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2	UNITED STATES PATENT AND TRADEMARK OFFICE
3	
4	BEFORE THE PATENT TRIAL AND APPEAL BOARD
5	
6	NALOX-1 PHARMACEUTICALS, LLC
7	Petitioner,
8	v.
9	OPIANT PHARMACEUTICALS, INC.,
10	Patent Owner.
11	
12	Case No. IPR2019-000685
13	Patent No. 9,211,253
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15	
16	DEPOSITION OF MAUREEN DONOVAN, PH.D.
17	Washington, D.C.
18	Friday , November 22, 2019
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20	
21	
22	
23	Reported by:
24	MATTHEW GOLDSTEIN, RPR
25	JOB NO. 172400



Pa	ge 2	Page 3
November 22, 2019 9:01 a.m.  Deposition of MAUREEN DONOVAN, In the professional Reporter and Notary Public of the District of Columbia.  Deposition of MAUREEN DONOVAN, In the professional Reporter and Notary Public of the District of Columbia.	1 2 3 4 5 6 7 8 PH.D., 9	APPEARANCES:  ARENT FOX Attorneys for Plaintiffs 1717 K Street Northwest Washington, DC 20006 BY: BRADFORD FRESE, ESQ. YELEE KIM, ESQ.  WILLIAMS & CONNOLLY Attorneys for Defendants 725 Twelfth Street Northwest Washington, DC 20005 BY: ANA REYES, ESQ. KEVIN HOAGLAND-HANSON, ESQ. JESSAMYN BERNIKER, ESQ.
1 2 A P P E A R A N C E S (CONT'D): 3 4 GREEN GRIFFITH & BORG-BREEN 5 Attorneys for Plaintiffs 6 676 N Michigan Avenue 7 Suite 3900 8 Chicago, Illinois 60611 9 312.882.8000 10 BY: JESSICA TYRUS MACKAY, ES 11 12 ALSO PRESENT: 13 JOSHUA H. HARRIS - BURFORD 14 15 16 17 18 19 20 21 22 23 24 25	5 6 7 8 9	M. DONOVAN, PH.D. MS. REYES: Do you want to state appearances? Ana Reyes for the respondents. MS. BERNIKER: Jessamyn Berniker and Kevin Hoagland-Hanson, also for the respondents, patent owners. MS. MACKAY: Jessica Tyrus Mackay from Green Griffith & Borg-Breen, also on behalf of the patent owners. MR. FRESE: Bradford Frese from the firm of Arent Fox on behalf petitioner and the witness. MS. KIM: Yelee Kim from Arent Fox on behalf of petitioner. MR. HARRIS: Joshua Harris, Burford Capital, for Nalox-1. Whereupon, MAUREEN DONOVAN, PH.D., being first duly sworn or affirmed to testify to the truth, the whole truth, and nothing but the truth, was examined and testified as follows: EXAMINATION BY COUNSEL FOR THE PATENT OWNER BY MS. REYES: Q. Ma'am, you did not attend medical school; correct?



M. DONOVAN, PH.D. A. No, I iddn't. DONOVAN, PH.D. Considering withdrawal effects from the administration of Naloxone; correct? A. No, I'm a registered pharmacist. Consult with a medical doctor who treats patients in clinics; correct? A. No, I make not. Consult with a medical doctor who treats patients in clinics; correct? A. Not pare not a medical doctor who treats patients in clinics; correct? Consult with a medical doctor who treats a patient; correct? A. Not have not. Consult with a medical doctor with withdrawal effects of Ireating a patient with Naloxone; correct? Consult with a modale to treat a patient suffering withdrawal effects from the administration of Naloxone; correct? A. Not directly, no. Consult with a medical doctor concerning the administration of Naloxone; correct? A. A gain, I'm not able to treat a patient Consult with a medical doctor concerning the administration of Naloxone; correct? A. If so to focused on it, no. Consult with a medical doctor concerning any of the opinions in your report, you did not consult with a medical doctor concerning any of the opinions in your report, correct? A. I have to look at the world forward for papers administration of Naloxone; correct? A. If so to focused on it, no. Consult with a medical doctor concerning any of the opinions in your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct? A. I have to a clinician part with a medical doctor concerning any of the opinions in your report; correct? A. I have to look at the world forward for papers administration of Naloxone; correct? A. If so to focused on it, no. Consult with a medical doctor concerning any of the opinions in your report; correct? A. I have to look at the papers and the paper		Page 6		Page 7
