:59 300:2	15:56:19 302:21	15:59:28 305:17	16:02:10 308:3	16:05:48 310:22
15:53:02 300:3	15:56:22 302:22	15:59:52 305:18	16:02:11 308:4	16:05:49 311:1
15:53:05 300:4	15:56:23 303:1	15:59:53 305:19	16:02:14 308:5	16:05:51 311:2
15:53:10 300:5	15:56:25 303:2	15:59:54 305:20,21	16:02:15 308:6	16:05:55 311:3
15:53:13 300:6	15:56:27 303:3	15:59:57 305:22	16:02:18 308:7	16:05:58 311:4
15:53:18 300:7	15:56:31 303:4	15:59:58 306:1	16:02:21 308:8	16:06:00 311:5
15:53:27 300:8	15:56:33 303:5	15:59:59 306:2	16:02:36 308:9	16:06:03 311:6
15:53:30 300:9	15:56:37 303:6	154 206:9	16:02:41 308:10	16:06:06 311:7
15:53:34 300:10	15:56:42 303:7	16 11:4,18 97:10	16:02:43 308:11	16:06:07 311:8
15:53:38 300:11	15:56:44 303:8	123:21 124:2 128:22	16:02:45 308:12	16:06:09 311:9
15:53:43 300:12	15:56:47 303:9	211:1 225:7 233:5,5	16:02:46 308:13	16:06:18 311:10
15:53:47 300:13	15:56:49 303:10	233:17,20 234:2,17	16:02:50 308:14	16:06:20 311:11
15:53:51 300:14	15:56:51 303:11	236:2,4,11 237:3	16:02:55 308:15	16:06:22 311:12
15:53:58 300:15	15:56:53 303:12	281:17 287:22 288:1	16:03:22 308:16,17	16:06:23 311:13
15:54:02 300:16	15:56:55 303:13	288:6,9 291:15	16:03:23 308:18,19	16:06:25 311:14
15:54:05 300:17	15:56:58 303:14	292:12,22	16:03:30 308:20	16:06:31 311:15
15:54:07 300:18,19	15:57:02 303:15	16th 4:5	16:03:32 308:21	16:06:32 311:16
15:54:10 300:20	15:57:03 303:16,17	16:00:04 306:3	16:03:33 308:22	16:06:33 311:17
15:54:14 300:21	15:57:04 303:18,19	16:00:08 306:4	16:03:37 309:1	16:06:37 311:18
15:54:16 300:22	15:57:05 303:20	16:00:10 306:5,6	16:03:40 309:2	16:06:38 311:19
15:54:18 301:1	15:57:08 303:21,22	16:00:19 306:7	16:03:42 309:3,4	16:06:39 311:20
15:54:21 301:2	15:57:33 304:1	16:00:23 306:8	16:03:45 309:5	16:06:45 311:21
15:54:27 301:3,4	15:57:34 304:2	16:00:25 306:9	16:03:49 309:6	16:06:50 311:22
15:54:30 301:5	15:57:36 304:3	16:00:30 306:10	16:03:53 309:7	16:06:55 312:1,2
15:54:34 301:6	15:57:37 304:4	16:00:32 306:11	16:03:56 309:8	16:07:33 312:3,4

