UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

GNOSIS S.P.A., GNOSIS
BIORESEARCH S.A., AND
GNOSIS U.S.A., INC.,

Petitioners,

Case IPR2013-00117 US Patent 6,011,040

v.

MERCK & CIE,

Patent Owner.

Deposition of AUDY KENT LADNER
Friday, November 22, 2013
Kenner, Louisiana
9:00 a.m.

Reported by: MARYBETH MUIR Job No. 32574

Gnosis Exhibit 1147
Gnosis v. Merck/SAMSF
IPR2013-00116,-117,-118,-119

	2		4
1	APPEARANCES:	1	AUDY KENT LADNER,
2		2	having been first duly sworn, was examined and
3	ATTORNEYS FOR THE PETITIONERS:	3	testified as follows:
4	HUSCH BLACKWELL, LLP	4	
5	120 South Riverside Plaza, Suite 2200	5	EXAMINATION
6	Chicago, Illinois 60606	6	BY MR. CWIK:
7	BY: JOSEPH E. CWIK, ESQ.	7	Q. Good morning, Mr. Ladner. Could you
8	joseph.cwik@huschblackwell.com	8	please state your full name for the record.
9	AN ONL THAT A TIL	9	A. Audy Kent Ladner.
10	AMIN TALATI	10	Q. Mr. Ladner, you've been deposed
11	55 West Monroe Street, Suite 3400	11	before, correct?
12	Chicago, Illinois 60603	12	A. Correct.
13	BY: JONATHAN J. KRIT, ESQ.	13	Q. Just a couple ground rules. Today
14	jonathan@amintalati.com	14	I'll be asking you a series of verbal questions.
15		15	It's important that you answer verbally rather than
16	A METOD NEVA POD MILE DA MENTO ONO 185 C	16	gestures such as shaking your head and nodding your
17	ATTORNEYS FOR THE PATENT OWNERS:	17	shoulders because the reporter cannot really take
18	ALSTON & BIRD, LLP	18	those things down. I'll ask you a series of
19	90 Park Avenue	19	questions. And I'll assume that you understand the
20	New York, New York, 10016-1387	20	question unless you tell me otherwise.
21	212.210.9400	21	Is that okay?
22	BY: THOMAS PARKER, ESQ.	22	A. Yes.
23	thomas.parker@alston.com	23	Q. Is there any reason medically that
24	DWAYNE C. NORTON, ESQ.	25	you can't give truthful testimony today? A. No.
25	dwayne.norton@alston.com	23	
	3		5
1	INDEX	1	Q. Mr. Ladner, I've handed you what
2	WITNESS PAGE	2	we've previously marked as Exhibit 2022, title
3	AUDY KENT LADNER	3	replacement declaration of Audy Kent Ladner. I'd
4	Examination by Mr. Cwik 4, 96	4	like you to take a look at this document and tell me
5	by Mr. Norton 90	5	if you've seen it before.
6		6	A. I have.
7	EXHIBITS	7	Q. And is this your declaration that you
8	IDENT. DESCRIPTION PAGE	8	submitted in connection with these matters before
9	Exhibit 1099 Parties' Joint Stipulation of	9	the Patent Board?
10	Undisputed Facts 11	10	A. It is.
11	Exhibit 1100 Jury Demanded 34	11	Q. Okay.
12	Exhibit 1101 Metanx Tablets Product Insert 36	12	Turning to page 28, which is your
13	Exhibit 1102 Jury Demand Complaint 45	13	signature page. Is that your signature?
14	Exhibit 1103 Jury Demanded 51	14	A. It is.
15		15	Q. The sentence before that says:
16		16	"I declare under penalty of perjury
17		17	that the foregoing is true and correct."
18		18	Is that an accurate statement?
19		19	A. Yes, it is.
20		20	Q. Referring to Paragraph 14 of your
21		21	declaration, the first sentence in Paragraph 14
22		22	says:
23		23	"One particular differentiate tour
24		24	that makes our product unique is our use of
25		25	Merck's Metafolin as our L-methylfolate

		6	8
1	ingredient."	1	include B vitamins in their product, correct?
2	In that sentence you have a phrase,	2	A. Yes.
3	"our product", and I just want to understand which	ch 3	Q. So that doesn't by itself make your
4	product or products you are referring to in that	4	product unique, correct?
5	sentence.	5	A. I'm not sure you mean by having B
6	A. All of our product that contain the	6	vitamins?
7	L5-methylfolate.	7	Q. Uh-huh.
8	Q. Did you say L-5-methylfolate?	8	A. No.
9	A. L5-methylfolin.	9	Q. Okay.
10	•	10	Let's go to Paragraph 17 of your
	Q. L5-methylfolin? A. Yes.	11	
11			declaration. It says:
12	Q. Okay.	12	"Pamlab entered into a license with
13	Is that L5-methylfolin sometimes also	13	Merck in 2002 and the latest agreement between
14	called L-methylfolate?	14	Merck and Pamlab was signed in 2013."
15	A. It is.	15	Now, under those agreements, you
16	Q. Is it also sometimes called	16	understand that Pamlab is a licensee under the four
17	5-methyl-6S-tetrahydrofolate?	17	patents that are listed on the front page of your
18	A. Sometimes.	18	declaration, correct?
19	Q. Okay.	19	MR. NORTON: Objection to form.
20	So which ingredients that Pamlab	20	A. Correct.
21	makes includes the methylfolin ingredient?	21	Q. Let's look at the front page so we
22	MR. NORTON: Objection to form.	22	can get some common language that we're using today.
23	A. Uhmm, Neevo DHA I just want to	23	Not page one, but the actual cover page. There you
24	make sure we get it. Dep line, Neevo, Cerefolin,	24	go.
25	Cerefolin NAC, Metanx.	25	Do you see towards the bottom there
		7	9
1	Q. Okay.	1	is a reference to a U.S. Patent No. 5997915?
2	Is that it that you can recall at	2	A. I'm not sure. I'm not seeing it.
3	this time?	3	Oh, okay, yes. I was looking down below.
4	A. The ones that I'm pertaining to in	4	Q. And below that is there is a
5	that statement.	5	reference to U.S. Patent 673381?
6	Q. The first sentence says:	6	A. Yes.
7	"One particular differentiate tour	7	Q. And U.S. Patent 7172778, correct?
8	that makes our product unique is our use of	8	A. Yes, correct.
9	Merck's Metafolin."	9	Q. And below that is a reference to a
10	Are you aware of any other	10	patent 6011040?
11	differentiate tours that make your product unique		A. Correct.
12	A. B vitamins.	12	Q. Okay.
13	Q. Okay.	13	And do you understand that Pamlab has
14	Which ones are those?	14	a license to use those patents under the
15		15	Merck-Pamlab license agreements?
16	A. B12, B6, all of the ones that we use that are covered under the Bailey patents.	16	A. Yes.
17	• •		
18	Q. Okay.	17	Q. Okay.
19	And are you saying that you are not	18	And with respect to those first three
	aware of any other products that use B vitamins on	I	patents, and, you know, we commonly call patents by
20	is it just the particular combination of these B	20	their last three digits. So, for example, the first
	vitamins and your L-methylfolate which makes you	I	one would be the 915 patent. You're familiar with
21	1 4 • 9		
22	product unique?	22	that, correct?
22 23	A. I'm not sure what you're asking.	23	A. Correct.
22	_		

10 12 1 declaration as the Bailey patents; is that correct? 1 and U.S. Patent 67490 and Canadian patent 2 2 CA-2243981." Correct. 3 3 Q. Is that okay if we call those three Mr. Ladner, does that refresh your 4 patents the Bailey patents today? 4 recollection as to whether or not Pamlab is a 5 5 licensee under additional patents under the Pamlab A. Yes. 6 6 And the last one is the 040 patent. license agreement? Q. 7 7 Is that okay if we call that the 040 patent? MR. NORTON: Objection, foundation. 8 8 A. Yes. It's the first time I've seen this. 9 O. Okav. 9 I don't -- you know, in my capacity I'm aware that 10 10 Under the Merck-Pamlab agreements, do we have license agreements. Under what and what 11 you understand whether Pamlab is a licensee under 11 with what, that I can't give specifics. 12 12 any additional patents? Ο. Okav. 13 MR. NORTON: Objection to form. 13 I don't know what any of these mean. A. 14 I'm not sure under those patents what 14 O. 15 15 you're referring to. Have you seen any of the Pamlab Merck 16 16 Q. Okay. license agreements? 17 Under the Merck-Pamlab license 17 Not in-depth. I'm just simply aware 18 18 agreement, is Pamlab licensed to use any patents that we have them because of, again, my capacity as 19 other than the Bailey patents or the 040 patent? 19 an officer of the company and a significance that 20 I'm not sure. I'm not familiar with 20 040 has to our business. 21 under that patent, so ... 21 In your declaration you make 22 22 Maybe it's just the language. Do you reference to the "Pamlab Patented Products"; is that Q. 23 understand that Pamlab has the rights to any patents 23 correct? Do you use that phrase? 24 other than the Bailey patents and the 040 patent 24 A. Where are we? 25 under the Merck agreements? 25 We can look at Paragraph 30. Do you 11 13 see Paragraph 30 lists the products Cerefolin, 1 A. That Pamlab has rights to other 2 2 Metanx, CerefolinNAC, Deplin, Neevo and NeevoDHA? patents? 3 Q. Yes. 3 A. 4 4 A. Q. Do you see after that list you define 5 5 them as collectively the "Pamlab "Patented Q. And do you know which patents those 6 6 Products"? are? 7 7 A. Not off memory. A. 8 8 MR. CWIK: Mark this 1099. Q. And is it okay if we use that phrase 9 9 today for today's deposition? (Whereupon Exhibit 1099, Parties' 10 10 A. Joint Stipulation of Undisputed Facts, was marked Yes. 11 11 for Identification.) 0. Okav. 12 Mr. Ladner, I've handed you what was 12 Is it your opinion that the Pamlab 13 marked as Exhibit 1099. And it's titled "Parties 13 Patented Products are covered by the 915778381 or 14 Joint Stipulation of Undisputed Facts". This is the 14 the 040 patents? 15 15 MR. NORTON: Objection, calls for public version of the document. 16 MR. NORTON: Counsel, it's 1099, 16 legal conclusion. Expert testimony. 17 17 right? Q. You can answer. 18 18 If we're referring to the 040 patent MR. CWIK: 1099, correct. A. 19 19 and the Bailey patents, yes. And, Mr. Ladner, I'd like you to look 20 20 at Paragraph 11 of the stipulation on page five that Okay. 21 says: 21 And is it your understanding that the 22 22 "Under the Merck-Pamlab license Pamlab Patented Products are covered by any patents 23 23 other than the Bailey patents and the 040 patent? agreement Pamlab is also licensee of U.S. 24 Patent 6254904, U.S. Patent 6441168 and U.S. 24 MR. NORTON: Same objection. 25 25 Patent No. 6451360, U.S. Patent No. 6808725 Not that I am aware of specifically

