# UNITED STATES INTERNATIONAL TRADE COMMISSION WASHINGTON D.C.

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IN THE MATTER OF:

INV. NO. 337-TA-857

REDUCED FOLATE
NUTRACEUTICAL PRODUCTS
AND L-METHYLFOLATE RAW
INGREDIENTS USED THEREIN.

CONFIDENTIAL BUSINESS INFORMATION
SUBJECT TO THE PROTECTIVE ORDER

May 6, 2013

9:00 a.m.

Videotaped Deposition of JOSHUA MILLER, taken by the Complainants, at the Hyatt Regency, Two Albany Street, New Brunswick, New Jersey, before David Levy, CSR, RPR, CLR, a Notary Public of the State of New York.

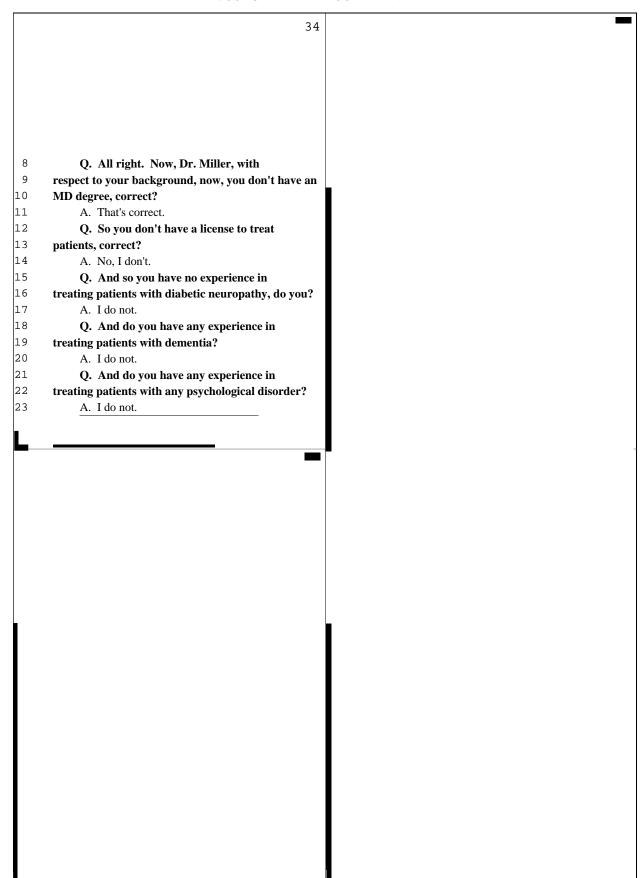
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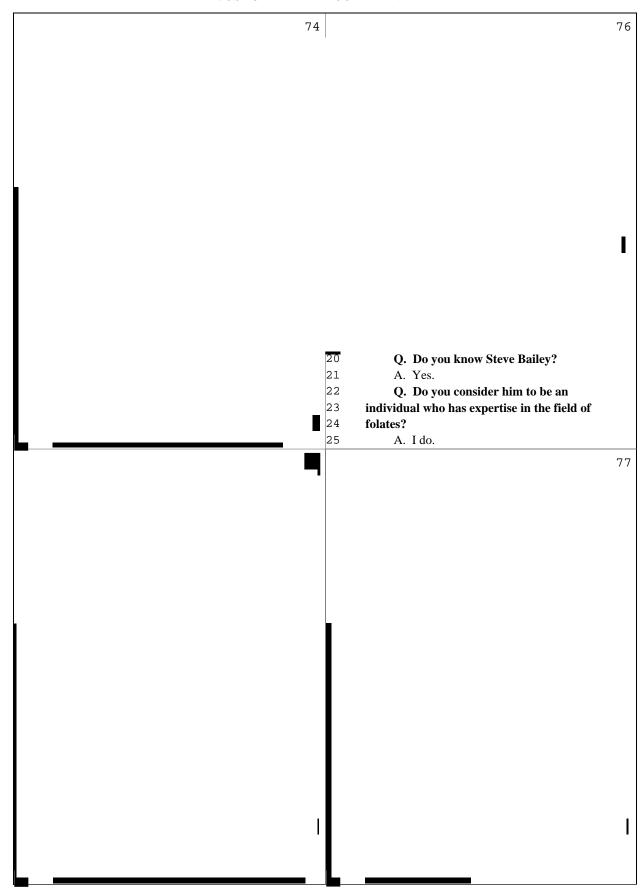
MERCK EXHIBIT REPLACEMENT 2063 Gnosis v Merck & Cie IPR2013-00117

