Page 1

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

_ _ _

HELSINN HEALTHCARE, S.A., and ROCHE PALO ALTO, LLC,	:	Civil Action DOCKET NO. 12-2867 (MLC)
Plaintiffs,	:	
v.	:	
DR. REDDY'S LABORATORIES, LTD., et al., Defendants.	:	
Derendantes.	•	_
Friday, Ap	ril	15, 2016

Videotaped deposition of DR. CHRISTOPHER A. FAUSEL, taken pursuant to notice, was held at the law offices of Lerner David Littenberg Krumholz & Mentlik, 600 South Avenue West, Westfield, New Jersey, beginning at 8:47 a.m., on the above date, before Constance S. Kent, a Certified Court Reporter, Registered Professional Reporter, Certified LiveNote Reporter, and Notary Public in and for the State of New Jersey.

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2	PAUL HASTINGS, LLP		3	5-Hydroxytryptamine-3	
2	BY: ISAAC S. ASHKENAZI, ESQUIRE		3	Receptor Antagonists Be Administered Beyond	
3	SABRINA MAWANI, ESQUIRE		4	24 Hours After	
4	200 Park Avenue		5	Chemotherapy to Prevent Delayed CINV, Systemic	
4	New York, New York 10166		5	Re-Evaluation of	
F	212.318.6432		6	Clinical Evidence and	
5	issacashkenazi@paulhastings.com		7	Drug Cost Implications	
c	sabrinamawani@paulhastings.com		1 '	Exhibit 8 Guidance for Industry 316	
6	Counsel for Helsinn		8	and Reviewers	
7	LERNER DAVID		9	Exhibit 9 Article, Volunteer 336 Models for Predicting	
0	BY: RUSSELL W. FAEGENBURG, ESQUIRE		10	Antiemetic Activity of	
8	600 South Avenue West		11	5-HT3 Receptor	
~	Westfield, New Jersey 07090		12	Antagonists Exhibit 10 US Patent Application 347	
9	908.654.5000			No 60,444,351	
1.0	rfaegenburg@lernerdavid.com		13	Exhibit 11 Frame PowerPoint Slides 364	
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20				Antagonist, for	
21			21	Preventing Postoperative Nausea and Vomiting	
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1 that. So granisetron, I think was in the 1 Q. If a patient is in the 2 neighborhood of maybe 70 or 80 bucks. So 2 outpatient setting, he is being given a 4 Q. Okay. 4 on multiple - are they given it afterwards? 5 A. So for inpatient population 6 where you're concerned with controlling 6 where you're concerned with controlling 6 7 you had two drugs which were - and these 7 9 from a toxicity standpoint there's no 9 11 formulations of the 5-HT3 antagonist, and 11 12 could gian a little bit of cost benefit, 13 13 could gian a little bit of cost benefit, 13 14 you would consider using the oral agents 14 14 you would consider using the oral agents 14 15 preferminally in the impaient setting 15 16 in the patient populations 17 17 Q. Okay. 18 20 A. Sorry. 20 And bat the rule of thumb is if you 21 four sequets and in that ansawer. 18 22		Page	274	Page 2	276
2 neighborhood of maybe 70 or 80 bucks. So 2 outpatient scriing, he is being yiven a 3 iit was a significant difference. 3 setron, okay? Are they given it only on 4 Q. Okay. 4 on multiple are they given it only on 5 A. So for inpatient population 5 setron, okay? Are they given it alterwards? 6 M. F.FAEGENBURG: Objection to the form. 7 you had two drugs which were - and these 9 9 from a toxicity standpoint there's no 9 10 difference between the 1V and the oral 10 11 involved with developing our own 11 12 if the efficacy was the same and you 12 institutional guidelines at the 13 could gain a little bit of cost benefit, 13 in mere in this document. 14 you would consider using the oral agents 14 was - it was an interesting time 14 you would consider using the oral agents 14 was - it was an interesting time 15 preferentially in the inpatient setting 15 anticulated in much better detail 15 preferentially in the inpatient setting 15	1	that. So granisetron. I think was in the		1 O. If a patient is in the	
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	Page 2	278		Page 28	80
1	believed the neurokinin 1 receptor		1	palonosetron, and we use that for	
2	antagonists work for chemotherapy-induced		2	prophylaxis for highly emetogenic and	
3	nausea and vomiting.		3	moderately emetogenic chemotherapy.	
4	If you give someone a dose		4	We also stock ondansetron,	
5	of a cytotoxic chemotherapy drug, it's		5	and the reason why we stock ondansetron	
6	going to release serotonin from these		6	is there are some patients that get	
7	enterochromaffin cells in the gut, which		7	either low emetogenic potential	
8	are these cells are just big vacuoles		8	chemotherapy or minimal emetogenic	
9	or big storage bags of serotonin. When		9	chemotherapy, but, you know, you may be	
10	the drug is when the chemotherapy drug	1	10	giving them a drug that doesn't have a	
11	is given systemically, a lot of the		11	highly likelihood of causing emesis, but	
12^{11}			12		
	serotonin is released, so it's released		13	because they've gotten a lot of	
13	locally, but a lot of it goes into the			chemotherapy with other regimens in the	
14	central nervous system and then starts		14	past, and because of where the tumor may	
15	hitting the chemoreceptor trigger zone.		15	be located in the GI tract, they may have	