2		M. DONOVAN, PH.D.	1	M. DONOVAN. PH.D.
3	2		I	
4 A. No, I'm a registered pharmacist. 5 Q. You're not a clinician? 6 A. Could you define what you mean by 7 "clinician." 7 Q. You're not a medical doctor who treats 9 patients in clinics; correct? 10 A. That's correct. 11 Q. You never treated a patient for any 12 purpose; correct? 13 A. Not in a medical sense, no. 14 Q. You have never administered Naloxone to 15 a patient; correct? 16 A. No, I have not. 17 Q. You have never administered Naloxone to 18 effects of treating a patient with Naloxone; 19 correct? 10 A. Not directly, no. 11 Q. You have never had to treat a patient 12 suffering withdrawal effects from the 23 administration of Naloxone; correct? 24 A. Again, I'm not able to treat patients. 25 Q. So you have never treated a patient 26 quelch products from the 27 administration of Naloxone; correct? 28 A. That's correct. 29 Q. Before preparing your report, you did 20 not consult with a medical doctor concerming any 21 of the opinions in your report, you did 22 not consult with a medical doctor concerming any 23 of the opinions in your report, you did 24 not consult with a medical doctor concerming any 25 of Glüenther Hochhaus; correct? 26 A. That's correct. 27 A. No to directly, no. 28 A. A tris my understanding he's not. 29 Q. You have reviewed the expert report of Glüenther Hochhaus; correct? 30 Q. Soy ou have reviewed the expert report of Glüenther Hochhaus; correct? 41 Q. Wou have reviewed the expert report of Glüenther Hochhaus; correct? 42 A. That's correct. 43 Q. You have reviewed the expert report of Glüenther Hochhaus; correct? 44 A. That's correct. 55 Q. Wou have reviewed the expert report of Glüenther Hochhaus; correct? 56 Q. Glüenther Hochhaus; correct? 57 A. I's my understanding he's not. 58 Q. He's not a clinician, correct? 59 Q. Glüenther Hochhaus; correct? 60 Q. Glüenther Hochhaus; correct? 71 A. I's my understanding he's not. 72 A. I's my understanding he's not. 73 A. I's my understanding he's not. 74 Correct National Paramacologist: 75 A. I's me an wareareas of the field, but I would not	3		3	
5 Q. You're not a clinician? 6 A. Could you define what you mean by 7 "clinician." 7 Q. You're not a medical doctor who treats 8 patients in clinics; correct? 10 A. That's correct. 11 Q. You never treated a patient for any 12 purpose; correct? 13 A. Not in a medical action who treats 14 Q. You have never administered Naloxone to 15 a patient; correct? 16 A. No, I have not. 17 Q. You have never observed the withdrawal 18 effects of treating a patient with Naloxone; 19 correct? 20 A. Not by formal education, but I have certainly education in areas related to clinical pharmacologys: 21 A. I have an awareness of the field, but I would not say that I am an expert. 22 Q. You have never observed the withdrawal effects of treating a patient with Naloxone; 21 Q. You have never had to treat a patient suffering withdrawal effects from the 22 administration of Naloxone; correct? 23 develop FDA-approved products, correct? 24 A. Again, I'm not able to treat patients. 25 Q. So you have never treated a patient 26 A. If a not focused on it, no. 27 Q. You work is not focused on trying to develop FDA-approved products, correct? 38 A. It's not focused on tying to develop FDA-approved product, but most of the time in my research, my goals are not to develop products that would be moved forward for FDA approval.  Page 8  1 M. DONOVAN, PH.D. 2 Q. Your work is not focused on trying to develop FDA-approved products, correct? 3 develop FDA-approved products, correct? 4 A. If an of focused on it, no. 5 Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report, you did not consult with a medical doctor concerning any of the opinions in your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct? 4 A. That's correct.  9 Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct?  14 A. That's correct. 15 A. That's correct. 16 Q. Güenther Hochhaus; correct? 17	4		4	
6 A. Could you define what you mean by 7 "clinician." 8 Q. You're not a medical doctor who treats 9 patients in clinics; correct? 10 A. That's correct. 11 Q. You never treated a patient for any 12 purpose; correct? 13 A. Not in a medical sense, no. 14 Q. You have never administered Naloxone to 15 a patient; correct? 16 A. No, I have not. 17 Q. You have never administered Naloxone to 18 effects of treating a patient with Naloxone; 19 correct? 10 A. Not directly, no. 21 Q. You have never had to treat a patient 22 suffering withdrawal effects from the 23 administration of Naloxone; correct? 24 A. Again, I'm not able to treat patients 25 Q. So you have never treated a patient 26 A. It's not focused on it, no. 27 Q. You're not an economist, correct? 28 A. It's not focused on it, no. 29 Q. You're not an economist, correct? 29 Q. You work is not focused on trying to 29 develop FDA-approved products; correct? 29 Q. Since 1991, you have never worked for 20 A. Not directly, no. 21 Q. You have never had to treat a patient 22 suffering withdrawal effects from the 23 administration of Naloxone; correct? 24 A. Again, I'm not able to treat patients. 25 Q. So you have never treated a patient 26 Q. You work is not focused on trying to 27 develop FDA-approved products; correct? 28 A. It's not focused on it, no. 39 Q. You're not an economist, correct? 40 A. It's not focused on it, no. 41 M. DONOVAN, PH.D. 42 Q. You're not an economist, correct? 43 A. It's not focused on it, no. 44 Q. You do not have any wadvanced training in economist (soft); correct? 45 A. That's correct. 46 A. That's correct. 47 A. It's not focused on it, no. 48 Q. You do not have any advanced training in economist (soft); correct? 49 A. That's correct. 40 Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report, correct? 40 A. That's correct. 41 Q. You have reviewed the expert report of Güenther Hochhaus; correct? 42 A. That's correct. 43 Q. You have never treated a patient or the product is a for	5		5	