16:07:34 312:5,6,7	16:10:41 314:21	16:18:23 317:22 318:1	206:10,15,19 207:2	306:2
16:07:37 312:8	16:10:43 314:22	16:18:25 318:2	207:13 208:13 227:3	226 252:18
16:07:38 312:9,10	16:10:45 315:1	16:18:27 318:3,4	229:13,17 230:7	23 14:10 124:2 147:1,2
16:07:41 312:11	16:10:48 315:2	16:18:30 318:5	280:20 281:8 291:14	151:11,14,15,16
16:07:45 312:12	16:10:50 315:3	16:18:31 318:6	2-amino-3 113:14	152:7 250:8 308:12
16:07:46 312:13	16:10:51 315:4	16:18:33 318:7	118:19 119:3,8 124:8	308:13,17,20,22
16:07:49 312:14	16:10:52 315:5	16:18:34 318:8,9	129:9 155:17 227:4	232 6:16
16:07:54 312:15	16:10:55 315:6	16:18:36 318:10,11	2.1 255:12	237 6:18
16:07:59 312:16	16:10:57 315:7	16:18:39 318:12,13	2.4 277:22	24 14:18 152:20 254:6
16:08:03 312:17	16:10:59 315:8	16:18:40 318:14	2:44 254:19 255:1	311:12,13 312:5,8,10
16:08:06 312:18	16:11:02 315:9	16:18:45 318:15	20 12:15 13:4 25:19	240 7:10
16:08:11 312:19	16:11:05 315:10	16:18:47 318:16	62:19 63:3,13 65:19	25 18:19,20 110:13,16
16:08:13 312:20	16:11:08 315:11	16:18:52 318:17	66:2 142:20 157:10	111:12,21 112:10
16:08:14 312:21	16:11:14 315:12	16:19:00 318:18	168:1 205:12 230:15	153:11 242:5,6,7
16:08:15 312:22	16:11:16 315:13	16:19:03 318:19	231:8 263:11,20	243:6 249:20 250:1
16:08:17 313:1	16:11:18 315:14	16:19:06 318:20	297:16 298:4,18,19	251:21 254:10
16:08:20 313:2	16:11:20 315:15	1625 16:5	299:1,4,6,10 300:19	257 7:17
16:08:22 313:3	16:11:22 315:16	167 206:19	2000 186:19 187:9,22	257-269 11:9
16:08:27 313:4	16:11:25 315:17	17 5:4 11:13 63:13 64:5	189:10 191:3,8	258 288:15 291:14
16:08:31 313:5	16:11:27 315:18	65:11 134:1,9 226:9	209:13,18 210:1,5,13	259 7:22
16:08:34 313:6	16:11:29 315:19,20	292:10,11,16,19,21	260:3,13 299:10,22	26 108:9,10,15 109:18
16:08:38 313:7	16:11:34 315:21	17,000 60:9	312:1,2	243:19 244:1,16,21
16:08:42 313:8	16:11:36 315:22 316:1	175-193 14:21	20001-4413 3:6	245:4,19 246:13,22
16:08:43 313:9	16:11:37 316:2	176 313:1	20006 16:6	247:5
16:08:45 313:10	16:11:39 316:3	18 5:12 12:4,8 98:9,10	2001 179:22 180:7,10	26th 2:4
16:08:52 313:11	16:11:46 316:4	98:17 99:6,16 100:11	180:13,17 181:5	262 8:9
16:08:53 313:12	16:11:47 316:5	100:20 101:5,11,16	183:2 184:5,15 185:5	265 8:14
16:08:54 313:13	16:11:50 316:6	102:2,9,14 103:1	185:21 186:2	267 8:18