	2	2	4
1		1	Miller - confidential
2	APPEARANCES:	2	VIDEOGRAPHER: Good morning. Here
3		3	begins video recording number one in the deposition
4	ON BEHALF OF THE COMPLAINANTS:	4	of Dr. Joshua Miller, taken by the complainants in
5		5	re, Reduced Folate Nutraceutical Products and
6	ALSTON & BIRD, LLP	6	L-methylfolate Raw Ingredients Used Therein,
7	90 Park Avenue, 15th Floor	7	investigation number 337 P.A. 857 in the United
8	New York, New York 10016	8	States International Trade Commission, Washington,
9	BY: THOMAS J. PARKER, ESQ.	9	D.C., before the Hon. Theodore R. Essex,
10	thomas.parker@alston.com	10	administrative law judge.
11	HAI'OU QUIN, Ph.D., ESQ.	11	This deposition is being held at the
12	haiou.qin@alston.com	12	Hyatt Regency, 2 Albany Street, New Brunswick, New
13		13	Jersey, 08901, in conference room J and K, on
14		14	Monday, May 6th, 2013, at approximately 9 o'clock.
15	ON BEHALF OF THE RESPONDENTS	15	My name is Howard Brodsky, in
16	MACOVEN PHARMACEUTICALS	16	association with the firm of David Feldman
17	AND PHARMACEUTICALS:	17	Worldwide, Inc., and I'm the legal video
18	THE THE HOLD HELD.	18	specialist. The court reporter is David Levy, in
19	JONES WALKER	19	association with David Feldman Worldwide.
20	8555 United Plaza Boulevard	20	Will counsel please state their
21	Baton Rouge, Louisiana 70809	21	appearance for the record.
22	BY: MICAH J. FINCHER, ESQ.	22	MR. PARKER: Tom Parker for the law
23	mfincher@joneswalker.com	23	firm of Alston & Bird, representing complainants in
24	mmener@joneswarker.com	24	this action.
25		25	MS. QIN: Hai'ou Qin, Alston & Bird,
	3	3	5
1		1	Miller - confidential
2	APPEARANCES (Cont'd):	2	for the complainants.
3	AFFEARANCES (Colled).	3	MR. CWIK: My name is Joe Cwik with
4	ON BEHALF OF THE GNOSIS PARTIES:	4	the law firm of Husch Blackwell. I'm here for
5	HUSCH BLACKWELL LLP, LLP	5	Gnosis USA, Gnosis SpA and Gnosis Bioresearch SA.
6	120 South Riverside Plaza, Suite 2200	6	MR. KRIT: Jonathan Krit with the law
7	Chicago, Illinois 60606	7	firm of Amin Talati. I'm also with the
0	BY: JOSEPH E. CWIK, ESQ.	8	Respondents.
9	· · · · · · · · · · · · · · · · · · ·	9	MR. FINCHER: Micah Fincher with the
10	joseph.cwik@huschblackwell.com	10	law firm of Jones Walker, representing Macoven
_	and	11	Pharmaceuticals, LLC and Viva Pharmaceuticals, Inc.
11	and	12	VIDEOGRAPHER: Will the court reporter
12 13	AMIN TALATI	13	please swear in the witness.
	55 West Monroe Street, Suite 3400	14	JOSHUA MILLER, having been duly
14 15	Chicago, Illinois 60603	15	sworn by the Notary Public, was examined
15 16	BY: JONATHAN J. KRIT, ESQ.	16	and testified as follows:
	jonathan@amintalati.com	17	EXAMINATION BY
17		18	
18			MR. PARKER:
19	ALCO DDECENT	19	Q. Good morning, Dr. Miller. If you
20	ALSO PRESENT:	20	could, state your full name and address for the
21	HOWARD BRODSKY, Videographer	21	record, please.
22		22	A. Joshua William Miller, 603 Route 518,
23		23	Skillman, New Jersey 08558.
24		24	Q. Now, Dr. Miller, have you ever been
25		25	deposed before?