16	The chemoreceptor trigger zone then sends		16	a lot of nausea to begin with.	
17	a signal to some another spot in the		17	Q. Okay.	
18	brain called the vomiting center. The		18	A. So we'll give ondansetron	
19	vomiting center says, Oh, wait, I'm being		19	for those folks, and if someone has a	
20	exposed to some sort of toxic moiety, I		20	headache with palonosetron so there's	
21	need to start the process of getting rid		21	a class effect with palo with 5-HT3	
22	of this compound.		22	receptor antagonists where they all cause	
23	So that's what starts the		23	headache. And anywhere between 5 and	
24	process of first nausea, and then	2	24	20-ish percent, depending on which	
	Page 2	279		Page 28	81
1	Page 2 retching, and them ultimately emesis.	279	1	Page 28 clinical trial you read, but it's	81
1 2		279	1 2		81
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2 3 4 5 6	retching, and them ultimately emesis. Q. Okay. All right. Sir, a couple of questions. Do you prescribe palonosetron? Do you work with doctors to prescribe palonosetron? A. Yes.	279	2 3 4 5 6	clinical trial you read, but it's reproducible, it happens. What is interesting is you can actually give another one of the 5-HT3s. So if I'm given palo and get a	81
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1	Page 282		Page 284
	can't, but I want to get you out of here	1	patient had a headache to one, hopefully
2	for your flight and the question is	2	when you switched them over to the second
3	getting a little long.	3	one, the headache would go away. In some
4	A. Fair enough.	4	cases it still stuck around, that
5	Q. I understand. So let's just	5	headache, and you may even have to try
6	try to keep it I'll try to keep it	6	and order in special the third one.
7	focused.	7	Q. So there's really no
8	The workhorse antiemetic	8	distinct advantage to having a fourth
9	that you use, you've described as	9	setron with respect to that to
10	palonosetron, correct?	10	avoiding the headaches because you were
11	MR. FAEGENBURG: Objection	11	basically able to treat a patient by
12	to the form.	12	using the other alternatives of the other
13	THE WITNESS: So the the	13	of the three setrons that were available,
14	main 5-HT3 receptor antagonist	14	correct?
15	that we use at our clinics at	15	A. You need you need at
16	Indiana University Health for our	16	least a second agent available, at least
17	cancer centers is palonosetron for	17	that's always been my long-standing
18	prophylaxis of highly emetogenic	18	clinical belief on formulary at a
19	and moderately emetogenic	19	hospital or in a clinic to manage the
20	chemotherapy.	20	headache situation.
21	BY MR. ASHKENAZI:	21	Q. So to be clear, for setrons,
22	Q. Great.	22	in order to manage any toxicity issues or
23	Now you use granisetron you	23	headache, side effect issues, having a
24	said for certain ondansetron?	24	second setron available is all that you
	Page 283		Page 285
1	A. Yeah.	1	needed to ensure the safety of your
2	Q. Okay. So you use	2	patients?
3	ondansetron for certain patients, either	3	MR. FAEGENBURG: Objection
4	they're given minimally emetogenic	4	to form.
5	chemotherapy or the patient had a side	5	THE WITNESS: From the
6	effect to palonosetron; is that correct?	6	hospital's standpoint, having two
7	A. Yes, that's fair.	7	agents would be best. I mean, it
8	Q. Okay. Now, the the side	8	would be great to have three but
9	effects that you discussed with the	9	there's a cost associated with
9	headache, as long as you have two setrons	10	having too many drugs in stock.
10		1	
10 11	available, you're in you're in good	11	So most most hospitals would
10 11 12	available, you're in you're in good shape? Let me make let me clarify	12	So most most hospitals would say, All right, let's just carry
10 11 12 13	shape? Let me make let me clarify that question.	12 13	say, All right, let's just carry two, if we need a third one we'll
10 11 12 13 14	shape? Let me make let me clarify	12 13 14	say, All right, let's just carry two, if we need a third one we'll order it in.
10 11 12 13 14 15	shape? Let me make let me clarify that question. For patients who had headaches back in 2002 and they were on	12 13 14 15	say, All right, let's just carry two, if we need a third one we'll order it in. BY MR. ASHKENAZI:
10 11 12 13 14 15 16	shape? Let me make let me clarify that question. For patients who had headaches back in 2002 and they were on granisetron, most of those patients would	12 13 14 15 16	 say, All right, let's just carry two, if we need a third one we'll order it in. BY MR. ASHKENAZI: Q. So back in 2002 with
10 11 12 13 14 15 16 17	shape? Let me make let me clarify that question. For patients who had headaches back in 2002 and they were on granisetron, most of those patients would not have the headache if you switched	12 13 14 15 16 17	 say, All right, let's just carry two, if we need a third one we'll order it in. BY MR. ASHKENAZI: Q. So back in 2002 with granisetron, ondansetron and dolasetron
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