	14		16
1	what it would be covering for those products. The	1	trademark?
2	ones of significance are the 040 and the Bailey	2	A. Yes.
3	patents.	3	Q. And do you know why Pamlab desired to
4	Q. Okay.	4	have rights to Merck's Metafolin trademark?
5	And why are they of significance?	5	A. No.
6	Why are only those of significance?	6	Q. Do you understand that Pamlab has
7	A. Because we have built our entire	7	rights to Merck's analytical support?
8	business around that those inventions and those	8	A. Yes.
9	patents. And the outcomes that have been associated	9	Q. Okay.
10	with those in the Pamlab Patented Products.	10	And do you know why Pamlab desired
11	Q. Well, given that we've seen in the	11	rights to Merck's analytical support?
12	joint stipulation that Pamlab took a license to	12	A. No.
13	patents other than the Bailey patents and the 040	13	Q. Do you understand that Pamlab has
14	patent, could you tell me why Pamlab obtained rights	14	rights to Merck's application know-how?
15	to those other patents?	15	MR. NORTON: Objection to foundation.
16	A. I didn't know what those patents were	16	A. No.
17	for or do I know what they're for. So I can't,	17	Q. When Pamlab first licensed the
18	therefore, say there is any significance.	18	patents from Merck, did Pamlab believe that Merck
19	Q. Is there someone at Pamlab who would	19	had a good business reputation?
20	know why Pamlab took rights to those other patents?	20	A. I wasn't with Pamlab at the time.
21	A. I don't I can't tell you.	21	Q. Okay.
22	Q. Regarding the patents that Pamlab	22	When did you arrive at Pamlab?
23	took a license to that are other than the Bailey	23	A. 2006.
24	patents and 040 patent, do you know if those other	24	Q. In 2006 did Pamlab believer that
25	patents and 040 patent, do you know it those other patents were deemed necessary to sell the Pamlab	25	Merck had a good business reputation in the
		23	
	15		17
1	Patented Products?	1	industry?
2	MR. NORTON: Objection to form.	2	A. Yes.
3	Calls for expert testimony.	3	Q. Has PamLab's association with Merck
4	A. No.	4	and Merck's reputation been important to Pamlab?
5	Q. Did you say no?	5	MR. NORTON: Objection to form.
6	A. I said no.	6	A. Only regarding 040.
7	Q. Do you know if Pamlab could make	7	Q. Only with respect to the 040 patent
8	Pamlab Patented Products without rights to the other	8	is that what you said?
9	patents other than the Bailey patents and the 040	9	A. Uh-huh.
10	patent?	10	Q. Has Pamlab put the name of the
11	MR. NORTON: Same objection.	11	Metafolin ingredient on its product insert for the
12	A. No.	12	Pamlab patented ingredients?
13	Q. Do you understand that Pamlab is	13	MR. NORTON: Objection to form.
	licensed to use Merck's Metafolin ingredient?	14	A. I'm not sure it's on each one of
14			
14 15	A. Yes.	15	them.
		15 16	them. Q. Okay.
15	A. Yes.		
15 16	A. Yes.Q. And do you know why Pamlab had a	16	Q. Okay.
15 16 17	A. Yes. Q. And do you know why Pamlab had a desire to use Merck's Metafolin ingredient?	16 17	Q. Okay. We'll look at that later then.
15 16 17 18	 A. Yes. Q. And do you know why Pamlab had a desire to use Merck's Metafolin ingredient? A. Because of its uniqueness and its 	16 17 18	Q. Okay.We'll look at that later then.A. I mean we've got
15 16 17 18 19	A. Yes. Q. And do you know why Pamlab had a desire to use Merck's Metafolin ingredient? A. Because of its uniqueness and its novel properties and it's truly a novel invention.	16 17 18 19	 Q. Okay. We'll look at that later then. A. I mean we've got Q. In your mind, is it beneficial for
15 16 17 18 19 20	 A. Yes. Q. And do you know why Pamlab had a desire to use Merck's Metafolin ingredient? A. Because of its uniqueness and its novel properties and it's truly a novel invention. Q. So, what is unique and novel about 	16 17 18 19 20	 Q. Okay. We'll look at that later then. A. I mean we've got Q. In your mind, is it beneficial for Pamlab to be associated with Merck in connection
15 16 17 18 19 20 21	A. Yes. Q. And do you know why Pamlab had a desire to use Merck's Metafolin ingredient? A. Because of its uniqueness and its novel properties and it's truly a novel invention. Q. So, what is unique and novel about Merck's Metafolin ingredient?	16 17 18 19 20 21	Q. Okay. We'll look at that later then. A. I mean we've got Q. In your mind, is it beneficial for Pamlab to be associated with Merck in connection with its license agreements and its use of the Metafolin product?
15 16 17 18 19 20 21 22	A. Yes. Q. And do you know why Pamlab had a desire to use Merck's Metafolin ingredient? A. Because of its uniqueness and its novel properties and it's truly a novel invention. Q. So, what is unique and novel about Merck's Metafolin ingredient? A. The outcomes that we see because of it.	16 17 18 19 20 21 22	Q. Okay. We'll look at that later then. A. I mean we've got Q. In your mind, is it beneficial for Pamlab to be associated with Merck in connection with its license agreements and its use of the Metafolin product? MR. NORTON: Objection to form.
15 16 17 18 19 20 21 22	A. Yes. Q. And do you know why Pamlab had a desire to use Merck's Metafolin ingredient? A. Because of its uniqueness and its novel properties and it's truly a novel invention. Q. So, what is unique and novel about Merck's Metafolin ingredient? A. The outcomes that we see because of	16 17 18 19 20 21 22 23	Q. Okay. We'll look at that later then. A. I mean we've got Q. In your mind, is it beneficial for Pamlab to be associated with Merck in connection with its license agreements and its use of the Metafolin product? MR. NORTON: Objection to form.

	18		20
1	040.	1	THE WITNESS: Have I heard? can I
2	Q. Is it beneficial to Pamlab that	2	repeat the question?
3	Pamlab has a license to the Metafolin trademark?	3	Q. Sure tell me what you understand in
4	A. No.	4	the question?
5	Q. Is it beneficial to Pamlab that	5	A. Have I heard or do I understand in
6	Pamlab has a license to Merck's analytical support?	6	hearing that we pay royalties to Merck for the
7	A. No.	7	Bailey patents? Is that what you're asking?
8	Q. Has Pamlab used any analytical	8	Q. And a portion each of those to Bailey
9	support from Merck in connection with the Pamlab	9	patents and the 040 patent.
10	Patented Products?	10	A. That's the part that I don't know.
11	A. I don't know.	11	Q. Do you know if Pam last has done any
12	Q. So it's possible that Pamlab has	12	internal analysis which royalties paid to Merck
13	obtained Merck's analytical support with respect to	13	relate to the Bailey patents and 040 patent?
14	the Pamlab Patented Products?	14	A. No.
15	A. What is I'm not sure what	15	Q. Do you understand that Pamlab has
16	analytical support is.	16	exclusive rights to the license patents in a certain
17	Q. Okay.	17	exclusive market?
18	Technical support on the use of the	18	A. Yes.
19	Metafolin ingredient.	19	Q. And do you recall what that exclusive
20	MR. NORTON: Objection to form.	20	market is?
21	A. That's medical. I'm not aware of it.	21	A. I know it's United States, Canada and
22	Q. I understood you previously testified	22	South America. That I am aware of.
23	that Pamlab having Merck's analytical support would	23	Q. Is it beneficial to Pamlab to be the
24	be valuable to Pamlab. Why is the analytical	24	exclusive licensee in that market?
25	support valuable if you don't know really what has	25	A. Yes.
	19		21
1	been done?	1	Q. Okay.
2	MR. NORTON: Objection, form and	2	Why is that beneficial to Pamlab?
3	foundation. Misstates the record.	3	A. Because of its novelness. Because of
4	Q. You can answer.	4	its value.
5	A. Any time anyone is offering any	5	Q. Is it valuable to Pamlab because in
6	support any support I think that's valuable.	6	that market Pamlab does not have to compete with
7	Q. Okay.	7	other companies that also have rights under those
8	A. And it is valuable.	8	patents?
9	Q. Now, under the Merck-Pamlab license	9	A. No.
10	agreement, you understand that Pamlab pays royalties	10	Q. No?
11	to Merck, correct?	11	A. No.
12	A. Correct.	12	Q. If Pamlab had a choice of being an
13	Q. And when Pamlab pays royalties to	13	exclusive licensee in a market or had the choice of
14	Merck, does Pamlab somehow apportion the royalties	14	competing with others under the same patents, would
15	to each of the Bailey patents and the 040 patent?	15	Pamlab prefer to be the exclusive licensee or
2.0	A. Uhmm, the apportionment and all that,	16	competing with others?
16			MR. NORTON: Objection. Calls for
17	I don't know how that's done or if that's done. I'm	17	-
17 18	I don't know how that's done or if that's done. I'm aware of royalties and the amount of royalties only	18	speculation.
17 18 19	I don't know how that's done or if that's done. I'm aware of royalties and the amount of royalties only because in my capacity as an officer and the	18 19	speculation. A. We'd always prefer to be exclusive.
17 18 19 20	I don't know how that's done or if that's done. I'm aware of royalties and the amount of royalties only because in my capacity as an officer and the business piece of it, I'm aware of it.	18 19 20	speculation. A. We'd always prefer to be exclusive. Q. And why is that?
17 18 19 20 21	I don't know how that's done or if that's done. I'm aware of royalties and the amount of royalties only because in my capacity as an officer and the business piece of it, I'm aware of it. Q. Have you ever heard of other from	18 19 20 21	speculation. A. We'd always prefer to be exclusive. Q. And why is that? A. Well, first of all, because if you
17 18 19 20 21 22	I don't know how that's done or if that's done. I'm aware of royalties and the amount of royalties only because in my capacity as an officer and the business piece of it, I'm aware of it. Q. Have you ever heard of other from Pamlab that Pamlab somehow does a portion the	18 19 20 21 22	speculation. A. We'd always prefer to be exclusive. Q. And why is that? A. Well, first of all, because if you have a patent, and if you have true if you have
17 18 19 20 21 22 23	I don't know how that's done or if that's done. I'm aware of royalties and the amount of royalties only because in my capacity as an officer and the business piece of it, I'm aware of it. Q. Have you ever heard of other from Pamlab that Pamlab somehow does a portion the royalties it pays for each of the licenses under the	18 19 20 21 22 23	speculation. A. We'd always prefer to be exclusive. Q. And why is that? A. Well, first of all, because if you have a patent, and if you have true if you have novelty and you have something that you believe in
17 18 19 20 21 22	I don't know how that's done or if that's done. I'm aware of royalties and the amount of royalties only because in my capacity as an officer and the business piece of it, I'm aware of it. Q. Have you ever heard of other from Pamlab that Pamlab somehow does a portion the	18 19 20 21 22	speculation. A. We'd always prefer to be exclusive. Q. And why is that? A. Well, first of all, because if you have a patent, and if you have true if you have

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22 1 don't have to deal with this. 1 2 2 Okay. 3 3 Paragraph 23 of your declaration, you 4 can take your time and read the whole paragraph if 5 you want, but I'm going to focus on the last two 5 6 lines of Paragraph 23. And starting off with "as 6 7 7 well as" at the end of the second to last line. 8 8 It says: 9 "As well as our enforcing the patents 9 10 10 against multiple third-party infringers." 11 My question is: I understand that 11 12 you've enforced the patents against Gnosis in 12 13 13 litigation, correct? 14 A. Pamlab specifically? 14 15 15 O. Yes. 16 16 A. That I'm not sure. 17 0. 17 Do you know if Pamlab has enforced 18 the patents against Macoven? 18 19 From a patent standpoint, Pamlab? 19 20 20 No. I'm not aware of it. 21 So, with respect to PamLab's 21 22 enforcing the patents against multiple third-party 22 23 infringers, who are those multiple third-party 23 24 infringers? 24 25 A. Those were -- what I was referring to 25 23 1 there was -- is what is referred to as imposters. 1 2 And you'll see that in here. In the actual 2 3 litigation against those third-party infringers, the 3 4 specifics of was -- was patent involved or was it 4 5 5 not. What I'm referring to there is the fact that 6 the exclusiveness of the 040 patent. Now, whether 6 7 7 it was mentioned in there -- but it was all around 8 the primary -- the primary ingredient, if you will, 8 9 9 in all of our products of being L5, which is covered 10 in the patent of 040. So it's the L5 that I'm 10 11 11 referring to. 12 You said that you were referring to 12 13 13 the imposter products among other things and those 14 are discussed in your declaration, right? 14 15 15 A. Uh-huh. 16 O. If you could look at page 26 of your 16 17 declaration. You have a table on page 26, correct? 17 18 18 A. Correct. 19 And it lists several companies that 19 20 are labeled as imposters, correct? 20 21 21 A. Correct. 22 22 Those include Macoven, Acella 23 Pharmaceutical, Trigen Labs, Seton Pharmaceutical 23

24

25

A.

and Virtus Pharmaceutical, correct?

Correct.

Q. Is it your understanding that Pamlab has enforced the patents against each of these companies that I just read?

A. No. As I explained earlier, it's -- I don't know if it's patent specifically was enforced in these, but we had -- we had litigation and we had specifics around the ability to be an imposter or the fact that they were copying our products.

Q. Okay.

So with respect to those companies, you're not sure whether there was actual patent lawsuit filed against those companies; is that correct?

- A. Not against all of them, no.
- Q. Okay.

And do you understand the difference between a lawsuit that's for patent infringement as opposed to a lawsuit that's for false advertising? I know you're not a lawyer.