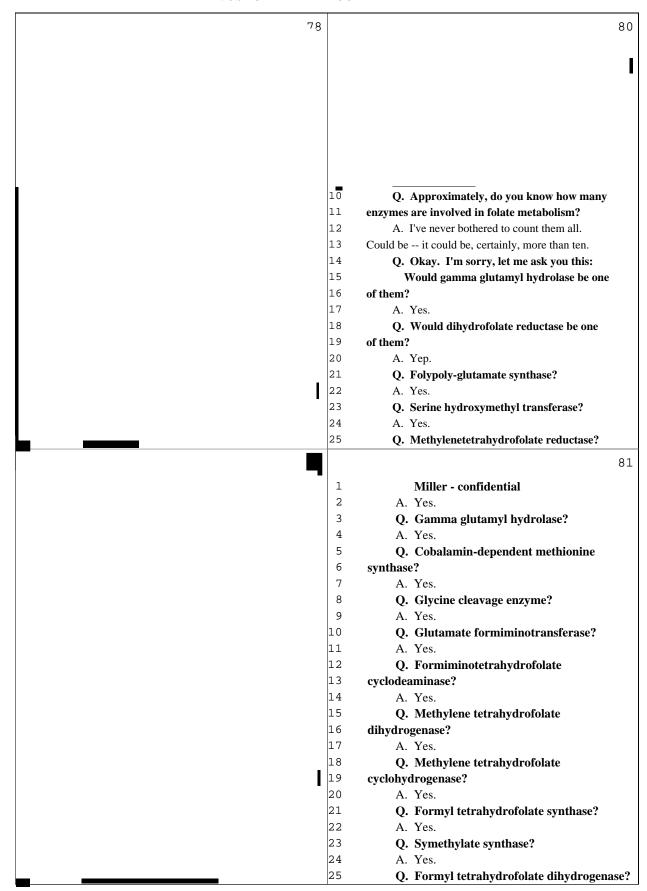
	6			8
1	Miller - confidential		1	Miller - confidential
2	A. No.		2	A. Um I actually have not been
3			3	compensated as of yet.
		.	4	Q. Have you submitted any invoices?
			5	A. No.
			6	Q. Do you intend to at some point in
		'	7	time?
			8	A. Yes.
			9	Q. Now, you've submitted an expert report
		1	0	in this case, correct?
		1	1	A. That's correct.
		1:	2	Q. And you've also submitted a
		1	3	declaration in connection with the proceeding
		1.	4	before the United States Patent and Trademark
		1	5	Office, is that correct?
		1	6	A. That's correct.
		1	7	Q. And are you aware that the proceeding
		1	8	is known by the lawyers as an interparties review?
		1	9	A. An interparties review, I'm not
		2	0	familiar with that phrase.
21	So with that, let me just begin. So,	2	1	Q. Well, let me ask you this:
22	Dr. Miller, you are an expert that's been retained	2		What is your understanding with
23	by Gnosis in this case?	2	3	respect to the proceeding in which you've submitted
24	A. Yes.	2		a declaration to the Patent Office?
25	Q. Are you also an expert retained by a	2	5	A. That that will be reviewed by the
	7			9
1	Miller - confidential		1	Miller - confidential
2	company called Macoven?		2	by the judge and the lawyers on both sides and that
3	A. That's what I'm told by Mr. Cwik.		3	my testimony will be used for judgments in this
4	Q. So you are an expert also retained	-	4	case.
5	on I'm sorry, you are an expert retained by		5	Q. Now, is it your understanding that the
6	Macoven as well?		6	patent involved in the proceeding before the United
7	A. I don't believe I'm being paid by	'	7	States Patent and Trademark Office in which you
8	Macoven for this. So I'm I guess, my testimony		8	submitted a declaration are the same patents that
9	is mainly for Gnosis.		9	are also at issue in this case, this investigation?
10	Q. Well, you understand that Macoven and	1	0	A. Yes.
11	Viva have retained a Dr. Shane as an expert as	1	1	Q. Now, with respect to declaration you
12	well.	1:		submitted to the United States Patent and Trademark
13	A. Yes, I do.	1	3	Office, that was a sworn statement, was it not?
14	Q. Is Macoven or is Viva, any of those	1.		A. Yes.
15	entities, are they compensating you for your time,	1		Q. And you submitted that declaration on
16	participating in this investigation?	1		behalf of not on behalf, but you submitted that
17	A. Just Gnosis.	1		declaration in connection with the petition that
18	Q. Now, what is your hourly rate for	1		was filed in the Patent Office by the Gnosis
19	providing services of the type that you're	1		entities?
20	providing in this case?	2	0	A. Yes.
21	A. It's \$450 per hour.	2		Q. When were you first approached by
22	Q. Any idea of how much you've been	2		anyone from Gnosis or the Gnosis attorneys seeking
23	compensated to date?	2		your participation in those proceedings before the
24	A. No, actually.	2.		Patent Office?
25	Q. Approximately?	2	5	A. It was in the fall of 2012. October

1 2 3	Miller - confidential or November. I'm not sure exactly when.	1 Miller - confidential 2 metabolites that participate in folate metabolism. 3 Methyltetrahydrofolate is the active form is the 4 6(S) isomer and it participates in folate 5 metabolism. 6
_		
19 20 21 22	Q. Now, just to be clear on nomenclature, when you say methylfolate, what are you referring to?  A. I'm referring to an active metabolite	
23 24 25	of folate, folate being the general term for all of the forms of folate, including the supplement form, which is folic acid, as well as all of the	