7 "climician."  8 Q. You're not a medical doctor who treats 9 patients in clinics; correct? 10 A. That's correct. 11 Q. You never treated a patient for any 11 2 purpose; correct? 12 purpose; correct? 13 A. Not in a medical sense, no. 14 Q. You have never administered Naloxone to a patient; correct? 15 A. No, I have not. 16 A. No, I have not. 17 Q. You have never administered Naloxone; correct? 18 correct? 20 A. Not directly, no. 21 Q. You have never had to treat a patient suffering withdrawal effects from the administration of Naloxone; correct? 21 A. Again, I'm not able to treat patients. 22 suffering withdrawal effects from the 22 suffering withdrawal effects from the 23 administration of Naloxone; correct? 24 A. Again, I'm not able to treat patients. 25 Q. So you have never treated a patient suffering withdrawal effects from the 23 develop FDA-approved products; correct? 24 A. Again, I'm not able to treat patients. 25 Q. So you have never treated a patient suffering withdrawal effects from the 22 develop products with other sponsors whose goals is to develop an FDA-approved product, but most of the time in my research, my goals are not to develop FDA-approved products; correct? 26 A. I'm not also to treat patients. 27 Q. You're not an economist, correct? 28 A. I's not focused on it, no. 29 Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct? 30 Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct? 31 Q. You have reviewed the expert report of Güenther Hochhaus; correct? 32 Q. You have reviewed the expert report of Güenther Hochhaus; correct? 33 Q. You have reviewed the expert report of Güenther Hochhaus; correct? 34 A. That's correct. 35 Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct? 46 A. That's correct. 47 A. That's correct. 48 A. That's correct. 49 Q. You have reviewed th	6		6	
9 patients in clinics; correct? 10 A. That's correct. 11 Q. You have never adato Maloxone to a purpose; correct? 12 purpose; correct? 13 A. Not in a medical sense, no. 14 Q. You have never administered Naloxone to a patient; correct? 15 A. Not, I have not. 16 A. No, I have not. 17 Q. You have never observed the withdrawal effects of treating a patient with Naloxone; correct? 18 A. Not directly, no. 20 A. Not directly, no. 21 Q. You have never observed the withdrawal suffering withdrawal effects from the administration of Naloxone; correct? 22 affering withdrawal effects from the administration of Naloxone; correct? 23 administration of Naloxone; correct? 24 A. Again, I'm not able to treat patients. 25 Q. So you have never treated a patient suffering withdrawal effects from the administration of Naloxone; correct? 24 A. Again, I'm not able to treat patients. 25 Q. So you have never treated a patient suffering withdrawal effects from the administration of Naloxone; correct? 26 A. In the product of the product, to troub of the time in my research, my goals are not to develop product that would be moved forward for FDA approved product, but most of the time in my research, my goals are not to develop product that would be moved forward for FDA approved products; correct? 3 develop FDA-approved products; correct? 4 A. It's not focused on it, no. 4 A. That's correct. 5 Q. Before preparing your report, you did not consult with a medical doctor concerning the administration of Naloxone; correct? 4 A. That's correct. 5 Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct? 6 A. That's correct. 7 A. In the machina administration of Naloxone; correct? 8 A. It's mot focused on it, no. 9 Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct? 8 A. That's correct. 9 Q. You have reviewed the expert report of Güenther Hochhaus; correct? 10 A. That's correct. 11 Q. You have a wav	7		7	A. Not by formal education, but I have
patients in clinics; correct?  A. That's correct.  Q. You never treated a patient for any purpose; correct?  A. Not in a medical sense, no. Q. You have never administered Naloxone to a patient; correct? A. No, I have not. Q. You have never observed the withdrawal effects of treating a patient with Naloxone; correct? A. Not directly, no. Q. You have never had to treat a patient suffering withdrawal effects from the administration of Naloxone; correct? A. A Again, I'm not able to treat patients. Q. So you have never treated a patient.  Page 8  M. DONOVAN, PH.D. Q. You work is not focused on trying to develop FDA-approved products; correct? A. It's not focused on it, no. Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report, you did not consult with a medical doctor concerning any of the opinions in your report, you did not consult with a medical doctor concerning any of the opinions in your report, correct? A. I have a may observed the field, but I A. I have a may areness of the field, but I would not say that I am an expert.  Q. Since 1991, you have never worked for any pharmacologist? A. I have to develop FDA-approved products; correct? A. I have to do sat my CV to look at dates, but if I - that's probably about right. Q. Okay. Your work is not focused on trying to develop FDA-approved products, correct? A. I participate in early-phase development in conjunction with other sponsors whose goals is to develop an FDA-approved product, but most of the time in my research, my goals are not to develop products that would be moved forward for FDA approval.  Page 8  Page 9  Page 9  M. DONOVAN, PH.D. Q. Your work is not focused on trying to develop FDA-approved products; correct? A. I's not focused on it, no. Q. You're not an economist; correct? A. No, I have any advanced training in economist [sic]; correct? A. No, I don't. Q. You do not have any advanced training in economist is a formulation unique onto itself; correct? A. I did not. Q. You have never	8	Q. You're not a medical doctor who treats	8	