16:08:59 313:14	16:11:52 316:7	137:2 191:1 227:10	2002 64:2 311:20	27 283:16
16:09:00 313:15	16:11:53 316:8,9,10,11	228:15 295:4,5,6,10	2003 145:6 148:5,15,18	27-36 10:7
16:09:05 313:16	316:12	295:13,15,16 297:11	149:5,16 150:7 188:9	279 9:10
16:09:07 313:17	16:11:55 316:13,14	19 12:9 62:18 63:3	188:16 189:2 263:16	28 65:19 66:2 68:9,12
16:09:09 313:18	16:12:03 316:15	138:7 139:20 141:19	275:14 276:5,13	251:15
16:09:11 313:19	16:12:09 316:16	229:11 230:5,6	2005 58:13	281 9:20
16:09:13 313:20	16:16:59 316:17,18	240:11 297:14,15,20	2006 70:1 263:4,14	283 10:9
16:09:17 313:21	16:17:37 316:19	298:1,3	2007 56:20	285 10:15
16:09:22 313:22	16:17:41 316:20	1903 280:6	2008 63:14,16 64:7	288 11:11
16:09:24 314:1	16:17:42 316:21	1903-1910 9:8	66:7	29 242:5 243:6 244:5
16:09:26 314:2	16:17:45 316:22	191 189:14	2009 70:1,3	249:20,21,21 250:2
16:09:30 314:3	16:17:48 317:1	192 190:21	2013 66:22	251:21 254:10
16:09:33 314:4	16:17:50 317:2	1987 6:14 207:2 208:6	2013/0210878 6:18	290 90:22 91:21 106:20
16:09:41 314:5	16:17:51 317:3	208:11	237:19 238:2	107:2,6,9,14,17,21
16:09:43 314:6	16:17:53 317:4	1991 5:16	2014 319:10	108:1,8,10,13,16
16:09:45 314:7	16:17:54 317:5	1993 55:6,10	2015 1:17 2:5 15:22	109:16,19 112:22
16:09:49 314:8	16:17:55 317:6	1994 11:9	80:18 81:2 136:13,19	113:21 114:10,11,20
16:09:51 314:9	16:17:57 317:7	1997 12:13	204:22 205:6 254:20	114:22 115:9,10,16
16:09:57 314:10	16:18:00 317:8		255:4 318:18	115:17 116:3,5
16:10:02 314:11	16:18:02 317:9,10	2	202 3:9,10	118:16 123:20 127:1
16:10:07 314:12	16:18:04 317:11	2 5:14 9:20 22:19 23:8	206 5:18	129:3 131:10 243:17
16:10:08 314:13	16:18:07 317:12	23:9 69:17 90:4 92:6	208 6:14	243:20 244:1,6,17,22
16:10:11 314:14	16:18:10 317:13	96:17 116:1,2,3	21 13:13 212:13 231:10	245:5,8,20 246:1,13
16:10:24 314:15	16:18:13 317:14	117:11 118:1,16	233:4 304:3,4,9,12,14	246:16,20,22 247:3,5
16:10:29 314:16	16:18:14 317:15	119:2,5,16 120:11	212 3:20,21	247:13
16:10:33 314:17	16:18:16 317:16	121:5,21 122:10,16	213 4:8,9	292 11:18
16:10:35 314:18	16:18:18 317:17	123:3,15,21 127:2	215 180:21	295 12:8
16:10:38 314:19	16:18:20 317:18,19	128:6 155:19 180:4,6	22 14:4 151:14 242:1	297 12:15
16:10:39 314:20	16:18:21 317:20,21	205:17,18 206:1,3,7	305:13,14,19,22	299 13:11