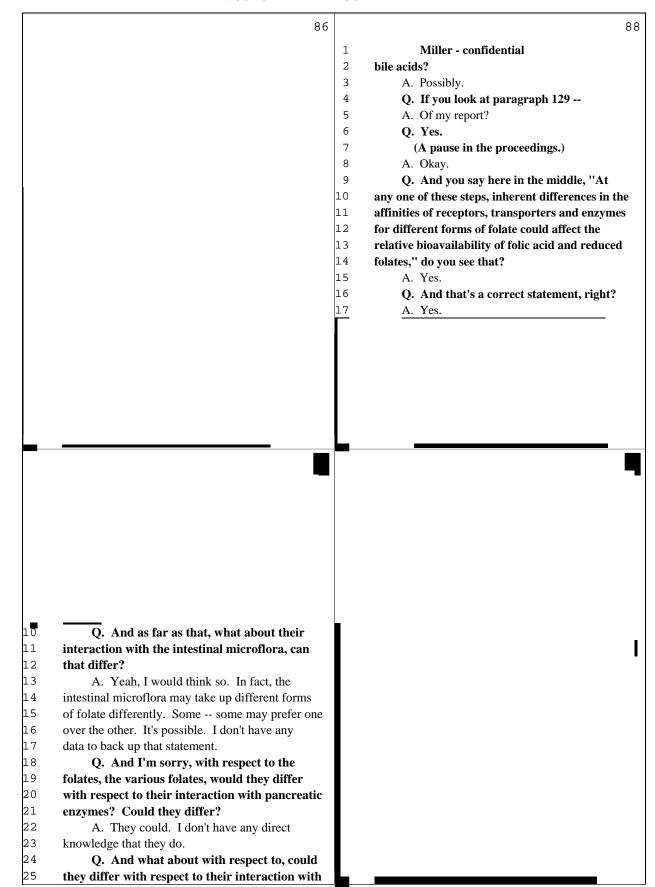




20 (Pages 74 to 77)



	82		84
1	Miller - confidential	1	Miller - confidential
2	A. Yes.	2	stomach
3	Q. Phosphoribiosylglycinamide formyl	3	A. Stomach is about pH 1.
4	transferase how about this, GAR formyl	4	Q. Let's go with pH 1.
5	transferase?	5	A. Um I can't say offhand. It's not
6	A. Yes, that's how we know it.	6	something that I have paid attention enough to, to
7	Q. And then there's phosphoribosylamino	7	learn it.
8	metazole carboxamide, which is AICAR formyl	8	Q. Now, but each folate has its own
9	transferase?	9	spectral properties.
10	A. Yes. Um-hum.	10	A. Yes.
11	Q. 5-formyl tetrahydrofolate cycloligase?	11	Q. And some folates are more susceptible
12	A. Cycloligase?	12	to oxidation than others at ambient temperature or
13	Q. Yes.	13	elevated temperatures?
14	A. Yes.	14	A. Yes.
15	Q. Then we have folate/ I have	15	Q. And some folates are more susceptible
16	folate/MTX transport mechanism enzymes associated	16	to oxidation than others at different pHs?
17	with that?	17	A. Very likely, yes.
18	A. Yes.	18	Q. Now, also, folates would have their
19	Q. And glycine methyl transferase?	19	their bioavailability when taken after
20	A. Yes.	20	administration would vary as well.
21	Q. Now, I mean, each folate, they have	21	A. Correct.
22	different chemical properties, correct?	22	Q. And just to be clear, bioavailability
23	A. Correct.	23	is the degree to which a drug or other substance
24	Q. And they have different physical	24	becomes available to the target tissue after
25	properties, correct?	25	administration; do you agree with that?
	83		85
1	Miller - confidential	1	Miller - confidential
2	A. Correct.	2	A. That is one definition of
3	Q. Different solubility characteristics?	3	bioavailability, yes.
4	A. Likely.	4	Q. What definition do you use?
5	Q. Now, the solubility of folates, is	5	A. It depends on the what we're
6	that influenced at all by the polar hydrophilic	6	talking about, the purpose of the question the
7	character of the X carboxyl group of glutamic acid?	7	subject matter is. In this case, I would agree
8	A. The solubility?	8	that the appropriate definition would be as you
9	Q. Yes.	9	stated it.
10	A. I can't say.	10	Q. Now, as far as factors that influence
11	Q. Well, let me ask you this, though:	11	bioavailability of folate after administration,
12	Would the glutamyl conjugates that are	12	viability would be one of them, correct?
13	added on to the folate, would they affect	13	A. Likely, yes.
14	solubility, if you had five versus ten versus	14	Q. How about dispersability?
15	three?	15	A. Yes.
16	A. Possibly. I don't know firsthand.	16	Q. And also their rate of absorption and
17	Q. Well, do you know whether or not	17	their transport in metabolism?
18	long-chain polyglutamyl folates are more	18	A. Yes.
19	hydrophobic than short-chain polyglutamyl folates	19	Q. They would each folate would have a
20	at low pH levels?	20	different physical interaction with foot
21	A. What I do know at low pH levels?	21	components, correct?
22	Q. Yes.	22	A. Uh possibly. I don't it's not
23	A. I'm I'm let me think. Can you	23	necessarily true. Some might have the same.
24	define low pH for me? What do you mean?	24	Q. And others may have different ones?
25	Q. What's the gastric in the	25	A. Yeah.
<b></b>			