- A. I know the difference for that, yes.
- Q. Okay.

A. But again, I'm not a lawyer and I'm not wrapped up in all of the legal wrangling that is going on regarding it. I know the reason why we do

it. I know the outcome that I expect from it. And I know the impact that it has while we're waiting on the outcome. And that's why -- in my capacity, that is what I focus on. So the specifics of what's all being brought forward in any litigation, it's all the same to me.

Q. Just to complete the loop here then, Paragraph 23 in the last line where you mention there is PamLab enforcing the patents against multiple third-party infringers, I understand your testimony to be that you don't recall exactly which third-party infringers those were; is that correct?

MR. NORTON: Objection to the extent that it misquotes the witness.

A. Jen specific to the patent tease piece and litigation associated with what's patent and what's false advertising? I don't recall the specifics of all those with all of the different imposters and infringers that we had.

Q. Okay.

And am I safe in assuming that you don't recall which specific patents were asserted in those actions against those infringers, correct?

MR. NORTON: Objection to form.

I don't know if patents were enforced

7 (Pages 22 to 25)

24

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model and business and the whole reason that I'm at

Pamlab is built on this.

- PROTECTIVE ORDER MATERIAL 26 28 1 to begin with. But if they were -- I don't know for 1 Q. When you say "on this", do you mean 2 2 sure, but if they were, I can tell you that those the Merck relationship? 3 3 are the ones that would be primary because it would I'm talking about on the novelty of A. 4 be the same. It would be the one that would be 4 the invention of the 040 and the Bailey patents. 5 associated with 040 and the Bailey patents. Because 5 Q. Okay. 6 those are the ones that are significant. 6 Paragraph 30 of your declaration, the 7 7 Q. Okay. last sentence of paragraph 30 says: 8 8 Do you recall if there are any other "Without the license from Merck, 9 patents that were asserted? 9 Pamlab would not have moved forward with the 10 10 No, because I can't recall any other development of Metanx, CerofolinNAC, Deplin, A. 11 11 Cerofolin, Neevo or NeevoDHA". patents. 12 Ο. Paragraph 26 of your declaration, the 12 And my question is: Did Pamlab 13 13 first sentence says: believe it needed a license to certain patents to 14 "Over the years Pamlab sought ways to 14 make the Pamlab Patented Products? 15 15 MR. NORTON: Objection to form. expand the scope of the agreements to capture 16 16 We needed a license for 040 and the more of the value of the intellectual property A. 17 covered by those agreements. In particular 17 Bailey patents. 18 the scope of the agreements became broader to 18 Q. Okay. 19 allow Pamlab to purchase more Metafolin from 19 Do you know if Pamlab believed that 20 Merck." 20 it needed a license to any other patents to make the 21 And the sentence continues. And my 21 **Pamlab Patented Products?** 22 question is: Where you say the scope of the 22 MR. NORTON: Objection to form. 23 agreements back broader to allow Pamlab to purchase 23 A. I don't know. 24 more Metafolin, was it beneficial for Pamlab to 24 Q. Do you understand that the Merck 25 purchase more Metafolin? 25 Metafolin ingredient is covered by its own patent? 27 29 MR. NORTON: Objection. Calls for 1 A. Yes. 1 2 2 Is it important that Pamlab purchase expert testimony. 3 the specific Metafolin ingredient versus a different 3 A. Yes. 4 version of L-methylfolate sold by a different 4 Q. 5 5 Do you understand that patent to be company? 6 6 U.S. Patent 6441168? MR. NORTON: Objection to form. 7 7 A. 8 Q. Why is it important that you purchase 8 Q. Do you know what the patent number 9 the specific Metafolin product? 9 is? 10 Because it's the one that we have 10 A. No. 11 11 associated with our outcomes. O. Okav. 12 When you say "outcomes", are you 12 Do you understand that patent covers 13 13 a crystalline version of L-methylfolate? referring to clinical outcomes of patients that have 14 14 used your products? A. 15 15 A. Yes. Q. Do you understand that all of PamLab 16 Q. If Metafolin was not for sale, would 16 Patented Products include the Metafolin ingredient? 17 17 Pamlab still continue to manufacture it's Pamlab MR. NORTON: Objection to form. 18 18 Patented Products with a different version of The ones that we're discussing? A. 19 19 Yes, the Pamlab Patented Products. L-methylfolate on the market? Q. 20 MR. NORTON: Objection, hypothetical, 20 A. Yes, I'm sorry. 21 calls for speculation. 21 Well, given that all of the Pamlab 22 22 I mean I can't answer that. Our Patented Products use Metafolin and Metafolin is 23 23 entire -- I will add this: Our entire business covered by a patent, do you agree that Pamlab

understands it needs rights to that patent covering

the Metafolin ingredient as well?

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MR. NORTON: Objection to form. 2		30		32
2 A. I would assume if it's part of the 3 patent, we need the Metafolin. 4 Q. The Metafolin patent? 5 A. We need the 040. The Bailey patents is are the ones that I - I hard's the one that I know creates outcomes. And that's the one that I know that is driving our whole bus. 9 that is driving our whole bus. 10 Q. Do you know if Merck has claimed that its Metafolin version of I -methylfolate is more effective in patients than other versions of 1 and its erystalline version of I -methylfolate is more effective than other versions of I -methylfolate is more effective in patients of the package. I more effective than other versions of I -methylfolate is more effective than other versions of I -methylfolate is more effective than other versions of I -methylfolate is more effective than other versions of I -methylfolate is more effective than other versions of I -methylfolate. 2	1	MR. NORTON: Objection to form.	1	O. Okav.
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foundation. A. No. Q. Referring to Paragraph No. 32 of your declaration, the first sentence says: "In general, the Pamlab Patented Products each have labels that provide 31 information about the products. But the most significant source of information for the product." Do you see that? A. I do. Why is the package insert for each significant source of information? A. I formation. Q. Why is the package inserts the most significant source of information? A. If swhere clinicians go to get their information. Q. Referring to Paragraph 37 of your declaration, you make reference and you cite to the Metanx product insert as Exhibit 2078; is that correct? I handed you what's been marked as Exhibit 2078; which is entitled "Metanx" at the top. Mr. Ladner, is this the Metanx product insert that you've identified as Exhibit 2078? A. I is. Q. Ookay. Who at Pamlab prepares this product insert: A. Medical/Regulatory. Q. Is that an internal division within patients of the approval. I believe that they do. Q. Now, the second page of this Exhibit 2078, there is a list of patents at the top, do you see that? A. I do. 33 4. I do. Q. And does the Med/Reg people prepare that list of patents? A. Yes. Q. Do you have personal knowledge as to which of these patents do apply to the Metanx product? MR. NORTON: Objection to form. A. No, I don't. Other than 040 and the Bailey patents and the 040 patent there is a U.S. Patent (5254904, correct? The third one, do you see that? A. Yes. Q. You would agree that is not a Bailey patent or 040 patent, correct? A. As I understand them, correct. A. As I understand them, correct? A. As I understand that is not a Bailey patent or 040 patent, correct?				- ·
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25 Products each have labels that provide 31 31 33 33 33 33 33 33 33 33 33 33 33 3	23	declaration, the first sentence says:	23	Exhibit 2078, there is a list of patents at the top,
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7 Q. Why is the package inserts the most significant source of information? 8 significant source of information? 9 A. It's where clinicians go to get their information. 10 information. 11 Q. Referring to Paragraph 37 of your declaration, you make reference and you cite to the Metanx product insert as Exhibit 2078; is that correct? I handed you what's been marked as Exhibit 2078, which is entitled "Metanx" at the top. 16 Mr. Ladner, is this the Metanx product insert that you've identified as Exhibit 2078? 17 Q. Okay. 18 A. It is. 19 Q. Okay. 19 Q. Okay. 20 Who at Pamlab prepares this product insert? 21 insert? 22 A. Medical/Regulatory. 23 Q. Is that an internal division within 23 767490 and you understand that is not a Bailey patent, correct? 24 Pamlab? MR. NORTON: Objection to form. A. No, I don't. Other than 040 and the Bailey patents. A. No, I don't. Other than 040 and the Bailey patents. A. No, I don't. Other than 040 and the Bailey patents. A. No, I don't. Other than 040 and the Bailey patents. A. No, I don't. Other than 040 and the Bailey patents. A. No, I don't. Other than 040 and the Bailey patents. A. No, I don't. Other than 040 and the Bailey patents. A. No, I don't. Other than 040 and the Bailey patents. A. No, I don't. Other than 040 and the Bailey patents. A. No, I don't. Other than 040 patent that bailey patents. A. No, I don't. Other than 040 patent than bailey patents and the 040 patent there is a U.S. Patent No. A. Yes. A. Yes. A. Correct. Q. Okay. The one below that is U.S. Patent No. 6441168 and you would agree that is not a Bailey patent or a 040 patent, correct? A. As I understand them, correct. Q. And the last one is U.S. Patent 767490 and you understand that is not a Bailey patent or 040 patent, correct?				
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9 A. It's where clinicians go to get their 10 information. 11 Q. Referring to Paragraph 37 of your 11 declaration, you make reference and you cite to the 12 declaration, you make reference and you cite to the 13 Metanx product insert as Exhibit 2078; is that 14 correct? I handed you what's been marked as 15 Exhibit 2078, which is entitled "Metanx" at the top. 16 Mr. Ladner, is this the Metanx product insert that 17 you've identified as Exhibit 2078? 18 A. It is. 19 Q. On this list other than Bailey 10 patents and the 040 patent there is a U.S. Patent 11 A. Yes. 12 Q. You would agree that is not a Bailey 13 patent or 040 patent, correct? 14 A. Correct. 17 Q. Okay. 18 A. It is. 18 The one below that is U.S. Patent No. 19 Q. Okay. 19 6441168 and you would agree that is not a Bailey 19 patent or a 040 patent, correct? 20 insert? 21 A. As I understand them, correct. 22 A. Medical/Regulatory. 23 Q. Is that an internal division within 24 Pamlab? 24 Pamlab? 26 On this list other than Bailey 26 On this list other than Bailey 27 Patents and the 040 patent there is a U.S. Patent 28 A. Yes. 40 O. You would agree that is not a Bailey 40 Patent or 040 patent, correct? 41 A. As I understand them, correct. 42 Q. And the last one is U.S. Patent 43 O. You would agree that is not a Bailey 44 Pamlab? 45 Patent or 040 patent, correct? 46 A. As I understand that is not a Bailey 47 patent or 040 patent, correct?		· · ·		
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Pamlab? 24 patent or 040 patent, correct?	22		22	Q. And the last one is U.S. Patent
	23	Q. Is that an internal division within	23	767490 and you understand that is not a Bailey
25 A. It is. It's two divisions. 25 A. Correct.	24	Pamlab?	24	patent or 040 patent, correct?