10 A. That's correct. 11 Q. You never treated a patient for any purpose; correct? 12 purpose; correct? 13 A. Not in a medical sense, no. 14 Q. You have never administered Naloxone to a patient, correct? 15 a patient, correct? 16 A. No, I have not. 17 Q. You have never observed the withdrawal effects of treating a patient with Naloxone; correct? 18 effects of treating a patient with Naloxone; correct? 19 A. Not directly, no. 20 A. Not directly, no. 21 Q. You have never had to treat a patient suffering withdrawal effects from the administration of Naloxone; correct? 22 suffering withdrawal effects from the administration of Naloxone; correct? 23 develop FDA-approved products; correct? 24 A. Again, I'm not able to treat patients. 25 Q. You work is not focused on trying to develop product, but most of the time in my research, my goals are not to develop products that would be moved forward for FDA approval.  Page 8  1 M. DONOVAN, PH.D. 2 Q. Your work is not focused on trying to develop FDA-approved products; correct? 24 A. Again, I'm not able to treat patients. 25 Q. So you have never treated a patient to develop an FDA-approved product, but most of the time in my research, my goals are not to develop products that would be moved forward for FDA approval.  Page 8  1 M. DONOVAN, PH.D. 2 Q. Your work is not focused on trying to develop product, but most of the time in my research, my goals are not to develop products that would be moved forward for FDA approval.  Page 9  1 M. DONOVAN, PH.D. 2 Q. Your work is not focused on trying to develop products that would be moved forward for FDA approval.  Page 9  1 M. DONOVAN, PH.D. 2 Q. You work is not focused on trying to develop products that would be moved forward for FDA approval.  Page 9  1 M. DONOVAN, PH.D. 2 Q. You work is not focused on trying to develop products that would be moved forward for focused in the products of the time in my research, my goals are not to develop products that would be moved forward for focused in the product of the time in my research, my g	9		9	
12 purpose; correct? 13 A. Not in a medical sense, no. 2	10		10	Q. Do you consider yourself an expert
12 purpose; correct? 13 A. Not in a medical sense, no. 14 Q. You have never administered Naloxone to 15 a patient; correct? 16 A. No, I have not. 17 Q. You have never observed the withdrawal 18 effects of treating a patient with Naloxone; 19 correct? 20 A. Not directly, no. 21 Q. You have never had to treat a patient 22 suffering withdrawal effects from the 23 administration of Naloxone; correct? 24 A. Again, I'm not able to treat patients. 25 Q. So you have never treated a patient 26 Q. Your work is not focused on trying to 27 develop FDA-approved products; correct? 28 A. I have. 29 Q. Your work is not focused on trying to 29 develop FDA-approved product, but most of 29 develop FDA-approved products; correct? 20 A. I have an awareness of the field, but I 21 would not say that I am an expert. 20 A. I'd have to look at my CV to look at 21 dates, but if I - that's probably about right. 20 Q. Okay, Your work is not focused on 21 trying to develop FDA-approved products; correct? 22 to develop a FDA-approved products; ortect? 23 the time in my research, my goals are not to 24 A. Again, I'm not able to treat patients. 25 Q. Your work is not focused on trying to 26 evelop FDA-approved products; correct? 27 A. I'm not an economist; correct? 28 A. That's correct. 29 Q. You do not have any advanced training in 29 correct? 30 A. That's correct. 40 A. That's correct. 41 A. That's correct. 42 A. That's correct. 43 A. That's correct. 44 A. That's correct. 45 Q. Before preparing your report, you did 46 not consult with a medical doctor concerning any 47 of the opinions in your report; correct? 48 A. That's correct. 49 Q. Before preparing your report, you did 40 not consult with a medical doctor concerning any 41 of the opinions in your report; correct? 42 A. I have. 43 A. I have. 44 C. I'm not an economist; correct? 45 A. That's correct. 46 A. That's correct. 47 A. That's correct. 48 A. That's correct. 49 Q. You do not have any advanced training in 40 consult with an ecical doctor concerning any 40 or to onsult with a medical	11	Q. You never treated a patient for any	11	clinical pharmacologist?
Q. You have never administered Naloxone to a patient, correct?   15	12		12	A. I have an awareness of the field, but I
15	13	A. Not in a medical sense, no.	13	would not say that I am an expert.
A. No, I have not.  Q. You have never observed the withdrawal effects of treating a patient with Naloxone; correct?  A. Not directly, no.  Q. You have never had to treat a patient suffering withdrawal effects from the administration of Naloxone; correct?  A. Again, I'm not able to treat patients.  Q. So you have never treated a patient  Page 8  M. DONOVAN, PH.D.  Q. Your work is not focused on trying to develop products that would be moved forward for FDA approval.  Page 9  M. DONOVAN, PH.D.  Q. Your work is not focused on it, no.  Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct?  A. That's correct.  Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct?  A. I have.  Q. You do not have any advanced training in consult with a medical doctor concerning any of the opinions in your report; correct?  A. I have.  Q. You agree that each pharmaceutical product is a formulation unique onto itself; correct?  A. I have.  Q. Gienther Hochhaus is not a medical doctor; correct?  A. I sy my understanding he's not.  A. I expect he's not a clinician.	14	Q. You have never administered Naloxone to	14	Q. Since 1991, you have never worked for
dates, but if I — that's probably about right.  Q. You have never observed the withdrawal effects of treating a patient with Naloxone;  A. Not directly, no. Q. You have never had to treat a patient suffering withdrawal effects from the administration of Naloxone; correct?  A. Again, I'm not able to treat patients. Q. So you have never treated a patient page 8  Page 8  M. DONOVAN, PH.D. Q. Your work is not focused on trying to develop FDA-approved product, but most of the time in my research, my goals are not to develop products that would be moved forward for FDA approval.  Page 9  M. DONOVAN, PH.D. Q. Your work is not focused on trying to develop FDA-approved product, but most of the time in my research, my goals are not to develop products that would be moved forward for FDA approval.  Page 9  M. DONOVAN, PH.D. Q. You're not an economist; correct? A. I's not focused on it, no. Q. Before preparing your report, you did not consult with a medical doctor concerning the administration of Naloxone; correct? A. That's correct. Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct? A. I have. Q. You have reviewed the expert report of Güenther Hochhaus; correct? A. I have. Q. Wou agree that each pharmaceutical product is a formulation unique onto itself; correct?  MR. FRESE: Objection; form.  THE WITNESS: Well, each pharmaceutical product have may have unique materials compared to other products.  A. I expect he's not a clinician.	15	a patient; correct?	15	any pharmaceutical company; correct?