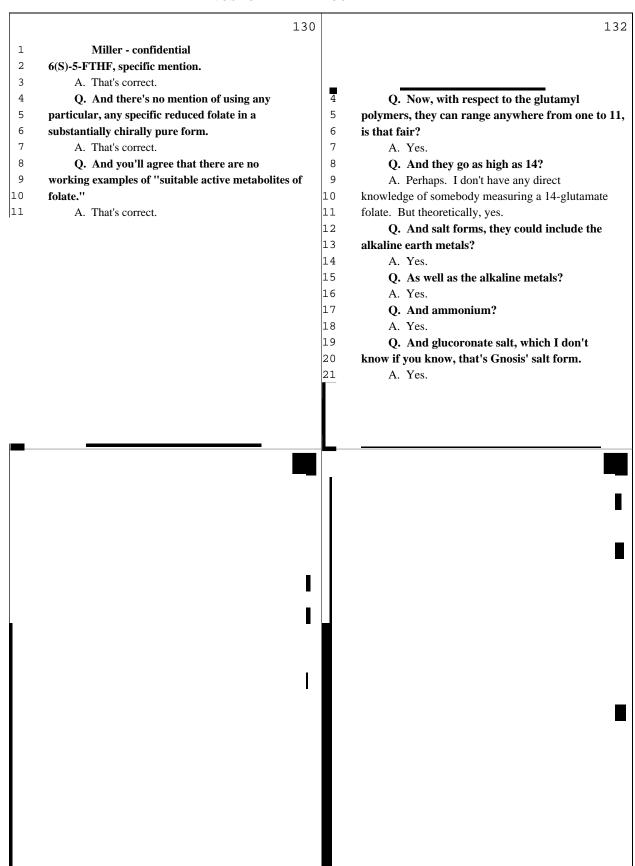
1	90		92
		1	Miller - confidential
		2	If you can answer.
		3	A. I would suspect that not every person
		4	of ordinary skill in the art would come to that
		5	conclusion, but that I and a significant percentage
		6	of those of ordinary skill in the art would come to
		7	that conclusion.
		8	Q. Not a hundred percent, but
		9	significantly.
		10	A. Yeah.
		11	Q. A significant amount of individuals.
		12	So just to be clear, it's not it
		13	doesn't necessarily have to happen each and every
	I	14	time with respect to each person of skill in the
		15	art, right?
		16	A. Yes.
		10	A. 1es.
		•	
L			
23	Q. Now, in paragraph 15, you state, "In		
24	general, a limitation is inherent and in the public		
25	domain if it is the "natural result flowing from" a	L	
	91		
	91		
	3.7111 01.3 .1.3		-
1	Miller - confidential		_
2	disclosure of the prior art reference.		
	disclosure of the prior art reference.  Do you see that?		ı
2	disclosure of the prior art reference.		ī
2	disclosure of the prior art reference.  Do you see that?		ı
2 3 4	disclosure of the prior art reference.  Do you see that?  A. Yes.		I
2 3 4 5	disclosure of the prior art reference.  Do you see that?  A. Yes.  Q. What did you mean by "natural result		I
2 3 4 5 6	disclosure of the prior art reference.  Do you see that?  A. Yes.  Q. What did you mean by "natural result flowing from"?		
2 3 4 5 6 7	disclosure of the prior art reference.  Do you see that?  A. Yes.  Q. What did you mean by "natural result flowing from"?  A. That one of I always forget the		
2 3 4 5 6 7 8	disclosure of the prior art reference.  Do you see that?  A. Yes.  Q. What did you mean by "natural result flowing from"?  A. That one of I always forget the phrase a person who has the ordinary skill in		
2 3 4 5 6 7 8 9	disclosure of the prior art reference.  Do you see that?  A. Yes.  Q. What did you mean by "natural result flowing from"?  A. That one of I always forget the phrase a person who has the ordinary skill in the art would recognize from what is said that it's referring to specific things, whether or not they		
2 3 4 5 6 7 8 9 10	disclosure of the prior art reference.  Do you see that?  A. Yes.  Q. What did you mean by "natural result flowing from"?  A. That one of I always forget the phrase a person who has the ordinary skill in the art would recognize from what is said that it's referring to specific things, whether or not they are explicitly said.		
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2 3 4 5 6 7 8 9 10 11 12 13	disclosure of the prior art reference.  Do you see that?  A. Yes.  Q. What did you mean by "natural result flowing from"?  A. That one of I always forget the phrase a person who has the ordinary skill in the art would recognize from what is said that it's referring to specific things, whether or not they are explicitly said.  Q. Okay. So basically, so so if information is not explicitly said, a person of		
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2 3 4 5 6 7 8 9 10 11 12 13 14	disclosure of the prior art reference.  Do you see that?  A. Yes.  Q. What did you mean by "natural result flowing from"?  A. That one of I always forget the phrase a person who has the ordinary skill in the art would recognize from what is said that it's referring to specific things, whether or not they are explicitly said.  Q. Okay. So basically, so so if information is not explicitly said, a person of ordinary skill in the art would understand it to be implicitly included within the reference; is that		
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	disclosure of the prior art reference.  Do you see that?  A. Yes.  Q. What did you mean by "natural result flowing from"?  A. That one of I always forget the phrase a person who has the ordinary skill in the art would recognize from what is said that it's referring to specific things, whether or not they are explicitly said.  Q. Okay. So basically, so so if information is not explicitly said, a person of ordinary skill in the art would understand it to be implicitly included within the reference; is that what your understanding is of "natural result flowing from"?  A. Yes, um-hum.  Q. And is that something that your understanding, I know you're not a lawyer, is that		