34 36 1 For those patents that are not the 1 Α. 2 2 Bailey patents or 040 patent, do you know whether Q. Do you recall if previous versions of 3 the claimed features in those other patents 3 the Metanx product insert listed this 496 patent? 4 contributed to PamLab's success? 4 MR. NORTON: Objection, form, 5 A. No 5 foundation. 6 Q. Do you recall if Pamlab has ever 6 A. No. 7 7 asserted that Metanx is covered by a patent other MR. CWIK: Mark this 1101. 8 than a patent that is listed here? 8 (Whereupon Exhibit 1101, Metanx 9 MR. NORTON: Objection to form. 9 Tablets product insert, was marked for 10 10 Identification.) A. I've handed you a document marked as 11 MR. CWIK: This is 1100. 11 Q. 12 (Whereupon Exhibit 1100, Jury 12 1101 and the title at the top is "Metanx Tablets". 13 13 Demanded, was marked for Identification.) Have you seen this document before, Mr. Ladner? 14 Mr. Ladner, we've handed you a 14 It looks familiar, yes. 15 15 document that we marked as 1100 and it's a case Do you recognize that's a product 16 titled Pamlab L.L.C. vs. Brookstone Pharmaceuticals, 16 insert for Metanx tablets? 17 L.L.C. a/k/a Acella Pharmaceuticals. I would like 17 An older version. A. 18 18 you to take a look at Paragraph 16 on page seven and Q. On the last page I see the last line 19 the first sentence of Paragraph 16 says: 19 it says revised 11/08. Do you know what that would 20 20 "Metanx's formulation and use falls indicate, that language right there? 21 within the scope of the '496 patent." 21 A. That there was a change made in 22 22 November of '08. Does that refresh your recollection 23 23 as to whether Pamlab has asserted Metanx is covered O. Okav. 24 by a patent other than the patents that are listed 24 And on the third page there is a 25 on the product insert? 25 listed Patent section. Do you see that? 35 37 It says it here. But I'm still not 1 I do. 1 A. 2 aware of it. I don't know what that means or the 2 On the right-hand column the last 3 significance that it has. 3 patent is U.S. Patent no. 6528496. And my question 4 Referring to Paragraph No. 2, if you 4 is: Does this refresh your recollection as to 5 whether 496 patent was included in previous product could turn to that on page 2, the last sentence, it 5 6 6 inserts for Metanx? savs: 7 7 "Metabolite is the owner of all A. It's here. 8 right, title, and interest in U.S. Patent No. 8 Q. Okav. 9 6,528,496, entitled 'Compositions treating, 9 So this does refresh your 10 10 recollection that, in fact, it was listed? preventing, or reducing elevated metabolic 11 11 MR. NORTON: Objection, asked and levels' (the '496 Patent)." 12 Does that sentence refresh your 12 answered. 13 13 recollection that Pamlab has asserted that is A. Yes. 14 14 Referring back to Metanx product covered by the 40? 15 15 insert Exhibit 2078, the one that's referred to in MR. NORTON: Objection as to 16 foundation and with respect to the document. 16 vour declaration? 17 17 A. Uh-huh. A. 18 18 Q. But it doesn't jog your memory? I see that has a revise date of Q. 19 19 August 2012, correct? A. 20 20 A. Correct. 0. Do you have a recollection of Pamlab 21 filing suit against Brookstone Pharmaceuticals and 21 Okav. 22 22 **Acella Pharmaceuticals?** Do you know why the 496 patent 23 23 A. appears in Exhibit 1101 in 2008, but does not appear Yes. 24 O. And do you recall that suit took 24 in Exhibit No. 2078 in 2012? 25 place in Federal Court in New Orleans? 25 MR. NORTON: Objection, foundation.

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1	A.	No.	1	that?
2	Q.	Referring to the Exhibit 2078, the	2	A. Yes.
3	-	insert referred to in your declaration?	3	Q. Okay.
4	A.	Uh-huh.	4	And with respect to this list, is it
5	Q.	Do you see there is a section on the	5	also your opinion that you don't know which patents
6	_	ge called "Precautions"?	6	cover these Cerofolin products other than the Bailey
7	A.	Yes.	7	and 040 patents listed here?
8	Q.	About halfway down?	8	MR. NORTON: Objection to form.
9	Q. A.	Yes.	9	A. Correct.
10	Q.	And the it looks like the second	10	Q. And Metafolin ingredient is included
11		begins "L-methylfolate calcium". Do you	11	in the Cerofolin product, correct?
12		sentence?	12	A. Correct.
13	A.	Yes.	13	Q. Do you know why the 168 patent by
14	Q.	It says:	14	Merck is not included in this list of patents?
15	Q.	"L-methylfolate calcium may be less	15	A. No.
16	likel	y than folic acid to mask vitamin B12	16	Q. With respect to the Bailey patents I
17		iency."	17	see that the 381 and the 778 Bailey patents are not
18	uciic	You see the footnotes, the 13 and 14?	18	listed in this list of patents. Is it your belief
19	A.	Yes.	19	that Cerofolin is covered by the 381 and 778
20	Q.	And is it your understanding that	20	patents?
21		otnotes, 13 and 14, would refer to the	21	MR. NORTON: Objection, speculation,
22		es on the second page of this exhibit?	22	calls for expert.
23	A.	Yes.	23	A. It doesn't have it here.
24	Q.	Okay.	24	Q. Do you have a personal belief whether
25	Q.	Do you see that reference 14 is	25	Cerofolin is covered by those patents or not?
		39		41
1			1	
1 2		e to Scott JM, et al, lancet 1981,	1 2	A. This Cerofolin?
	2:337-34			Q. Yes.
3 4	Α.	Do you see that? Yes.	3 4	A. Uhmm, no. Because the only ones that
5		Does Pamlab agree that it was known	5	I really again, care about, is 040 and the Bailey patents. But I don't know which patent is specific
6	Q.	ne of this Scott article in 1981 that	6	to Cerofolin individually. And why or why not it's
7			7	not listed here.
8	-	Ifolate calcium may be less likely than folic nask vitamin B12 deficiency?	8	
	acia to n	•	9	Q. On the front page of this exhibit,
9	foundatio	MR. NORTON: Objection form,	10	2251, there is a section entitled "Precautions". Do you see that?
10 11	A.	Medical has it in here.	11	A. I do.
12	A. Q.	If Medical has it in there, Medical	12	Q. And the second sentence says:
13	-	it was true?	13	"The 1 mg of cyanocobalamin contained
14	A.	I can't answer for Medical.	14	in Cerofolin has been shown to provide an
15	Q.	Would you expect Medical to only	15	adequate amount of cyanocobalamin to address
16		information that it believed was true,	16	this precaution."
17	correct?		17	Do you see there is a citation to No.
j '	A.	Correct.	18	4 there?
1 2	Δ.	Mr. Ladner, I'm handing you what we	19	A. I do.
18 19		wii. Daunci, i in nanuniz yuu what we	1 ,	
19	Q.		20	O Do you understand that to be a
19 20	Q. mark as	Exhibit 2251. Mr. Ladner, do you recall	20	Q. Do you understand that to be a
19 20 21	Q. mark as this exhi	Exhibit 2251. Mr. Ladner, do you recall bit was cited in your declaration as a	21	citation to reference No. 4 on the second page of
19 20 21 22	Q. mark as this exhi product	Exhibit 2251. Mr. Ladner, do you recall bit was cited in your declaration as a insert for Cerofolin tablets?	21 22	citation to reference No. 4 on the second page of this exhibit?
19 20 21 22 23	Q. mark as this exhi product A.	Exhibit 2251. Mr. Ladner, do you recall bit was cited in your declaration as a insert for Cerofolin tablets? Yes.	21 22 23	citation to reference No. 4 on the second page of this exhibit? A. It's not a very good citation, but
19 20 21 22	Q. mark as this exhi product A. Q.	Exhibit 2251. Mr. Ladner, do you recall bit was cited in your declaration as a insert for Cerofolin tablets?	21 22	citation to reference No. 4 on the second page of this exhibit?

	42		44
1	"Lederle FA, oral cobalamin for	1	Q. Okay.
2	pernicious anaemia: medicine's best kept	2	And I see there is a 915 patent which
3	secret? JAMA 1991; 265:94-95."	3	is part of the Bailey patents, correct?
4	Are these references, references that	4	A. Correct.
5	you believe the Med division of Pamlab created?	5	Q. Okay.
6	MR. NORTON: Objection to form.	6	And there is the 040 patent
7	A. Or Regulatory.	7	underneath that, correct?
8	Q. Okay.	8	A. Correct.
9	And do you assume that Medical or	9	Q. With respect to the other patents
10	Regulatory believed this information to be accurate?	10	listed there, do you have knowledge as to whether
11	MR. NORTON: Objection, calls for	11	CerofolinNAC is covered under those other patents?
12	speculation.	12	A. No.
13	A. I don't know. It wouldn't be in here	13	Q. The Metafolin ingredient is included
14	I wouldn't think if they didn't think that it was	14	in the CerofolinNAC product; is that correct?
15	accurate.	15	A. Correct.
16	Q. This product insert also would have	16	Q. Do you have any knowledge why the 168
17	been created by the Med/Reg divisions of Pamlab,	17	patent is not listed in this list of patents?
18	correct?	18	MR. NORTON: Objection, foundation.
19	A. Correct.	19	A. No.
20	Q. Is that true for all the product	20	Q. Do you have any explanation as to why
21	inserts for all of the Pamlab Patented Products?	21	the 381 or the 778 patents are not listed in this
22	MR. NORTON: Objection, form calls	22	list of patents?
23	for speculation.	23	A. No.
24	_	24	
25		25	Q. Do you have an understanding as to
	Q. By the Med/Reg divisions at Pamlab?	25	whether CerofolinNAC is actually covered by the 381
	43		45
1	A. It's everyone has a creates	1	or 778 patent?
2	this they are responsible for them, Med/Reg.	2	A. No.
3	They are the ones that are medical, does all the	3	Q. Do you have an understanding as to
4	clinical. And Regulatory makes sure that it meets	4	whether CerofolinNAC is covered by any other patents
5	all the Regulatory requirements.	5	that list June Ailing and Steve Bailey as the
6	Q. Okay.	6	inventors?
7	So, you're saying that the other	7	MR. NORTON: Objection to form,
8	people from even outside of those divisions provide	8	foundation.
9	input?	9	A. I don't know specifics around 915. I
10	A. Yes.	10	don't know the specifics, no.
11	Q. But Med/Reg has the supervision of	11	Q. Do you recall if Pamlab has ever
12	actually	12	asserted that CerofolinNAC is covered by patents
13	A. Yes, yes, the final.	13	other than the Bailey patents or the 040 patent?
14	Q. Mr. Ladner, I handed you what we've	14	A. I don't know.
15	marked as Exhibit 20 '85, which has been described	15	(Whereupon Exhibit 1102, Jury
16	in your declaration as a product insert for	16	Demand Complaint, was marked for Identification.)
17	Cerofolin in a credit.	17	Q. Mr. Ladner, we handed you what's been
18	Mr. Ladner, in fact, is this the	18	marked as Exhibit 1102, which is a complaint filed
19	product insert for CerofolinNAC that you had cited	19	by Pamlab among others against Macoven and the
20	in your declaration?	20	Allied Fire & Safety Equipment Co. entities in the
21	A. It is.	21	earn district of Texas.
22	Q. The middle column towards the bottom	22	Are you aware of that lawsuit, Mr.
23		23	Ladner?
24	I see there is a list of patents there. Do you see that?	24	A. Yes.
25	A. I do.	25	Q. I'd like you to take a look at

46 48 1 Paragraph 60 of this complaint, page seven. 1 regarding the references have come from the Med/Reg 2 2 divisions at Pamlab? Paragraph 60 says: 3 3 A. Yes. "NeevoDHA, Metanx, CerofolinNAC and 4 Deplin are covered by one or more claims of 4 O. And you assume that Med/Reg Pamlab 5 the 915, 904381778, 490 and/or 040 patents." 5 divisions at PamLab would have believed that to be 6 Do you see that? 6 true, correct? 7 7 Yes. MR. NORTON: Objection, calls for A. 8 8 O. Does that refresh your recollection speculation. 9 that Pamlab has asserted that CerofolinNAC is 9 A. They would validate it. These could 10 10 come from other places, but they validate it. covered by patents other than the 040 patent? 11 11 MR. NORTON: Objection form, And "validate it" means that they 12 12 foundation. would go back and read the references and make sure 13 13 it says what it says or? A. Based on this, yes. 14 0. You would agree that Pamlab has 14 MR. NORTON: Objection, calls for 15 15 asserted that? speculation. 16 16 I don't know their process. Α. Someone at Pamlab has, yes. A. 17 O. Does that refresh your recollection 17 MR. NORTON: We've been going for an 18 18 as to whether CerofolinNAC is, in fact, covered by hour. Want to take a break? 19 the 409 or 040 patents? 19 MR. CWIK: Yes, just a couple of 20 20 MR. NORTON: Calls for speculation, minutes. Let's finish this exhibit. 21 21 MR. NORTON: All right. foundation. 22 22 I still don't know, but somebody has Okav. 23 23 said it does. So they, obviously, know more about There's several other references 24 24 cited in this product insert, correct? it than I. 25 25 Correct. Q. Okay. 47 49 Who at Pamlab would know more about 1 And for each of those it's your 1 2 2 that than you do? understanding that the Med/Reg division would 3 Harold Coch. 3 validate the accuracy of those references with A. 4 Q. Referring back to the CerofolinNAC 4 respect to this product insert, correct? 5 5 MR. NORTON: Objection to form. product insert Exhibit 2085, do you see in the 6 6 left-hand column toward the top there is a section Speculation. 7 7 called "Pharmacology"? A. Correct. 8 8 A. Yes. MR. CWIK: Okay. We can take a break 9 9 And the first sentence says: now. Q. 10 10 "L-methylfolate or 6(S)5 (Recess.) 11 11 MR. CWIK: On the record. methyltetrahydrofolate, 6(S)5 MTHF, is the 12 primary biologically active isomer of folate." 12 Mr. Ladner, I've handed you a 13 13 And there is a citation to a footnote document that's been marked as 2162 and this exhibit 14 1. Do you see that? 14 is described in your declaration as a Deplin product 15 15 insert; is that correct? A. Yes. 16 O. Do you see that referring to footnote 16 A. Correct. 17 17 1 under the references there is a description of: Q. And on the right-hand column towards 18 18 "Donaldson, K and KJC, Naturally the bottom there is a list of patents and I see 19 19 there is the 040 patent, correct? occurring forms of folic acid to enzymatic 20 20 A. Correct. conversion of methyltetrahydrofolate acid to 21 prefolic A methyltetrahydrofolate, J Biol Chem 21 And under that is U.S. Patent No. 22 22 1962 237:P1298 to 304?" 6441168. Do you see that? 23 23 B1, yes. Do you see that? A. 24 Yes. 24 Q. Okay. A. 25 25 Do you know whether the Deplin And, again, would this information

13 (Pages 46 to 49)

product made by Pamlab is covered by this 6441168

I don't know. That's not something

I'm asking you to see if things jog

Now, you understand that Metafolin is

And you understand that Metafolin is

Do you recall if Pamlab has ever

asserted that Merck's ability to synthesize a stable

MR. NORTON: Objection, form,

L-methylfolate in crystalline form was a key

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patent?