18 effects of treating a patient with Naloxone; 19 correct? 20 A. Not directly, no. 21 Q. You have never had to treat a patient 22 suffering withdrawal effects from the 23 administration of Naloxone; correct? 24 A. Again, I'm not able to treat patients. 25 Q. So you have never treated a patient 26 Q. So you have never treated a patient 27 M. DONOVAN, PH.D. 28 Q. You're not an economist; correct? 29 A. I'm not an economist; correct? 30 develop FDA-approved product, but most of the develop products that would be moved forward for FDA approval.  Page 8  1 M. DONOVAN, PH.D. 2 Q. You're not an economist; correct? 3 develop FDA-approved products; correct? 4 A. It's not focused on it, no. 5 Q. Before preparing your report, you did not consult with a medical doctor concerning the administration of Naloxone; correct? 4 A. That's correct. 5 Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct? 4 A. That's correct. 5 Q. You have reviewed the expert report of Güenther Hochhaus; correct? 4 A. I have. 5 Q. You have reviewed the expert report of Güenther Hochhaus is not a medical doctor; correct? 4 A. I have. 5 Q. Güenther Hochhaus is not a medical doctor; correct? 6 Q. Güenther Hochhaus is not a medical doctor; correct? 7 A. I have. 7 A. I k's my understanding he's not. 8 A. I k's my understanding he's not. 9 Q. He's not a clinician; correct? 10 Q. He's not a clinician. 11 doctor; correct? 12 measurable properties that are quite similar to other products.	16	A. No, I have not.	16	A. I'd have to look at my CV to look at
19 correct? 20 A. Not directly, no. 21 Q. You have never had to treat a patient 22 suffering withdrawal effects from the 23 administration of Naloxone; correct? 24 A. Again, I'm not able to treat patients. 25 Q. So you have never treated a patient 26 Q. So you have never treated a patient 27 page 8  28 Page 8  1 M. DONOVAN, PH.D. 2 Q. Your work is not focused on trying to develop FDA-approved product, but most of the time in my research, my goals are not to develop products that would be moved forward for FDA approval.  29 Page 9  1 M. DONOVAN, PH.D. 2 Q. Your work is not focused on trying to develop FDA-approved product, but most of the time in my research, my goals are not to develop products that would be moved forward for FDA approval.  20 Page 9  21 M. DONOVAN, PH.D. 22 Q. Your work is not focused on trying to develop FDA-approved product, but most of the time in my research, my goals are not to develop products that would be moved forward for FDA approval.  22 Page 9  23 M. DONOVAN, PH.D. 24 A. I's not focused on it, no. 45 Q. You do not have any advanced training in economist. 46 A. That's correct. 47 A. No, I don't. 48 A. That's correct. 48 A. That's correct. 49 Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct? 40 Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct? 41 A. That's correct. 42 A. That's correct. 43 A. That's correct. 44 A. That's correct. 45 A. That's correct. 46 A. That's correct. 47 A. I'did not. 48 A. That's correct. 49 Q. You have reviewed the expert report of Guenther Hochhaus; correct? 40 Guenther Hochhaus is not a medical 41 Guenther Hochhaus is not a medical 42 A. I shave. 43 A. I shave. 44 A. I shave. 45 I'm not an economist. 46 A. No, I don't. 47 Q. You agree that each pharmaceutical product is a formulation unique onto itself; 48 A. I shave. 49 Q. Guenther Hochhaus is not a medical doctor concerning any of the opinions in	17	Q. You have never observed the withdrawal	17	dates, but if I that's probably about right.