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	disclosure of the prior art reference.  Do you see that?  A. Yes.  Q. What did you mean by "natural result flowing from"?  A. That one of I always forget the phrase a person who has the ordinary skill in the art would recognize from what is said that it's referring to specific things, whether or not they are explicitly said.  Q. Okay. So basically, so so if information is not explicitly said, a person of ordinary skill in the art would understand it to be implicitly included within the reference; is that what your understanding is of "natural result flowing from"?  A. Yes, um-hum.  Q. And is that something that your understanding, I know you're not a lawyer, is that		
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	98		100
		1	Miller - confidential
		2	A. That's correct.
		3	Q. Okay.
		4	A. Yes. And specifically, the conditions
5	Q. Okay. So let me just hand you the	5	that are stated here are "treatment and/or
6	why don't we go with the '778 patent, which is the	6	prevention of vascular disease and/or a female's
7	formulation patent. Are you familiar with that	7	risk of having a miscarriage and/or having a fetus
8	one?	8	with a neural tube defect, or other birth defects
9	A. Yes.	9	as listed here."
10	Q. All right. What was, when you read	10	Q. Now, would you also agree that one of
11		11	
	that patent, what was the problem that the	12	the problems that the inventors were trying to
12	inventors were trying to solve?		solve was develop formulations or means in which to
13	A. Could I look at the patent itself?	13	treat individuals who were folate deficiency with
14	Q. Yes.	14	something other than folic acid?
15	A. Do we need a sticker?	15	MR. CWIK: Objection, form,
16	Q. No, because this has been previously	16	foundation.
17	marked as Complainant's Exhibit number 76.	17	A. I believe so.
18	MR. CWIK: I'm going to object to	18	Q. This is Dr. Shane's report, which is
19	form, foundation, speculation.	19	JM-9.
20	Q. You don't have to answer 'till I give	20	EXH (Deposition Exhibit 9, report of
21	counsel a copy.	21	Dr. Barry Shane, marked for identification, as of
22	(A pause in the proceedings.)	22	this date.)
23	Q. Okay, if you'd just let me know,	23	Q. Did you read Dr. Shane's report,
24	Dr. Miller, when you're ready?	24	Dr. Miller?
25	A. I'm ready.	25	A. Yes, I did.
	99		101
1	Miller - confidential	1	Miller - confidential
2	Q. So when you read the '778 patent which	2	Q. Okay. Now, prior to the '95-'96 time
3	is in front of you now, when you read this patent,	3	frame, folic acid was generally considered to be
4	what was the problem that the inventors were trying	4	relatively safe, inexpensive, bioavailable and he
5	to solve?	5	efficacious, correct?
6	MR. CWIK: Objection, form,	6	A. Yes, except there were expressed
7	foundation, speculation.	7	concerns that were published that suggested that
8	If you can answer.	8	excess non-metabolized folic acid might have some
9	Q. Well, if you didn't consider it,	9	harmful effects.
10	that's fine, too.	10	Q. And if you look at paragraph 27, page
11	A. No, I can I can refer to my report.	11	9 of your report, you state that it was yes, you
12	Q. Sure.	12	say that "the non-naturally occurring compound,
13	A. Where I have made a statement about	13	folic acid, is often used to provide folate to
14	this.	14	human subjects," do you see that?
15	I wrote, "Like the '915 patent, the	15	A. Yes.
16	asserted claims of the '778 patent generally relate	16	
17	to compositions comprising one or more natural		Q. That's a true statement, right? A. Yes.
	isomers of folate and a vitamin or other food	17	
18		18	Q. And one of the reasons why it was
19	substance."	19	often used was because it was safe, correct?
20	And then there is a picture	20	A. Generally considered safe.
21	Q. A claim.	21	Q. Right. It was inexpensive, correct?
22	A a snapshot of one of the claims	22	A. Yes.
23	directly as written, and	23	Q. It was also considered stable,
24	Q. And just to be clear, you're reading	24	correct?
25	from paragraph 64?	25	A. Yes.