A. that I keep up with.

Q.

A.

Q.

A.

Q.

A.

breakthrough?

read back please.

foundation.

A.

Q.

Okay.

Yes.

Okav.

Correct.

Correct.

your memory here today. Okay?

included in the Deplin product, correct?

the only active ingredient in Deplin?

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back.) MR. NORTON: Thank you.

(Whereupon the last question was read

MR. NORTON: Can I have that question

MR. CWIK: Mark this 1103 please. (Whereupon Exhibit 1103, Jury

Demanded, was marked for Identification.)

Mr. Ladner, I've handed you what we mark as Exhibit 1103, which is titled "Original Complaint" and listed parties as Pamlab as the Plaintiff and list of Defendants are Acella Pharmaceuticals and others.

Mr. Ladner, are you aware of this lawsuit that Pamlab filed against Acella?

Yes. A.

I'd like you to look at Paragraph 27 on page eight. The first sentence says:

"In the mid-1990's, Merck & Cie (formerly known as Merck Eprova AG) ("Merck") made a key breakthrough, and invented a process to synthesize L-methylfolate in a stable form. Offered under the name Metafolin. L-methylfolate calcium is the crystalline, stable and diastereoisomerically pure form of folate directly usable by cells in the body."

Does that refresh your recollection

- are tied to this comment.
- Referring back to Exhibit 2162, the 0. Deplin product insert, on the right-hand column there is a series of references on the bottom. Do you see that?
 - A.
- Q. And would those references be approved by the Med/Reg division at Pamlab?
- At the time it had to come through somehow, yeah.
 - 0. Okav.

And these references would have been validated by the --

A. I can't say that. I know the process. I'm not involved in the process. But I can't say whether they validated. These package inserts change all the time. As you get updated and

14 (Pages 50 to 53)

	54		56
1	sometimes things aren't taken out, things are left	1	A. No. Not to me.
2	in. And as you get more information and more	2	Q. Is it important to Pamlab?
3	clinical information, they update it and they go	3	MR. NORTON: Objection, calls for
4	through the process and that's part of the process.	4	speculation.
5	That's all that I'm saying. I'm not the one that	5	A. Again, this is how you're defining
6	validates it. I'm not even involved in the process.	6	important from a business standpoint which is
7	Q. I understand.	7	from a commercial standpoint, no.
8	A. Because the most important things on	8	Q. Are you aware of a federal law that
9	this package insert is what the clinician uses, in	9	says patented products must have patent numbers
10	here is indication, contraindication, adverse events	10	marked on them?
11	and dose.	11	MR. NORTON: Objection.
12		12	A. I'm not. But if that's the case,
13	Q. And how do you know that? How do you	13	,
14	know what is most important to the physicians? A. Twenty-three years of experience in	14	that's why they're in here. O. And in Exhibit 2079 there is a list
15			
16	dealing directly with physicians has shown me in my	15 16	of patents on the third page, Neevo product insert
17	experience that this is the most important thing.		2079. And the same questions as before. I assume
	Q. You would agree that it's important	17	that you don't know whether Neevo is covered by the
18 19	to Pamlab that the product insert be as accurate as	18	patents listed here other than the Bailey patents
	possible, correct?	19	and 040 patent, correct?
20	A. Correct.	20	A. Correct.
21	Q. Mr. Ladner, I'm handing you what we	21	Q. And you would agree that the 168
22	marked as Exhibit 2079, which is a product insert	22	patent is not listed in this list, correct?
23	for Neevo caplets. And, Mr. Ladner, would you agree	23	MR. NORTON: Objection to foundation.
24	that this is the product insert for the Neevo	24	A. Correct.
25	product that's cited in your declaration?	25	Q. The Bailey patent, the 381 patent, is
	55		57
1	A. Again, it must be the specific one.	1	not listed, correct?
2	We have multiple ones, but yes.	2	A. Correct.
3	Q. You can verify in Paragraph 60 of	3	Q. The Bailey patent, the 781 patent, is
4	your declaration if you want to.	4	not listed, correct?
5	A. Okay, got it. You do understand that	5	A. Correct.
6	these change?	6	Q. Mr. Ladner, I've handed you a
7	Q. I do understand.	7	document that's been marked as Exhibit 2080 and it's
8	That's the question. In your	8	a product insert for NeevoDHA. Mr. Ladner, is this
9	declaration you have cited various product inserts	9	the product insert for the NeevoDHA that's cited in
10	and the ones that you cited in your declaration,	10	your declaration?
11	were they the most current declarations at the time	11	A. It is.
12	that you submitted them?	12	Q. Okay.
13	A. Those are the ones that I quoted or	13	Do you know if this is the most
14	cited. They could have been they may or may not	14	recent product insert?
15	have been the most current.	15	A. No.
16	Q. Okay.	16	Q. Referring to the second page there,
17	Was it important to you that the most	17	towards the bottom, there is a list of patents and
18	current product inserts be submitted in connection	18	the same question. I assume that you do not know
19	with your declaration?	19	which patents cover the NeevoDHA product other than
20	A. Yes. But understand the most	20	the Bailey patents and the 040 patent, correct?
21	important to me, the most important in this package	21	A. Correct. I know the 040 covers it.
22	insert is what we use. Which is indications,	22	Q. And would you agree with me that the
23	contraindications, adverse events and dose.	23	915 patent is not listed on this list of patents?
24	Q. Is the marking of correct patent	24	A. Correct.
25	numbers important to Pamlab in its product inserts?	25	Q. Referring to Paragraph 68 of your

58 60 1 1 advertising promotional expenses for Pamlab have declaration it says: 2 2 been in 2012? "Although Pamlab historically has not 3 3 MR. NORTON: Objection to form. tracked the profitability of its products on 4 an individual product basis, the significant 4 On an aggregate basis just looking at 5 growth in sales and revenue year over year 5 that small piece of it, roughly around 6 shows that the Pamlab Patented Products are 6 percent. 7 7 commercially successful." percent of Pamlab revenues? Ο. 8 8 My question is regarding the first A. Of the promoted product sales --9 part of that sentence, that Pamlab has historically 9 revenues. 10 10 not tracked profitability of its products on an Q. Okay. 11 individual product basis. 11 In 2011 do you know? 12 12 Has Pamlab ever tracked the It's been about the same. It's never 13 13 profitability of its products on an individual percent. 14 basis? 14 Q. Okay. 15 15 A. Obviously, as your revenues get 16 16 Q. And still does not today? higher, if you're maintaining that same level, that 17 We're trying to get there. 17 percentage is going to go down. So if you went back A. 18 to -- it's always going to be somewhere around Has Pamlab ever tracked its marketing 18 19 and promotion expenses for its products on a 19 -- somewhere in percent. 20 20 product-by-product basis? Q. Paragraph 79 of your declaration, the 21 No. We -- let me back up. Let me 21 first sentence: 22 22 correct that. When we are talking about overall "The substantial sales of the Pamlab 23 23 Patented Products are particularly remarkable product expenses down to the fully absorbed costs --24 because you've got all expenses associated with a 24 because Pamlab had to cultivate a niche market 25 product. Which could be marketing, which could be 25 for prescription-only medical foods, where 61 1 sales force, everything. But then you have your 1 traditional drug products approved by the FDA 2 2 were the norm." marketing spend, which the brand spend is directly tied to the product. So, in that case it is, but 3 3 I guess my question is: Why did you say that "Pamlab had to cultivate a niche market"? 4 the entire spend is not. 4 5 5 Q. Okay. Because to fully realize the 6 So you do keep track of a direct 6 potential of this novel -- of this novel -- I'll say 7 7 brand spend for each of the Pamlab Patented invention and this novel ingredient that we have. 8 **Products?** 8 To really fully reach the potential, you have to 9 9 A. For what the brand spends, correct. invest in clinical outcomes. And what physicians 10 10 Q. What is included in the brand spend? know today in clinical outcomes are drug-type 11 11 That would be any promotional studies. They are used to that kind of education. 12 activities, anything that they are investing in 12 And they are used to that kind of methodology. And 13 sharing outcome data in regards to speaker programs. 13 they are used to those kind of protocols. And so, 14 14 It could just be disease state programs and it could you have to do that with a medical -- to do that 15 15 with a medical food. It's -- to take that and to be supporting grants and doing grand rounds. It 16 could be actual educational pieces. It could be 16 see -- first of all, realize the outcomes that this 17 17 videos. CME, that's how physicians get their -brings is truly novel. And utilize those outcomes 18 18 keep their license up-to-date through Continuing because -- I mean we're saving lives here. I mean 19 Medical Education. They have to have so many CMEs 19 depression is a serious illness. And there is --20 each year. 20 there are studies that are protocol-like drug 21 21 Do you know what the brand spends studies that show the outcome and show the benefit. 22 22 have been for each of the Pamlab Patented Products And to be able to do that with a medical food, 23 23 as you sit here today? you've got to have that kind of outcome data, that 24 A. As I sit here today, no. 24 kind of evidence. Otherwise, it's the credibility 25 25 O. Do you know what the overall piece. The FDA automatically provides that

16 (Pages 58 to 61)

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credibility. We don't have that because we have the -- you know, orphan amendment. And to be able to say -- you mean to tell me that a food can have this kind of outcome, that is novel.

Q. Uh-huh.

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Now, is it your understanding that a reason a prescription for the Pamlab Patented Products is required is because of the high dosage amounts of the B vitamins and the L-methylfolate?

- It's because of the definition and requirements of a "medical food". It has to be under medical supervision and that's somewhat dose related. Do I know the specifics around that? No.
- Did Pamlab ever consider selling these Pamlab Patented Products at a lower dosage that would not have required a prescription or a classification of a medical food?

MR. NORTON: Objection, calls for speculation.

- A. Not that I am aware of. Not that I was involved in anyway.
- With respect to your discussion of 23 advertising and your declaration, was there a reason that you didn't provide the actual dollars spent? 24
 - I don't recall directly saying

more than what we could even come close to. Also, that spend depends on the product life cycle and where you are and the outcome that you have. And it varies. But there was not any -- it's just so nominal. In fact, it's almost embarrassing that we have not been able to have more investment in what we have.

So did I answer your question?

Q. Yes, thank you.

Paragraph 88, the last sentence of Paragraph 88, it's on actually Page 20. It says: "Cerofolin and Neevo and NeevoDHA are not detailed."

Why are those products not detailed?

- I know I said that. I'm sorry. Could you repeat that?
- It's Paragraph No. 88, but it's the O. last sentence which starts on Page 20.
 - I got it, I'm sorry. So why --
- Q. Why are those not detailed and the other ones are?
- A. Because you only have -- you only have limited capacity in regards to detailing. And notice that word is not selling, it's detailing. That is an industry word. Our reps by title are not

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advertising.