A. Not directly, no. Q. You have never had to treat a patient suffering withdrawal effects from the administration of Naloxone; correct? A. Again, I'm not able to treat patients. Q. So you have never treated a patient  Page 8  Page 8  M. DONOVAN, PH.D. Q. Your work is not focused on trying to develop FDA-approved products; correct? A. It's not focused on it, no. Q. Before preparing your report, you did not consult with a medical doctor concerning the administration of Naloxone; correct? A. That's correct. Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct? A. I have. Q. You have reviewed the expert report of Güenther Hochhaus; correct? A. I have. Q. G. He's not a clinician; correct? A. I cryou disprove that each pharmaceutical product is a formulation unique onto itself; correct?  MR. FRESE: Objection; form. THE WITNESS: Well, each pharmaceutical product has — may or may not have unique materials compared to other products.  A. I respect he's not a clinician.  A. I respect he's not a clinician.	18		1	
21 Q. You have never had to treat a patient 22 suffering withdrawal effects from the 23 administration of Naloxone; correct? 24 A. Again, I'm not able to treat patients. 25 Q. So you have never treated a patient 26 Page 8  Page 8  Page 9  1 M. DONOVAN, PH.D. 2 Q. Your work is not focused on trying to 3 develop FDA-approved products; correct? 4 A. It's not focused on it, no. 5 Q. Before preparing your report, you did 6 not consult with a medical doctor concerning the 7 administration of Naloxone; correct? 8 A. That's correct. 9 Q. Before preparing your report, you did 10 not consult with a medical doctor concerning any 11 of the opinions in your report, correct? 12 A. That's correct. 13 Q. You have reviewed the expert report of 14 Güenther Hochhaus; correct? 15 A. I have. 16 Q. Güenther Hochhaus is not a medical 17 doctor; correct? 18 A. It's my understanding he's not. 19 Q. He's not a clinician; correct? 20 A. I expect he's not a clinician. 21 in conjunction with other sponsors whose goals is to develop pan FDA-approved product, but most of the develop products that would be moved forward for FDA approval.  18 M. DONOVAN, PH.D. 2 Q. You're not an economist; correct? 3 A. I'm not an economist. 4 A. I'm not an economist. 5 Q. You do not have any advanced training in economist [sic]; correct? 4 A. No, I don't. 6 Q. Before preparing your report, you did not consult with an economist concerning any of the opinions in your report; correct? 4 A. I did not. 6 Q. You agree that each pharmaceutical product is a formulation unique onto itself; correct? 4 MR. FRESE: Objection; form. 5 THE WITNESS: Well, each pharmaceutical product has may or may not have unique materials compared to other products. They may have may new under properties, or they may have measurable properties that are quite similar to other products.	19		I	
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25 my review. 25 may actually be an identical formulation, and it	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Q. Before preparing your report, you did not consult with a medical doctor concerning the administration of Naloxone; correct?  A. That's correct.  Q. Before preparing your report, you did not consult with a medical doctor concerning any of the opinions in your report; correct?  A. That's correct.  Q. You have reviewed the expert report of Güenther Hochhaus; correct?  A. I have.  Q. Güenther Hochhaus is not a medical doctor; correct?  A. It's my understanding he's not.  Q. He's not a clinician; correct?  A. I expect he's not a clinician.  Q. He does not indicate anywhere in his report that he consulted with a medical doctor in preparing his report; correct?  A. I didn't see anything about that during	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Q. You do not have any advanced training in economist [sic]; correct?  A. No, I don't.  Q. Before preparing your report, you did not consult with an economist concerning any of the opinions in your report; correct?  A. I did not.  Q. You agree that each pharmaceutical product is a formulation unique onto itself; correct?  MR. FRESE: Objection; form.  THE WITNESS: Well, each pharmaceutical product has may or may not have unique materials compared to other products. They may have unique properties, or they may have measurable properties that are quite similar to other products.  Q. But each pharmaceutical product is a formulation unique onto itself; correct?  MR. FRESE: Objection; cumulative.  THE WITNESS: It may or may not be. It

Page 10 Page 11 1 1 M. DONOVAN, PH.D. M. DONOVAN, PH.D. 2 2 may actually have an identical manufacturing THE WITNESS: All of the things you've 3 3 sequence to another pharmaceutical product. listed, the pharmaceutical product, the 4 BY MS. REYES: 4 ingredients in that, the container, the packaging 5 5 O. A pharmaceutical formulation can contain system, again, they must meet quality 6 therapeutic and nontherapeutic ingredients; 6 specifications as determined by the developer. 7 7 And they have been evaluated by the FDA and correct? 8 8 approved for the characteristics of that A. Yes. 9 9 Q. The formulation must be such that all particular product and its packaging. 10 10 components are compatible? BY MS. REYES: 11 MR. FRESE: Objection; form. 11 Q. And that would include that they would 12 THE WITNESS: The formulation and the 12 have to be compatible with each other; correct? 13 A. Not in an infinite sense. 13 product itself need to meet compendial quality 14 14 standards and standards specified by the O. What about in a finite sense? 15 15 manufacturer and understood by the FDA. A. The quality standards define the finite 16 16 Q. They have to be compatible with each sense --17 other? 