Page 1 1 2 UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE 3 4 -----X ALCON RESEARCH, LTD., 5 Plaintiff, Civil Action No. 6 16-129(LPS)(SRF) v. 7 WATSON LABORATORIES, INC., 8 Defendant. 9 -----X 10 VIDEOTAPED DEPOSITION 11 OF 12 MAUREEN DONOVAN, PH.D. 13 New York, New York 14 Friday, August 24, 2018 15 16 17 18 19 20 21 22 23 Reported by: 24 ANNETTE ARLEQUIN, CCR, RPR, CRR, CLR JOB NO. 145678 25

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1	M. Donovan, Ph.D.	¹ M. Donovan, Ph.D.		
2	And, again, nearly every product in	² you correctly, that the person of ordinary skill		
3	the armamentarium of all drug products could	³ would have thought there was room for		
4	have something done to it that would make	⁴ improvement in the Nevanac product like there		
5	somebody happier with it.	⁵ room for improvement in many products.		
6	Q. In the course of your work in this	⁶ A. Um-hmm.		
7	case, did you consider what options were	⁷ Q. Fair?		
8	available to the person of ordinary skill in the	⁸ A. Right. Yes.		
9	art in 2009 who wanted to improve the Nevanac	⁹ Q. And the question I have is: Looking		
10	product?	¹⁰ at the Nevanac product and thinking there may	be	
11	A. Yes. I looked at, you know, what was	¹¹ ways to improve this product, what sorts of		
12	known about ophthalmic formulations in 2009 and	¹² options would the person of ordinary skill have	э	
13	preceding that, or at least refreshed my memory	¹³ thought of as ways it could be improved,		
14	regarding the specific date 2009 and what was	¹⁴ formulation steps that could be taken to improv	ve	
15	already being done in the art; investigated	¹⁵ it?		
16	regarding ophthalmic delivery; and, you know,	¹⁶ A. Right. But I mean, each of those		
17	looked at a little bit of information in	¹⁷ formulations steps is directed at improving an		
18	specific about Nevanac.	18 aspect		
19	Q. And in your view, what options would	19 Q. Okay.		
20	the person of ordinary skill have considered in	²⁰ A or maybe a group of aspects or		
21	2009 if they wanted to improve the Nevanac	²¹ something. So I think I need a little bit more		
22	product?	²² definition in the question of what aspect would	ł	
23	A. Can you specify what improvement	²³ you like me to focus on.		
24	the	Q. I'm asking you about let's ask		
25	Q. Well, you said that, if I understood	this: What aspects do you think the person of		
	Page 20	Page 2	1	
1	Page 20	Page 2	1	
1	M. Donovan, Ph.D.	¹ M. Donovan, Ph.D.		
2	M. Donovan, Ph.D. ordinary skill would have focused on in order to	 M. Donovan, Ph.D. and development time. And there would be other 	her	
	M. Donovan, Ph.D. ordinary skill would have focused on in order to improve Nevanac?	 M. Donovan, Ph.D. and development time. And there would be otl approaches that, again, were well-known in the 	her e	
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1	M. Donovan, Ph.D.	1	M. Donovan, Ph.D.		
2	Q. Okay.	2	a comparison, you either either you		
3	Okay. And based on that, what is the	3	understand that all of the drug you gave, the		
4	answer to the question?	4	body was exposed to the same amount of drug and		
5	A. Well, Figure 2 actually is a	5	gave the same area under the curve, or it was		
6	graphical depiction of how someone calculates	1	 ⁶ not exposed to the same amount of drug, or it 		
7	the AUC and demonstrates the area under the	1	 ⁷ was exposed in a different time frame, which ye 		
8		1	 may tease out of your data or whatever. 		
9	curve.	9			
10	The bioavailability of a and we'll	10	So the bioavailability is a		
11	do this might as well stay well, the	11	description relative to a well-understood		
12	bioavailability of a drug product is a measure	12	control of what you're willing to represent as		
13	or a description of the amount of drug that the	13	100 percent. It may not be 100 percent. And		
13	body was exposed to following administration of	14	that's where relative bioavailability in my		
	that formulation or dosage form.		report, I chose to include that because whatever		
15	Okay. So the initial comparator is	15	your reference is, whatever you're using as 100		
16	an intravenous or interarterial administration	16	percent, what's your fractional comparison to		
17	typically because you don't have absorption	17	that is the, is the bioavailability.		
18	effects. You don't have other dosage form	18	But if you're using blood as a		
19	effects.	19	measure, for example, the built-in assumption to		
20	So that is your baseline that you	20	that is that blood represents the rest of the		
21	compare against is what were the distribution	21	body, which it may or may not.		
22	parameters when you gave something	22	So there's always assumptions on what		
23	intravenously. And then when you added a	23	your sampling matrix means regarding the rest of		
24	formulation, delivery system, whatever, to that,	24	the systems exposure.		
25	how much drug, what time course and so forth as	25	Q. Okay. So let's go back to page 52.		
	Page 44		Page 45		
1	M. Donovan, Ph.D.	1	M. Donovan, Ph.D.		
2	M. Donovan, Ph.D. (Witness complies.)	2	M. Donovan, Ph.D. don't have any more receptors to accept the		
2 3	M. Donovan, Ph.D. (Witness complies.) Q. You say, "Although AUC is generally	2 3	M. Donovan, Ph.D. don't have any more receptors to accept the drug, it can't have any more response regardless		
2 3 4	M. Donovan, Ph.D. (Witness complies.) Q. You say, "Although AUC is generally an indicator of bioavailability, formulations	2 3 4	M. Donovan, Ph.D. don't have any more receptors to accept the drug, it can't have any more response regardless of how much more drug is in the system. And so		
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	Page 54		Page 55		
1	M. Donovan, Ph.D.	1	M. Donovan, Ph.D.		
2	A. No, I didn't.	2	you've never worked on an ophthalmic suspension		
3	Q. And since 1991, am I correct that you	3	formulation that had been administered to a		
4	haven't worked as an employee for any	4			
5	pharmaceutical company?	5	A. So "worked on" is that I've never		
6	A. No, I haven't.	6	developed a formulation for an ophthalmic		
7	Q. And have you ever the developed an	7	· ·		
8	ophthalmic suspension?	8	-		
9	A. I've worked on formulations in my	9	A. Yes, that's true.		
10	laboratory that could have or, you know, even	10	Q. And have you ever developed an		
11	were applied in an experimental sense as I	11	FDA-approved product of any kind?		
12	think they were suspensions. I don't even	12	A. No. My work is not focused on trying		
13	the issue at hand that I'm thinking of was	13	to develop FDA-approved products.		
14	something that was a multi-component formulation	14	Q. Now your CV is at the end of your		
15	that we were looking at. I don't remember	15	opening report, but you may not need it for this		
16	whether all of the components were in suspension	16	question.		
17	or whether one was in solution. But we've	17	Am I correct over the years you've		
18	certainly looked at formulations that could have	18	published a number of articles and abstracts in		
19	been used ophthalmically. I don't recall since	19	professional scientific journals; is that		
20	I've been at Iowa actually personally being the	20	correct?		
21	principal investigator at least of a formulation	21	A. Yes.		
22	development activity where we've actually tested	22	Q. Would it be fair to say that you have		
23	anything even in an animal model for ophthalmic	23	published many articles related to the nasal		
24	use.	24	administration of drugs?		
25	Q. Would it be fair to say, then, that	25	A. Yes, I think it's fair to say.		
	Page 56				
	rage 50		Page 57		
1	M. Donovan, Ph.D.	1	-		
1 2		1 2	M. Donovan, Ph.D. short break?		
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