- Well, if you look on page 18, you had a section called "Marketing of Pamlab Patented Products. Do you see that, section No. 7?
 - A. Uh-huh.
- Then you have several paragraphs discussing marketing. And my question is: Do you recall why you did not decide to list what the actual expenses for marketing of the Pamlab Patented Products were?
- First of all, I want to clarify the A. use of advertising. That was your word.

12 Q. Yes. 13 We share outcome data. We educate. 14 Nothing in particular for not including that in 15 there. In fact, what you'll see compared to Pharma, 16 17 and what we do, and the expense that we have to go 18 to, to provide the outcomes and the evidence, that truly show the novelty of what we have, Pamlab 19 Patented Products, which is again going back to what 20 21 I referred to earlier, the 040 and the Bailey 22 patent, I primarily believe that. That is the 23 significance. If you look at the spend that would be associated with reaching an opportunity and 24

launching that, uhmm, it would be -- it would be way

sales representatives. They are medical representatives. We take that to heart in that we share outcomes. The reason why we do not promote those or detail those, because the sales -- they only have limited capacity. They have limited capacity, so much capacity. And with the outcomes that we have and data that we have, the studies, the double-blind, randomized, placebo-controlled studies that are similar -- well, they are the same as drug studies for the most part. When you have that kind of -- that kind of outcome data, you've got to put everything on it to maximize that opportunity. So this is just a business revenue decision. To -- is the only reason, the only reason why.

Were those three products, Cerofolin, Neevo and NeevoDHA ever detailed at PamLab?

- A.
- Q. And do you recall when that stopped?
- A. Cerofolin, you could say for the most part, is. It's somewhat detailed in CerofolinNAC because even though you're talking about CerofolinNAC, a lot of times that leads to -- leads to conversations with Cerofolin. But Cerofolin we really don't have to talk about it because it just stays in there. It's, basically, just -- it's

17 (Pages 62 to 65)

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maintaining the levels that it has. It's declining, but we moved it from the outside sales force to CerofolinNAC is promoted inside. Cerofolin, we actually stopped promoting just Cerofolin, the actual product. Because we believe CerofolinNAC -- again, you can only do so much. It may have been '07. And I'm guesstimating on that and I know I shouldn't do that here. But '07.

And Neevo, we stopped promoting it period, this year. But some would argue that inside promotion versus outside promotion are two different things.

Q. And NeevoDHA, do you recall when you stopped detailing that?

A. December 31st of 2011 -- I'm sorry 12. We're already -- '13 is done, isn't it?

Q. Paragraph 91 on Page 20, the first sentence says:

"Based on my experience working in the pharmaceutical industry, the size of PamLab's sales force are in line with what you would ordinarily see for a company of our size."

How did you determine that the size of your sales force was in line with what you would

pharmaceutical-related companies that you've worked at in your career just Eli Lilly and PamLab, which

is now Nestle?
A. Yes.

Q. You've not worked at other companies that are approximately the same size as Pamlab, correct?

A. Correct.

Q. You mentioned benchmarks. Is there published benchmarks that you're thinking of or is that just --

A. No, it's just looking at -- it's looking at other -- just other medical food companies and other companies that have the total revenue-promoted products that we have and the amount of sales reps, but that varies. In our business there are a lot of dynamics. It all depends on -- it all depends on the novelty of the product that you have. It depends on your outcome data and it depends on where you are in your life cycle. For example, if you were launching a product, and you had outcome data when you were launching it, you may launch with 200. So, again, it depends on the company and where they are. You know, you hear of lately a lot of Pharma is going

ordinarily see for a company of your size? Was there a ratio that you looked at or how did you determine that?

Just using industry benchmarking. When I'm talking about a company of our size, I'm talking about a company of our revenue. If you look at our total revenue that's based on the product sales, it's very conservative. Now, what I really mean by that is if we had outcome -- I'll put it to you like this: I had 17 years with Eli Lilly and we got 23 years in this business. If someone in Pharma had the outcome data that we had currently, you would look at -- your basis would be 500 promoting it with that kind of outcome data. If it was again -- now if you were Pharma and we are medical food, we put our -- we put all of our -- we're all in because of the Merck and Bailey patents. So we're putting everything here. But if we were a Pharma company and this was a drug, you're looking at a sales force with our kind of outcome data, 500 to a thousand. When you look at a company of our size though, to answer your question, just benchmarking revenues just in experience, we're conservative at 160.

Q. And are the only two

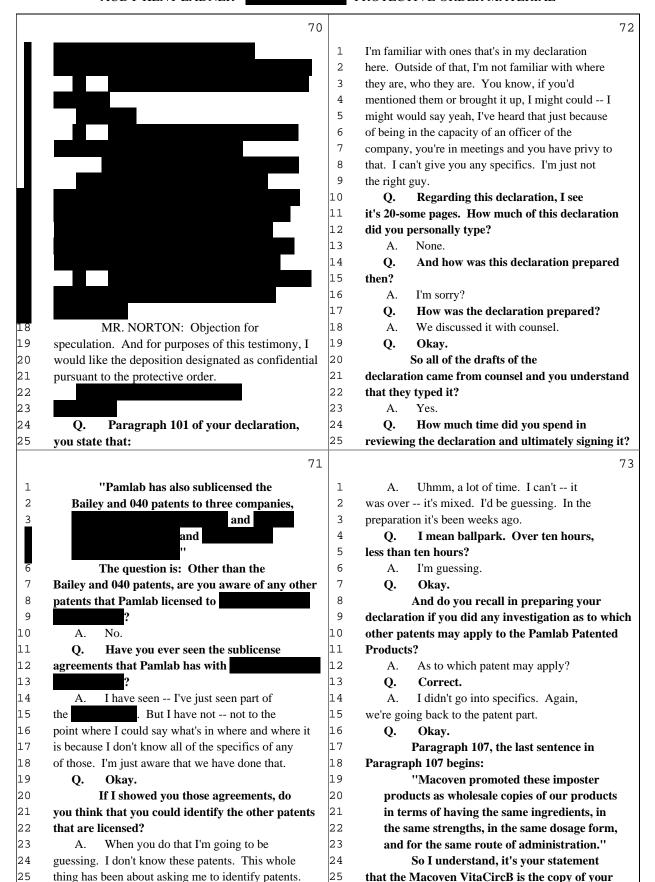
through down-sizing because their products are in that life cycle where they're maturing. They're even beyond being a cash cow any longer. So that varies. And it's just, in general, based on our outcome. I can tell you we're very small.

Q. Regarding your opinion that the Pamlab Patented Products are commercially successful,

MR. NORTON: Objection, foundation.

A. First of all, it's not my opinion that we've been commercially successful. There's fact in that. You can look at the sales revenue associated with it. You can look at the outcomes that is associated with it which drive those revenues. You can look at industry thought leaders and look at the -- look at their opinions on it. Their participation in the studies. You can look at testimonials if you want. And you can look at the studies and that's why it's commercially successful. Not because of my opinion.

18 (Pages 66 to 69)



74 76 1 Metanx product; is that right? 1 presented yourself as a copy, an exact copy, an 2 2 A. Correct. identical copy to our product. And that's public. 3 3 With respect to Macoven's Q. Are you aware of any differences 4 between the VitaCircB product and the Metanx 4 L-methylfolate calcium product, are you aware of any 5 product? 5 differences between that product and your Deplin 6 6 MR. NORTON: Objection to form. product? 7 7 Uhmm, they say they are exactly the MR. NORTON: Objection to form. A. 8 8 same. A. They're saying they're the same. 9 o. Do you know if the Macoven VitaCircB 9 With respect to your Deplin product, 10 10 product has a version of 6(S)5 MTHF, otherwise known did your Deplin product ever include an ingredient 11 as L-methylfolate that exists in amorphous form 11 called LGS? 12 12 instead of crystalline form? A. Yes. 13 MR. NORTON: Objection to form. 13 O. When did that occur? 14 Relevance. 14 A. End of -- March of 2013. 15 15 I'm only aware of that of just again, Q. And was that product ever sold? 16 just being associated, because of that morphous 16 A. 17 crystalline stuff, I let the scientists and medical 17 O. With respect to the sales figures 18 and R&D deal with that, but I hear it. Two 18 that you investigated for this matter, did your 19 questions earlier than that -- I don't know the 19 sales figures for Deplin include the version of 20 20 specifics enough to specifically talk about it. But Deplin that includes the LGS ingredient? 21 I know through just the discussion of Macoven and 21 I'm going to say no, I don't believe 22 22 legal action that that was -- that was associated so, no. Because that was just as of March. So 23 23 that's been recent. with it. And I believe we talked about that 24 24 earlier. Or you asked me a question about that Q. Do you know why Pamlab decided to add 25 25 earlier. LGS to its Deplin product? 77 75 1 1 MR. NORTON: Objection, relevance. O. Okav. 2 2 So, you do understand that to be one That's confidential. 3 3 MR. PARKER: It's privileged. difference between the VitaCircB product and the 4 Metanx product, the crystalline versus the 4 MR. NORTON: I want to caution the 5 5 witness to the extent that you are referring to amorphous? 6 6 MR. NORTON: Objection to the extent communications that you are aware of or 7 7 communications with lawyers, do not recite that that you are misstating the testimony. 8 8 I didn't know the difference is what testimony. I also object on attorney/client 9 9 I'm saying. I'm not a scientist. I don't know the privilege grounds. 10 10 difference or if there is a difference. They say Q. Are you not going to answer that 11 11 question then? there is not a difference. 12 12 A. No. Q. 13 13 "They" being Macoven at the time. Q. Okay. A. 14 14 Do vou recall who at Macoven said With respect to Macoven's LAZ-NAC O. 15 15 that? product, are you aware of any differences between 16 I don't have to recall who said it. 16 that product and PamLab's CerafolinNAC product? 17 17 They posted it publicly for everyone to see. A. They say they are the same. 18 Q. 18 Q. I know what they say. But are you And where was that? 19 19 A. In the compendium. personally aware of any differences? 20 20 When you look at them and you list 0. Do you recall if the compendium had 21 21 them, they are saying they're the same. In regards an indication of crystalline versus amorphous 22 22 to getting into the science and everything, I don't discussion in it? 23 23 know the differences. Now, based on what some of I'm not privy to their discussions. 24 But by simply submitting it to the compendium and 24 the R&D people say, they could tell you something 25 25 being linked to our product, says that you have different.

78 80 1 Paragraph 108, the first sentence, 1 No. Q. A. 2 2 you state: Q. Okay. 3 3 "Macoven's objective was to have In coming to that conclusion, have 4 their product be prescribed for the same uses 4 vou seen any statements by Macoven telling 5 5 physicians, pharmacists or patients for what medical as our products as specified in the Pamlab 6 6 conditions their products should be used for? Patented Products package inserts." 7 7 What is your support for the MR. NORTON: Objection to form. 8 8 statement that it was Macoven's objective to do A. 9 9 Q. And with respect to your 10 10 Because they linked directly to us in understanding of the linking process, in order for 11 the compendium. They had to provide information 11 Macoven to link their products to the Pamlab 12 12 that said that they were identical to our product, products, did Macoven have to tell the compendium 13 to the compendium to be linked. And that's --13 what conditions the products will be used for? 14 that's an intentional scheme to ride the coattails 14 Yes, I believe that they did. 15 15 of our products. Because by being linked, it, Q. And do you know what they told the 16 16 basically, dupes, if you will, the system in saying compendium, what conditions? 17 here's the generic. And so there is a generic 17 A. The compendium doesn't share that. 18 18 alternative and automatic substitution for Q. Now, starting in Paragraph 110 you 19 something. 19 identify some products from Brookstone\Acella that 20 20 Q. Okay. you believe were copies of the Pamlab Patented 21 21 Are you giving your personal opinion Products, correct? 22 22 as to what Macoven Corporation's intent was with A. Yes. 23 23 respect to the product? 0. Okav. 24 24 What I'm saying is based on my And the same question: Are you aware 25 experience and what I know. The only reason why you 25 of any differences between the Pamlab Patented 79 81 1 link is to do that. So I'm just telling you that is 1 Products and the Brookstone/Acella products that you 2 2 -- otherwise, they would not have linked. There is identify there? 3 no reason to be linked. So I can tell you with a 3 A. On these? 4 4 high confidence level that's exactly why they would Q. Uh-huh. 5 5 Other than -- just like the others, do it. A. 6 6 other than questionable between what the patents O. Okav. 7 7 And you would agree that you've never cover and what they don't, it's the same for all --8 worked for Macoven though, correct? 8 I mean you've got -- again, I'm going back in 9 9 A. Correct. history. You've got multiple products and multiple 10 10 You've never been on the Board of companies. It's the same scheme. It's the same O. 11 **Directors of Macoven?** 11 thing to say we are exactly the same. That's what 12 A. Correct. 12 they say there. They are pretending to be copies 13 Did you review any Macoven deposition 13 and they are saying they're copies and they are Q. 14 14 testimony in coming to that conclusion? getting linked. It's on and on and on and I don't 15 15 Not that I recall, no. I saw it understand how they can do that. 16 linked in the compendium. I monitor it daily. 16 So, essentially, with respect to the 17 17 Q. And do you recall reviewing any Brookstone/Acella, it's the same situation that 18 18 Macoven document in coming to that conclusion? because of the linking and their communications with 19 A. I don't recall. 19 the compendium and database company that that is the 20 20 basis of your conclusion that they are copies, Q. And in coming to that conclusion, 21 have you seen any promotional material where Macoven 21 correct? 22 22 told physicians, pharmacists or patients what They are saying they're copies. 23 23 medical conditions the product should be used for? That's what I'm saying. Now, are the ingredients 24 A. Where Macoven told? 24 identical? No. I'm saying that they're saying 25 25 Q. Yes. they're copies simply by getting linked. That's the