<p style="text-align: center;"><b>3</b></p> <p>3 6:5 11:9 80:11 81:6 128:6 131:10,11,14 131:17,21 189:8,9 207:20,21 208:9,11 208:19 240:18,22 241:3 245:12,13 246:4,6,6,7 292:1</p> <p><b>3D</b> 260:11</p> <p><b>3-D</b> 261:1 262:1</p> <p><b>3-Dodecylcarbonylo...</b> 13:6</p> <p><b>3:00</b> 255:1,3</p> <p><b>30</b> 157:10 198:10 243:19 244:1,17,22 245:4,19 246:13,22 247:5</p> <p><b>304</b> 13:18</p> <p><b>305</b> 14:9</p> <p><b>308</b> 14:17</p> <p><b>31</b> 272:11</p> <p><b>312</b> 14:22</p> <p><b>32</b> 155:12 166:9,12 273:6 276:22</p> <p><b>325</b> 258:1</p> <p><b>325-356</b> 7:16</p> <p><b>33</b> 13:11 298:20 299:7</p> <p><b>333</b> 4:5</p> <p><b>35</b> 171:17 172:8 277:14</p> <p><b>3541</b> 201:14</p> <p><b>3542</b> 182:14</p> <p><b>3543</b> 183:5,15</p> <p><b>3544</b> 180:12,16 182:2 182:14 185:12 201:15</p> <p><b>355-3333</b> 3:21</p> <p><b>36</b> 244:5</p> <p><b>38</b> 125:3</p> <p><b>39</b> 6:14 208:7 277:21 311:21 312:15</p> <hr/> <p style="text-align: center;"><b>4</b></p> <p><b>4</b> 1:17 2:5 6:16 15:22 69:17 80:17 81:1 88:21 119:3 136:13 136:19 195:15 205:6 232:10,11,14 254:19 255:3 318:17</p> <p><b>4th</b> 204:22</p> <p><b>4-bromobenzoyl</b> 113:14 118:19 119:8 124:8 129:9 155:17 227:4</p> <p><b>4:13</b> 316:15,17</p> <p><b>4:18</b> 316:17,19</p> <p><b>4:19</b> 318:17,22</p> <p><b>40</b> 113:17 125:3 227:15</p>	<p>228:20 229:22 230:1 235:19</p> <p><b>408-4000</b> 3:9</p> <p><b>408-4400</b> 3:10</p> <p><b>417-424</b> 10:14</p> <p><b>42</b> 172:14 203:18</p> <p><b>423</b> 285:16</p> <p><b>43</b> 175:15</p> <p><b>431</b> 90:16 91:21 98:5 98:10,18 99:6,16 100:12,21 101:5,9,12 101:14,17,22 102:3,7 102:10,15 103:2,7,10 104:1 179:8</p> <p><b>438</b> 203:6</p> <p><b>44</b> 178:17</p> <p><b>45</b> 179:21</p> <p><b>47</b> 13:18 186:18 206:16 206:18,20 207:2 208:12 304:5,15</p> <p><b>48</b> 195:4</p> <p><b>49</b> 12:13 14:9 202:19 305:15 306:3</p> <p><b>49-60</b> 11:16</p> <hr/> <p style="text-align: center;"><b>5</b></p> <p><b>5</b> 5:18 6:17 22:16,21 23:3,7,8 65:13,14 134:1,6 137:1 205:13 205:19 206:3 237:16 237:17,21 252:5,6</p> <p><b>50</b> 192:2 193:5,7</p> <p><b>52-1</b> 214:14 215:19</p> <p><b>53</b> 212:11,15</p> <p><b>546-553</b> 14:16</p> <p><b>576-1000</b> 4:8</p> <p><b>576-1100</b> 4:9</p> <p><b>58</b> 209:12,17 210:22 293:3</p> <p><b>585-589</b> 9:19</p> <p><b>59</b> 225:7</p> <p><b>594-600</b> 12:13</p> <hr/> <p style="text-align: center;"><b>6</b></p> <p><b>6</b> 7:4,10 55:2 73:22 125:3,3,11 127:2 141:19,20 142:19 146:22 151:10 203:1 238:11,13,15 240:2,3 240:4,8,10,11,14 241:7,20 255:9,9</p> <p><b>60</b> 113:13 114:15 118:22 119:7 128:22 129:6 230:10</p> <p><b>606</b> 91:19,22 97:9,15 97:16,22 106:8,10,11 106:13,15</p>	<p><b>61</b> 226:10</p> <p><b>62</b> 17:9 128:9 227:1</p> <p><b>620</b> 2:3 3:17 15:20 180:10 183:4</p> <p><b>621</b> 6:14 208:7</p> <p><b>626</b> 6:14 208:7</p> <p><b>63</b> 128:5 227:9</p> <p><b>64</b> 128:5,9 228:16</p> <p><b>65</b> 229:12,16</p> <p><b>65-76</b> 7:9</p> <p><b>65-83</b> 14:8</p> <p><b>66</b> 230:6 255:11</p> <p><b>67</b> 230:16</p> <p><b>69</b> 231:8,9,14,20</p> <hr/> <p style="text-align: center;"><b>7</b></p> <p><b>7</b> 7:12,17 113:3 117:14 117:14,15 125:12 153:1,11 189:16 192:6,7 