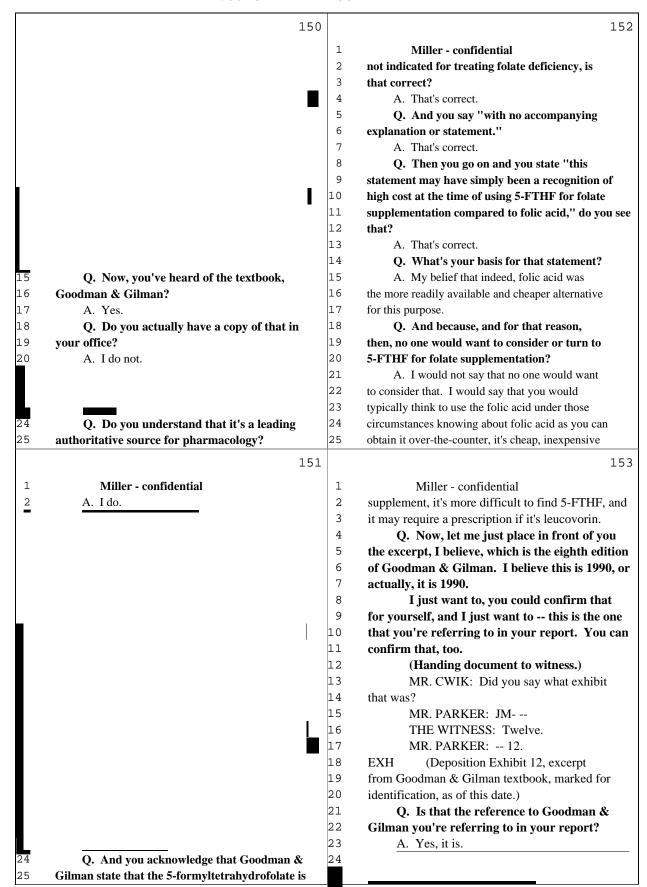
102 104 1 Miller - confidential 1 Miller - confidential 2 2 O. And it was considered to be have been available for over 50 years, they are 3 3 bioavailable, correct? less stable than folic acid, particularly in 4 A. Yes. 4 solution, and are more expensive to produce," do 5 Q. And it had shown some efficacy. 5 you see that? 6 A. Yes. 6 A. Yes. 7 7 O. Okay. Now, if you look at Dr. Shane's O. Do you agree with that statement? 8 8 report at page 13, which is JM-9, if you look at A. Yes, we talked about the solution 9 the third -- well, actually, the second full 9 issue. I have to take Dr. Shane's word for that. 10 paragraph, page 13 of Dr. Shane's report, he says, 11 "Folic acid" -- hold on, strike that. 12 Okay, second sentence, he's referring 13 to folic acid, but tell me if I'm wrong, he states, 14 "Folic acid is the most common form of folate used 15 in supplements and in fortified food products 16 because it is highly bioavailable and chemically 17 stable and it is converted to tetrahydrofolate, the 18 active co-enzyme form of folate." 19 Do you see that? 20 21 Q. And you agree with that statement, 22 right? 23 A. Yes. 24 Q. And then on page 25 of Dr. Shane's 25 report -- if I can find it -- okay. Then he goes 103 Miller - confidential 1 2 on, if you look at the second full paragraph, 3 second sentence, he says, "As folic acid is 4 normally metabolized to all tetrahydrofolates, it 5 continues to be the primary folate form added to 6 fortified foods and supplements to improve folate 7 status." 8 And Dr. Miller, do you agree with that 9 statement? 10 A. Yes. 11 Q. And then on page 19, the second full 12 paragraph, but the very last sentence, he states, 13 "As 5-methyltetrahydrofolate is a poor substrate 14 for the synthesis of polyglutamates, the ability of 15 tissues to accumulate folate is reduced and the 16 functional folate deficiency is compounded by a 17 reduction in cellular folate levels," and then he 18 goes on, "Paradoxically, this can lead to an 19 increase in plasma folate because tissues fail to 20 retain folate." 21 Do you agree with that statement? 22 23 Q. And then, one more, if you'll just go 24 back to page 25, and the first, second full 25 paragraph, he states, "Although tetrahydrofolates