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1 only way that you can get linked because you have to 2 say that you are identical. With regard to Acella, 3 the district court ruled that, basically, they lied 4 by saying they are the same. It's -- that's public 5 knowledge. It's the same thing with every single 6 one that comes. We have settled -- the district 7 court ruled that with Acella, but we settled with 8 all of them and there is a reason for that. Because

it's a scheme. It's absurd that they can even do

- Now, with respect to Trigen, Seton, Midlothian and Virtus, is that the same situation where your basis for calling their products copies of your own products is the fact that they engaged in this linking process?
 - A. And they say they are copies.
- And they say they are copies? You O. don't have any personal knowledge as to whether chemically they actually are identical copies?
- All of these we had court proceedings with. And, in fact, I've been in some here. So there is -- I'm sure there's evidence that theirs has some differences. But what I'm quoting here is that they're saying they're the same.
 - Okay.

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1 differences between these imposter products and your 2 products as you sit here today?

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A. Uhmm, we can go through it. It varied by product. If you're looking at specific differences, it would vary by product by product. Obviously, I would like to have that in front of me, but it would vary by product by product. And I can't recall exactly which was what for what product. But they were copies and they were saying that they were copies.

Q. Okay, I understand.

A. I mean I hate to be talking about two different things. But the point that creates a -that creates a commercial -- frankly, outcome issue for us is the fact that they are saying they are a copy and they are publicly doing it.

Okav.

Okay.

In this linking process, is it your understanding that the databases will actually verify whether the ingredients of the Brookstone and Acella and Trigen are actually identical to what vour ingredients are?

Α. I can't speak for what they do. I mean based on my knowledge, clearly they don't. But I can't speak for what they do.

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Do you recall if Brookstone, Trigen, Seton, Midlothian and Virtus were sued for patent infringement by Pamlab?

You asked me that earlier. And it's -- I know that in some -- those I believe were Lanham Act, making false claims. Macoven was -- I think Macoven was different. I mean I get it confused. I don't know if patents were included in those either.

- You said that you had a Metafolin O. Business Unit within your company. Who came up with that name, was it you?
- A. I think it was the presidency at the time.
- Did they express to you why they called it the Metafolin Business Unit?
- To differentiate from the Women's Health Business Unit. Which was Neevo and NeevoDHA. So there wasn't any specific reason for doing it.
- You have the Women's Health Business Unit and I can't remember the name -- the Metafolin Business Unit. Are there any other units of PamLab?
- Inside Sales. We don't have the Women's Health Business Unit now. We're going way

And that's what's -- because with a difference -- with being a difference, they would not be able to be linked. They are saying -- they are making the claim which is -- that's my point. Because we have put all of our -- we have -- in fact, you know, that's the reason why I'm here -when I came to Pamlab was to start the Metafolin Business Unit. There is a reason it's called the Metafolin Business Unit. That was our future. And that's what we're building our future on. In fact, it with outcome data and evidence and helping patients in the things that we've done to the point that Nestle came in and said you know what? Your little bitty company in Covington, Louisiana, we see something here. It's because of the novelty of what we have. It's because -- and to have all these others come in and say they are the same. You know? Regardless of what they actually have in there, they saying they're the same and that's the problem.

I understand. 0.

So, yeah, they could be different. You know. There are differences. But they're saying they're the same.

0. Okav.

Do you recall any of the actual

22 (Pages 82 to 85)

back. You just went way back when we're talking about Metafolin Business Unit. Because that's not ceven—that was just at the time. That was at the time when we were launching Deplin and it was a different theater that we used. But we were — we knew where we were headed. Q. Okay. I scem to recall that you testified aerafier, and correct me if I'm wrong, but you said that the Bailey patents and the 040 patent are, basically, the entire business of Pamlab these days. Is that correct? Q. Okay. Is that correct? Q. Okay. Is that correct? Q. Okay. Is that pamlab does have other products that they sell that are beyond the Bailey patent and the 040 patent, correct? A. Uhman I don't believe we have any others. MR. NORTON: Objection, asked and answered. MR. NORTON: Objection, asked and A. I can't give you the timelines on it. I don't know. I can't recall the actual launch and roll-out of that. Was there any overlap is, basically, what It hink you're asking? Q. Yeah. MR. CWIK: Okay. Why don't you give me five minutes to look at my notes and then we'll try to wrap up, okay? MR. NORTON: Obay. MR. NORTON: Objection, asked and answered. A. I was three any overlap is, basically, what It hink you're asking? Q. Yeah. MR. CWIK: Okay. Why don't you give me five minutes to look at my notes and then we'll try to wrap up, okay? MR. NORTON: Okay. MR. NORTON: Objection, asked and A. I can't give you the timelines on it. I don't know. I can't recall the actual launch and roll-out of that. Q. Does Pamlab does have other products that the saliey patents and the 040 patent, or rect? A. Was actually the we'll try to wrap up, okay? MR. CWIK: On the record. Q. Just a couple more questions, Mr. Ladner. Are you aware of any patents owned by a company called MR. CWIK: On the record. Q. Just a couple more questions, Mr. Ladner. Are you aware of any patents owned by a company called MR. CWIK: On the record. Q. Just a couple more questions, Mr. Ladner. A. I've heard file that I had seen some of the agreements, but			86			88
2 about Metafolin Basiness Unit. Because that's not 4 time when we were launching Deplin and it was a 5 different theater that we used. But we were — we 5 knew where we were handed. 7 Q. Okay. 8 I Seem to recall that you testified 9 earlier, and correct me if I'm wrong, but you said 10 that the Bailey patents and the 040 patent are, 11 basically, the entire business of Pamlab base selling Folts and Pamlab Patented 12 Is that correct? 13 A. Yeah. I mean that's my opinion. 14 yeah. 15 But Pamlab does have other products 16 that they sell that are beyond the Bailey patent and 17 that they sell that are beyond the Bailey patent and 18 the 040 patent, correct? 19 A. Uhmm, I don't believe we have any 20 others. 21 MR. NORTON: Objection, asked and 22 answered. 22 answered. 23 Q. Does Pamlab sell a product called 24 Folts? 25 A. Yes. 26 To Q. Doy ou understand that Foltx is 2 covered by the Bailey patents and the 040 patent; 3 A. Yes. Because it now has — if we're 24 talking about now—it now has — we may still have 25 some of the old Foltx that could be out there, but 26 all othen hew Foltx is covered by the 040 and 27 Bailey patents. 28 Q. Does the current Foltx have folic 29 acid instead of 1—methylfolate? 20 A. That's my understanding. 21 Q. Doil it previously have folic acid or 21 A. That's my understanding. 22 A. That's my understanding. 23 Q. Doil it previously have folic acid. 24 A. It did. 25 Breckenridge sells a generic version of Foltx called. 26 Folic; is that correct? 27 A. That's my understanding. 28 Did it previously have folic acid. 29 Do you know if the generic 20 Do you know if the generic 21 Q. Do you know if the generic 22 Breckenridge Fobic product includes folic acid or 24 A. L-methylfolate. 25 L-methylfolate. 26 A. L-methylfolate. 27 L-methylfolate. 28 A. L-methylfolate. 29 L-methylfolate. 20 L-methylfolate. 20 L-methylfolate. 21 Q. Do you know the generic exposition of Foltx called folic acid or L-methylfolate. 21 Q. Do you know the generic version of Foltx called folic acid or L-methylfolate. 22	1	back V	ou just went way back when we're talking	1	folic ació	d version?
even — that was just at the time. That was at the time when we were launching Deplin and it was a different theater that we used. But we were — we knew where we were headed. 7 Q. Okay. 8 I seem to recall that you testified earlier, and correct me if Tm wrong, but you said that the Bailey patents and the 040 patent are, basically, the entire business of Pamlab these days. 12 Is that correct? 13 A. Yeah. I mean that's my opinion, 14 yeah. 15 Q. Okay. 16 But Pamlab does have other products that the syell that are beyond the Bailey patent and the 040 patent, correct? 17 that they self that are beyond the Bailey patent and the 040 patent, correct; 19 A. Uhmm, I don't believe we have any others. 10 Q. Does Pamlab sell a product called Product sat the same time? 11 A yes. 12 answered. 13 A. Yes. 14 Ves. 15 Pool Nay. 16 But Pamlab does have other products that the yelf that are beyond the Bailey patent and the 040 patent, correct; 19 A. Uhmm, I don't believe we have any others. 10 Q. Does Pamlab sell a product called Product sat the same time? 11 Vestable that the yelf that are beyond the Bailey patent and the 040 patent, correct; 19 A. Yes. 10 Q. Does Pamlab sell a product called Product sat the same time? 11 Vestable that the yelf that are beyond the Bailey patent same and the 040 patent? 12 A. Yes. 13 A. Yes. 14 Q. Does Pamlab sell a product called Product sat the same time? 15 Q. Do you understand that Foltx is covered by the 040 and Pamlab sell a product called Product sat the same time? 16 (Recess.) 18 A. Vana threa saking? 19 A. Yes. 20 A. Yes. 21 A. Yes beard the vest manual transmarks of the new Folts is covered by the 040 and Pamlab sell a product called Product sat the same time? 22 A. Yes beard that could be out there, but all of the new Folts is covered by the 040 and Pamlab Patented Products, correct? 24 A. No. 25 A. Ves beard of L-methylfolate? 26 A. That's my understanding. 27 A. That's my understanding. 28 A. I tail. 29 A. Debet the current Foltx have folic acid? 29 A. The heard of Allen. 29 A. Th			•			
time when we were launching Deplin and it was a different theater that we used. But we were —we knew here we were headed. Q. Okay. I seem to recall that you testified earlier, and correct me if I'm wrong, but you said that the Bailey patents and the 040 patent are, law yeah. I basically, the entire business of Pamlab these days. Is that correct? A. Yeah. I mean that's my opinion. yeah. Q. Okay. But Pamlab does have other products that they sell that are beyond the Bailey patent and the 040 patent, correct? A. Uhmm, I don't believe we have any others. MR. NORTON: Objection, asked and answered. A. Wes. MR. NORTON: Objection, asked and answered. A. Yes. A. Yes. Poby ou understand that Foltx is covered by the Bailey patents and the 040 patent? A. Yes. Because it now has — if we're talking about now—it now has — we may still have some of the old Folts that could be out there, but all of the new Foltx is covered by the Bailey patents. Q. Does the current Foltx have folic acid instead of L-methylfolate? A. No. Does the current Foltx have folic acid instead of L-methylfolate? A. It did. A. It did. Products at the same time? A. Ican't give you the date. Products at the same time? A. Ican't give you the date. Products at the same time? A. Ican't give you the date. Products at the same time? A. Ican't give you the date. Products at the same time? A. Ican't give you the date. Products at the same time? A. Ican't give you the date. Products at the same time? A. Ican't give you the date. I don't know. I can't recall the actual launch and of the Mark and the 404 patents and the						
5 Gifferent theater that we used. But we were - we knew where we were headed. 5 Q. Was there a period of time when knew where we were headed. 7 Q. Okay. I seem to recall that you testified earlier, and correct me if I'm wrong, but you said that the Bailey patents and the 040 patent are, basically, the entire business of Pamlab these days. 12 Is that correct? 13 A. Yeah. I mean that's my opinion, 14 yeah. 15 Q. Okay. 15 MR. NORTON: Objection, asked and an the 040 patent, correct? 16 MR. NORTON: Objection, asked and an aswered. 17 MR. NORTON: Objection, asked and an aswered. 18 Q. Does Pamlab sell a product called 18 A. Yes. Because in now has - if we're talking about now - it now has - we may still have some of the old Foltx that could be out there, but all of the new Foltx is covered by the Bailey patents. Q. Does the current Foltx have folic acid instead of L-methylfolate? A. It did. Q. Foltx now has L-methylfolate? A. It did. Q. And through Breekenridge - well, Breekenridge sells a generic version of Foltx called Folibic; is that correct? Q. Doos the current Foltx have folic acid instead of L-methylfolate? A. It did. Q. Dooy to wook the generic provided in the folic is that correct? A. It did. Q. And through Breekenridge - well, Breekenridge sells a generic version of Foltx called Folibic; is that correct? Q. Dooy ow fif the generic			5			
6 Ramew where wee were headed. 7 Q. Okay. 8 I seem to recall that you testified earlier, and correct me if I'm wrong, but you said to that the Bailey patents and the 040 patent are, basically, the entire business of Pamlab these days. 12 Is that correct? 13 A. Yeah. I mean that's my opinion, 14 yeah. 15 Q. Okay. 15 But Pamlab does have other products that they sell that are beyond the Bailey patent and the 040 patent, correct? 18 MR. CWIK: Okay. Why don't you give me five minutes to look at my notes and then we'll try to wrap up. okay? 16 MR. NORTON: Objection, asked and answered. 17 A. Yes. 18 Correct by the Bailey patents and the 040 patents? 18 A. Yes. Because it now has if we're talkling about now it now has we may still have some of the old Folts that could be out there, but all of the new Foltx is covered by the Old Folts that could be out there, but all of the new Foltx is covered by the Old and Bailey patents. Q. Does the current Foltx have folic acid instead of L-methylfolate? A. No. 10 Q. Foltx now has L-methylfolate? 11 Q. Foltx now has L-methylfolate? 12 A. It did. Q. And through Breckenridge well, 15 Q. Doy ou won't fine generic Policy is that correct? 18 A. Correct. They do all the Foltx. I'm not really involved in it. That's the reason why I not really involved in it. That's the reason why I not really involved in it. That's the reason why I not really involved in it. That's the reason why I not really involved in it. That's the reason why I not really involved in it. That's the reason why I not really involved in it. That's the reason why I not really involved in it. That's the reason why I not really involved in it. That's the reason why I not really involved in it. That's the reason why I not really involved in it. That's the reason why I not really involved in it. That's the reason why I not really involved in it. That's the reason why I not really involved in it. That's the reason why I not really invol						
Products at the same time? A. Was there any overlap is, basically, what I think you're asking? Q. Yeah.					_	-
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dearlier, and correct me if I'm wrong, but you said that the Bailey patents and the 040 patent are, basically, the entire business of Pamlab these days. Is that correct? A. Yeah. I mean that's my opinion, 14 yeah. But Pamlab does have other products that they sell that are beyond the Bailey patent and the 040 patent, correct? A. Uhmm, I don't believe we have any 19 others. 19 A. Yes. Does Pamlab sell a product called 24 Foltx? A. Yes. Does Pamlab sell a product called 25 A. Yes. 24 Tolking about now — it now has — if we're talking about now — it now has — we may still have some of the old Foltx that covide be ut there, but all of the new Foltx is covered by the Bailey patents. A. No. Q. Does the current Foltx have folic acid instead of L-methylfolate? A. It did. Q. Doid it previously have folic acid? A. It did. Q. Do you know if the generic 24 Recentidge Fobic product includes folic acid or teach that the name and I've heard it hat name. But, again, it's the same? I don't know. To any the heard of the Allen patents that they sell that are covered by the Patent incorrect? A. I've heard of Allen. Pe never heard of the Allen patents that they sell that name. But, again, it's the same? I don't know what it's in reference to. MR. CWIK: Okay. Why don't you give me five minutes to look at my notes and then we'll try to wrap up, okay? MR. CWIK: Okay. Why don't you give me five minutes to look at my notes and then we'll try to wrap up, okay? MR. CWIK: Ohay. Why don't you give me five minutes to look at my notes and then we'll try to wrap up, okay? MR. CWIK: Ohay. Why don't you give me five minutes to look at my notes and then we'll try to wrap up, okay? MR. CWIK: On the record. Q. Just a couple more questions, Mr. Ladner. Are you aware of any patents owned by a company called line actual launch and roll-net five me five minutes to look at my notes and then we'll try to wrap up, okay? A. I've heard the name. I've seen when license from? A. I've heard the name. I've seen when license from? A. I've h		Q.				
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1 MR. NORTON: I've got a couple of 2