251:2,4,15 257:9,10,11,14,17,19 257:20 258:2</p> <p><b>7.0</b> 113:13</p> <p><b>7.5</b> 125:12,19 126:5</p> <p><b>70</b> 231:9</p> <p><b>71</b> 231:10,14,20</p> <p><b>72</b> 212:12,15</p> <p><b>73</b> 66:6</p> <p><b>74</b> 240:14 242:3</p> <p><b>75</b> 235:19 242:11</p> <p><b>755</b> 232:17,19,20 233:4 233:17 234:2,17 236:3,9 237:1</p> <p><b>76</b> 250:9</p> <p><b>78</b> 254:7,8,12</p> <p><b>798-806</b> 13:10</p> <p><b>799</b> 300:7</p> <hr/> <p style="text-align: center;"><b>8</b></p> <p><b>8</b> 7:18,22 10:9 96:15 103:6,9,22 114:9,10 114:22 115:10,17 116:5 117:15 155:11 166:10 212:5,7 246:8 259:11,12,13,16,19 259:21,22 260:3,6 283:3,13</p> <p><b>8,129,431</b> 90:12,15 178:22</p> <p><b>8,192,755</b> 6:16 232:12 232:16</p> <p><b>8,669,290</b> 90:18,21</p> <p><b>8,754,131</b> 91:2,5</p> <p><b>8,871,813</b> 91:8,11</p> <p><b>8,927,606</b> 91:15,18</p> <p><b>8.5</b> 125:13,19 126:5</p> <p><b>8:00</b> 2:5</p>	<p><b>8:12</b> 15:21</p> <p><b>80</b> 227:14 263:12,20</p> <p><b>80-containing</b> 113:18 228:22</p> <p><b>813</b> 91:12,21</p> <p><b>813-8800</b> 3:20</p> <p><b>82</b> 66:15 306:6</p> <p><b>826-832</b> 12:7</p> <p><b>827</b> 295:19</p> <p><b>83</b> 66:15</p> <p><b>84</b> 66:15</p> <p><b>859-868</b> 13:17</p> <p><b>866</b> 304:18</p> <p><b>87</b> 14:17 308:14 309:1</p> <p><b>878</b> 238:2,5,16 239:1</p> <p><b>89</b> 66:15</p> <hr/> <p style="text-align: center;"><b>9</b></p> <p><b>9</b> 8:4 10:15 58:5,8 65:15 125:12,12 171:17 262:11,12,17 262:20,22 263:4 284:22 285:13</p> <p><b>9-23</b> 7:21</p> <p><b>9:31</b> 80:17,21</p> <p><b>9:46</b> 80:21 81:1</p> <p><b>90</b> 114:13 230:9,17 231:2</p> <p><b>90071</b> 4:6</p> <p><b>901</b> 3:5</p> <p><b>916</b> 192:12</p> <p><b>917</b> 193:22 194:16</p> <p><b>93</b> 66:15</p> <p><b>95</b> 195:19 196:15</p> <p><b>96</b> 196:7,16,18 197:3 197:20 199:4 201:18 202:3,5</p> <p><b>97</b> 196:16,20 197:3,11 197:20</p> <p><b>987</b> 213:6 214:12</p> <p><b>990</b> 216:8</p> <p><b>992</b> 218:15</p>
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PLEASE ATTACH TO THE DEPOSITION OF DR. JAYNE LAWRENCE

DATE TAKEN: September 4, 2015

CASE CAPTION: Senju Pharmaceutical Co., Ltd. v. Lupin Ltd. And Lupin Pharmaceuticals, Inc.

ERRATA SHEET

PAGE	LINE	CHANGE	REASON
61	1	"or using" should be "non-ionic"	transcription error
84	12	"it" should be "I"	transcription error
167	1	"positive and negative" should be "positively or negatively"	transcription error
167	4	"they're" should be "their"	transcription error
187	21	"SGA" should be "FDA"	transcription error
217	19	frequent" should be "frequently"	transcription error
301	15	"non" should be "amine"	transcription error

I have read the foregoing transcript of my deposition and except for any corrections or changes noted above, I hereby subscribe to the transcript as an accurate record of the statements made by me.

Executed this 8th day of October, 2015.



1 I HEREBY CERTIFY that I have read this transcript of  
2 my deposition and that this transcript accurately  
3 states the testimony given by me, with the changes  
4 of corrections, if an, as noted.

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Subscribed and sworn to be before this \_8th\_ day of  
October, 2015