17 Q. Okay. Ma'am --18 18 MR. FRESE: Objection; form. A. -- by which materials are compatible or interact with one another or don't interact with 19 19 THE WITNESS: They have to meet 20 compendial requirements for pharmaceutical 20 one another. 21 quality. 2.1 Q. Ansel's Pharmaceutical Dosage Forms and 22 22 Q. The active therapeutic agents, the Drug Delivery is a textbook in your field? 23 23 pharmaceutical ingredients and the packaging A. I'm familiar with that, yes. containers must all be compatible; correct? 24 24 Q. It is a textbook in your field that you 25 MR. FRESE: Objection to form. 25 and your students refer to; right? Page 12 Page 13 1 1 M. DONOVAN, PH.D. M. DONOVAN, PH.D. 2 2. A. I've referred to it, certainly. I don't BY MS. REYES: 3 know that my students have, but I don't recall all 3 Q. Here you go. 4 of the references in all of their dissertations 4 A. Actually, I don't think you correctly 5 5 and papers we've written. characterized where this came from. 6 6 Q. Okay. You tell me where it comes from. Q. Have you looked at your website 7 7 recently? A. This appears to me to be a hard copy of 8 8 A. To tell you the truth, not recently. the web page -- of a web page that is curated by 9 Q. It's a reference book listed on your 9 our University of Iowa libraries. And it also 10 10 website. Would that surprise you? appears to be in the subsection that is likely the 11 A. On my personal website? 11 guides or the subset of materials that our 12 Q. On the Iowa website for your graduate 12 university libraries have placed into sort of an 13 school, the one that you participate in. 13 easy access site based on subject matter. 14 A. I guess I'd like to see what you're 14 Q. If you turn to page 5 of this, ma'am, do 15 actually talking about. 15 you see that it says, "Compounding reference 16 Q. Sure. No problem. 16 resources"? 17 (Deposition Exhibit 2040, University of 17 A. Yes. Iowa Printout, was marked for identification and 18 18 Q. And that one of the compounding 19 attached to the transcript.) 19 reference resources is Pharmaceutical Dosage Forms 20 MR. FRESE: I object to this document. 20 and Drug Delivery, which is the Ansel's that I 21 It's outside the scope of the deposition. 21 just cited to you? 22 MS. REYES: Okay. You do that. 22 A. It doesn't indicate that it's the Ansel I'm going to introduce Exhibit 1, which 23 23 text. It just --24 is -- Exhibit 2040, which is a portion of the Iowa 24 Q. Was there a different text that's 25 graduate school website. 25 Pharmaceutical Dosage Forms and Drug Delivery,

	Page 14		Page 15
1	M. DONOVAN, PH.D.	1	M. DONOVAN, PH.D.
2	ma'am?	2	what your library tells people is a reference
3	A. There actually may be.	3	book.
4	Q. But do you know, sitting here today?	4	MR. FRESE: Is this marked as an
5	A. I'm not aware of exact titles of all the	5	exhibit?
6	reference texts in the area.	6	MS. REYES: Yeah, 2041.
7	Q. You just don't know? You've been doing	7	(Deposition Exhibit 2041, Ansel's
8	this for how long? How many decades have you been	8	Pharmaceutical Dosage Forms and Drug Delivery
9	teaching?	9	Systems 9th Edition, was marked for identification
10	MR. FRESE: Objection to form.	10	and attached to the transcript.)
11	Q. How many decades have you been teaching	11	MR. FRESE: Okay. I'm going to object
12	in this area, ma'am?	12	to this as outside the scope of the deposition and
13	A. I've been teaching about 30 years.	13	an improper excerpt of a larger reference.
14	Q. Okay. In the 30 years that you've been	14	MS. REYES: Okay.
15	teaching, you know that there's an Ansel's	15	BY MS. REYES:
16	Pharmaceutical Dosage Forms and Drug Delivery	16	Q. Ma'am, Exhibit 2041 is an excerpt from
17	textbook; correct?	17	Ansel's Pharmaceutical Dosage Forms and Drug
18	A. I believe the name actually for the	18	Delivery Systems, the ninth edition.
19	series of textbooks that Ansel has edited actually	19	Do you see that?
20	may have changed during the time period of those	20	A. Well, I see the cover page that looks
21	texts, but I will I will choose to believe that	21	like the cover page that I've seen.
22	you've given me the correct title.	22	Q. Okay.
23	Q. Thank you.	23	A. And certainly this title page indicates
24	And this Pharmaceutical Dosage Forms and	24	what I would expect from the title page of that
25	Drug Delivery, if we could turn to that, that is	25	textbook series.
	Page 16		Page 17
1		_	
1 2	M. DONOVAN, PH.D. Q. And it's the ninth edition. And if you	1 2	M. DONOVAN, PH.D.
	O And it's the ninth edition. And it volt		A (Nizovi
2			A. Okay.
3	look at the if you look at this page right	3	Q. And that is prior art that the POSA
4	look at the if you look at this page right here, it's a 2011 date.	3 4	Q. And that is prior art that the POSA would be aware of; correct?
4 5	look at the if you look at this page right here, it's a 2011 date.  A. Oh, so you've indicated the most recent	3 4 5	Q. And that is prior art that the POSA would be aware of; correct?  A. I don't know. I haven't had a chance to
4 5 6	look at the if you look at this page right here, it's a 2011 date.  A. Oh, so you've indicated the most recent copyright date as 2011.	3 4 5 6	Q. And that is prior art that the POSA would be aware of; correct?  A. I don't know. I haven't had a chance to review this. It's a single sentence that you've
4 5 6 7	look at the if you look at this page right here, it's a 2011 date.  A. Oh, so you've indicated the most recent copyright date as 2011.  Q. And this would be prior art?	3 4 5 6 7	Q. And that is prior art that the POSA would be aware of; correct?  A. I don't know. I haven't had a chance to review this. It's a single sentence that you've asked me about.