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3 **EXAMINATION**

BY MR. NORTON:

Mr. Ladner, do you recall you were asked questions why DHA was added to the Pamlab **Patented Products?**

A. Yes.

Q. Did you gain any understanding that you have of why DHA was added to the Pamlab Patented Products based on communications with attorneys?

A. No.

O. Any understanding that you have of why the DHA was added to the Pamlab Patented Products, is that related to any interactions that you've had with legal department at Pamlab?

A.

0. During your testimony today you were asked, and I don't recall the specific paragraph, but you were asked questions with regard to your understanding or your basis for understanding that Macoven products were used for the same prescription as the Pamlab Patented Products. Do you recall that line of questioning?

A. Yes. product.

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And why are you confident that the prescription would be written for a Pamlab product as opposed to another one of the imposter products as you refer to them?

MR. CWIK: Objection, foundation and form.

Based on feedback from clinicians, based on the compendium, based on the outcomes and the evidence that's being provided and the discussions around those outcomes and the indication specifically for those, that's why.

MR. CWIK: Add objection to hearsay to that.

MR. NORTON: I'm going to object to that objection for the record.

Do you have an understanding of 0. whether or not a company like Macoven details their products in the same way that Pamlab does for example?

MR. CWIK: Objection, foundation.

No. They do not is my understanding. As Pamlab does with the exception of negotiating contracts at the wholesaler and retailer level for preferred positions all based on discounts and cost

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What is your basis for understanding that the Macoven products were being used for the same prescriptions as the Pamlab Patented Products?

MR. CWIK: Objection to form.

- The linking in the compendium, the contracting that they did directly with wholesalers and retail pharmacy chains to get Direct Access instead of Pamlab product. And in replace of Pamlab products.
- With respect to the actual filling of O. a prescription with a Macoven product, do you have an understanding based on your experience of how that works?
 - A.
 - Q. And how does that work?

MR. CWIK: Objection, foundation.

17 A clinician writes a prescription 18 based on the indication for Pamlab, for example, 19 Metanx. And when they fill out the prescription. 20 It's Metanx. And then its substituted when it goes

21 to the pharmacy level for whatever is in the 22 preferred position. And in this case Macoven,

because that's what you are speaking of. But it

24 could be any of the imposters, depending upon the 25

one. And it is directly substituted for the Pamlab

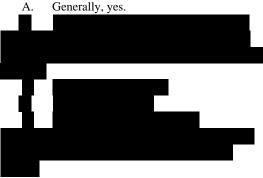
1 and price.

> Do you recall your testimony earlier today related to the forecasting with respect to the

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A. Yes.

O. Strike that and let me ask it again. You were asked questions by counsel related to whether or not there were missed projections with respect to forecasting of sales for Pamlab Patented Products. Do you recall that generally?



Q. Are you aware of the main "imposter" as you refer to them?

Primarily Macoven, Virtus, those are

24 (Pages 90 to 93)

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the main two of late.

Q. To your knowledge, does Virtus use L5-MTHF calcium salt in its products?

- A. Uhmm, as I put in my declaration, they say they're the same. Is it the same that Virtus uses or does Virtus use the same? I can't say it's the same.
- Q. With respect to your discussions or your prior testimony related to Brookstone, Trigen, Seton, Midlothian, are you aware that at least some of those companies use the racemic in their products?

MR. CWIK: Objection, scope, form.

A. They are saying -- and I'll go back to this. And my comment in here is that they were copying -- was that they were saying that they are the same. But from my understanding is that they were racemic. And I believe -- it forget which company is which, because there were multiple different things. And that's the reason why I don't like to go into specifics. But it was Brookstone, Acella, Seton, primarily that were using racemic. Macoven and Virtus were using another form. Again, I don't want to get into all the crystalline and calcium salts and all that. That is not my area of

series of questions and examined on several package inserts today?

A. Yes.

Q. With respect to those package inserts that you were shown, are you in any way able to confirm the accuracy of the content of those package inserts?

A. No.

MR. NORTON: That's it.

MR. CWIK: Just a couple of follow-up questions.

CONTINUED EXAMINATION BY MR. CWIK:



Q. When did the Macoven products stop being sold?

A. That's one of the things that's questionable, if you want to know the truth.

expertise. But they were saying that they were identical and that they were a copy. So that's the way that I approach it. Because that's the way clinicians see it and that's the way that the database was seeing it.

Actually, for clarification, it's the way pharmacists see it. Clinicians don't see it. Pharmacists see it.

Q. With respect, and I know that you're not really mired in the specifics of it, but with respect to the companies that were using a racemic, what does that say in your mind as to their willingness to claim that their products were copies? What does that say about the Pamlab Patented Products?

MR. CWIK: Objection, foundation, form.

A. It says that they're willing -- and I'll use the district court ruling -- that they, basically, lied. They are willing to lie to ride the coattails to get on the bus. To get a seat on the bus, the Pamlab bus, to try to ride our invention and our commercial success of our Pamlab Patented Products.

Q. And you recall that you were asked a

Because they have too much -- there is still too much in the distribution channels that, basically, I've been questioning with legal counsel to try to

understand. So my understanding is that as of the
settlement date, which I don't know exact date. We
can probably look on one of the exhibits here. But

that is when they were required to quit providing their product. However, it's still in the markets.

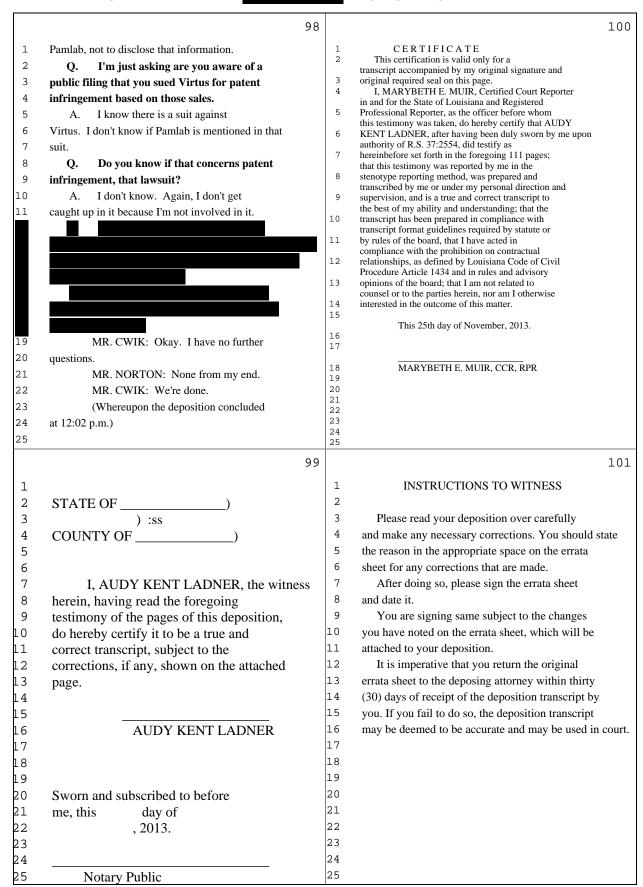
Q. Okay.

Q. Have you sued Virtus for being in that same database and selling their products?

MR. NORTON: Objection, form.

I'm going to caution the witness to the extent this gets into privileged conversations he's had with counsel or the legal department at

25 (Pages 94 to 97)



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