4 5 6 7 8	look at the if you look at this page right here, it's a 2011 date.  A. Oh, so you've indicated the most recent copyright date as 2011.  Q. And this would be prior art?  A. It's my understanding it would be prior	3 4 5 6 7 8	Q. And that is prior art that the POSA would be aware of; correct?  A. I don't know. I haven't had a chance to review this. It's a single sentence that you've asked me about.  Q. And I'm asking you
4 5 6 7 8 9	look at the if you look at this page right here, it's a 2011 date.  A. Oh, so you've indicated the most recent copyright date as 2011.  Q. And this would be prior art?  A. It's my understanding it would be prior art.	3 4 5 6 7 8 9	Q. And that is prior art that the POSA would be aware of; correct?  A. I don't know. I haven't had a chance to review this. It's a single sentence that you've asked me about.  Q. And I'm asking you A. I see that sentence on the page.
4 5 6 7 8 9	look at the if you look at this page right here, it's a 2011 date.  A. Oh, so you've indicated the most recent copyright date as 2011.  Q. And this would be prior art?  A. It's my understanding it would be prior art.  Q. Okay. And if we could	3 4 5 6 7 8 9	Q. And that is prior art that the POSA would be aware of; correct?  A. I don't know. I haven't had a chance to review this. It's a single sentence that you've asked me about.  Q. And I'm asking you A. I see that sentence on the page. Q. Yes, the sentence is on the page.
4 5 6 7 8 9 10	look at the if you look at this page right here, it's a 2011 date.  A. Oh, so you've indicated the most recent copyright date as 2011.  Q. And this would be prior art?  A. It's my understanding it would be prior art.  Q. Okay. And if we could MS. REYES: Now it's back in the scope.	3 4 5 6 7 8 9 10	Q. And that is prior art that the POSA would be aware of; correct?  A. I don't know. I haven't had a chance to review this. It's a single sentence that you've asked me about.  Q. And I'm asking you  A. I see that sentence on the page.  Q. Yes, the sentence is on the page.  And the POSA would see that sentence on
4 5 6 7 8 9 10 11	look at the if you look at this page right here, it's a 2011 date.  A. Oh, so you've indicated the most recent copyright date as 2011.  Q. And this would be prior art?  A. It's my understanding it would be prior art.  Q. Okay. And if we could MS. REYES: Now it's back in the scope. Q. Now, if we could please turn to page 2.	3 4 5 6 7 8 9 10 11	Q. And that is prior art that the POSA would be aware of; correct?  A. I don't know. I haven't had a chance to review this. It's a single sentence that you've asked me about.  Q. And I'm asking you A. I see that sentence on the page. Q. Yes, the sentence is on the page. And the POSA would see that sentence on the page; correct?
4 5 6 7 8 9 10 11 12	look at the if you look at this page right here, it's a 2011 date.  A. Oh, so you've indicated the most recent copyright date as 2011.  Q. And this would be prior art?  A. It's my understanding it would be prior art.  Q. Okay. And if we could  MS. REYES: Now it's back in the scope.  Q. Now, if we could please turn to page 2.  If you could go to the second column, third	3 4 5 6 7 8 9 10 11 12	Q. And that is prior art that the POSA would be aware of; correct?  A. I don't know. I haven't had a chance to review this. It's a single sentence that you've asked me about.  Q. And I'm asking you A. I see that sentence on the page. Q. Yes, the sentence is on the page. And the POSA would see that sentence on the page; correct?  A. The POSA would see the sentence on the
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4 5 6 7 8 9 10 11 12 13 14	look at the if you look at this page right here, it's a 2011 date.  A. Oh, so you've indicated the most recent copyright date as 2011.  Q. And this would be prior art?  A. It's my understanding it would be prior art.  Q. Okay. And if we could  MS. REYES: Now it's back in the scope.  Q. Now, if we could please turn to page 2.  If you could go to the second column, third paragraph, it says, "Each particular pharmaceutical product."	3 4 5 6 7 8 9 10 11 12 13 14	Q. And that is prior art that the POSA would be aware of; correct?  A. I don't know. I haven't had a chance to review this. It's a single sentence that you've asked me about.  Q. And I'm asking you A. I see that sentence on the page. Q. Yes, the sentence is on the page. And the POSA would see that sentence on the page; correct?  A. The POSA would see the sentence on the page Q. Okay. Thank you.
4 5 6 7 8 9 10 11 12 13 14 15	look at the if you look at this page right here, it's a 2011 date.  A. Oh, so you've indicated the most recent copyright date as 2011.  Q. And this would be prior art?  A. It's my understanding it would be prior art.  Q. Okay. And if we could  MS. REYES: Now it's back in the scope.  Q. Now, if we could please turn to page 2.  If you could go to the second column, third paragraph, it says, "Each particular	3 4 5 6 7 8 9 10 11 12 13 14 15	Q. And that is prior art that the POSA would be aware of; correct?  A. I don't know. I haven't had a chance to review this. It's a single sentence that you've asked me about.  Q. And I'm asking you A. I see that sentence on the page. Q. Yes, the sentence is on the page. And the POSA would see that sentence on the page; correct?  A. The POSA would see the sentence on the page
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