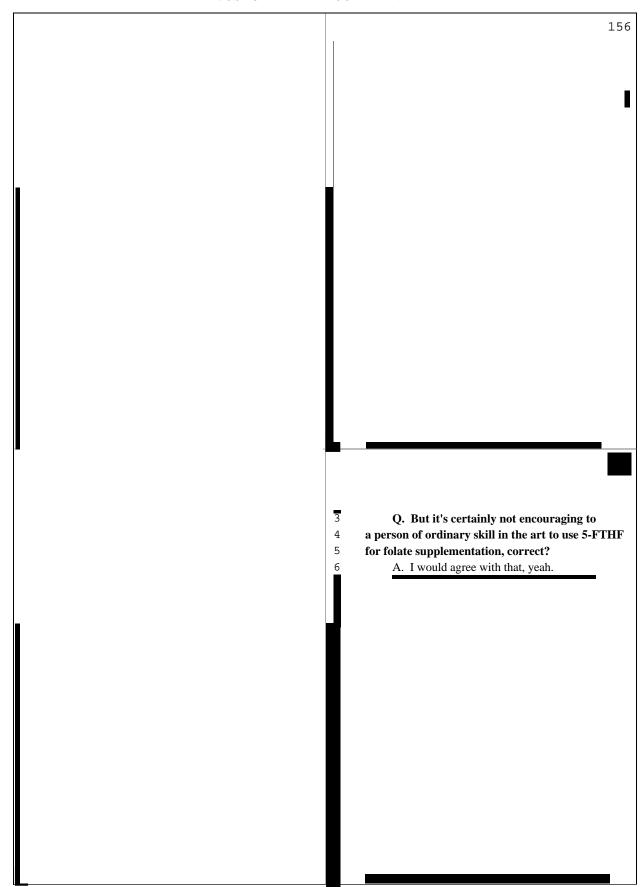
	122		124
1	Miller - confidential	1	Miller - confidential
2	I mean, is the use of the term	2	AFTERNOON SESSION
3	"folate" in Serfontein any different from the way	3	(12:59 p.m.)
4	in which you understand that term to be used?	4	JOSHUA MILLER, having been
5	A. Um when Serfontein uses the phrase	5	previously sworn, resumed the stand and
6	"folate or a suitable active metabolite of folate"	6	testified further as follows:
7	suggests to me that the first word, "Folate" in	7	VIDEOGRAPHER: Here begins video
8	that phrase, is reference to the folic acid.	8	recording number 2. The time is 12:59. We are on
9	Often this occurs that, even with	9	the record.
10	scientists who should know better, that they will	10	EXAMINATION (Cont'd.)
11	use folate when they really intend to mean folic	11	BY MR. PARKER:
12	acid and vice-versa, and it's dependent on the	12	Q. Okay. Dr. Miller, before we broke for
13	context.	13	lunch, we were talking about the Serfontein
14	Q. So in Serfontein, it's your position	14	reference. Is that reference still in front of
15	that the term "folate" is equated with folic acid?	15	you?
16	A. I believe so. That would be my	16	A. Yes.
17	reading of that that phrase.	17	Q. Now, and I believe you testified
18	Q. And the substance which releases	18	previously that you're familiar with this
19	folate in vivo, would that also include folic acid	19	reference, correct?
20	as well?	20	A. Yes.
21	A. Well well, if there was a substance	21	Q. Okay. Now, Serfontein is directed to
22	that releases folate, it could that folate that	22	pharmaceutical preparations, is that correct?
23	is released could very well be folic acid. I will	23	A. Yes.
24	say that I don't really understand, or I don't know	24	Q. And if you look on the first page, the
25	of anything that that phrase, part of the phrase is	25	title well, it says here, "Pharmaceutical
	123		125
1	Miller - confidential	1	Miller - confidential
2	referring to. I don't know of any substance that	2	preparations for lowering homocysteine levels
3	releases folic acid. I don't quite understand what	3	containing vitamin B-6, folic acid and vitamin
4	is meant by that.	4	B-12;" do you see that?
5	Q. Is that because Serfontein doesn't	5	A. Yes.
6	define what it meant by that?	6	Q. And then it goes on and it has another
7	A. Yeah, I don't believe that's the case.	7	description. Do you see that below that, another
8	Q. All right.	8	pharmaceutical preparation?
9	MR. PARKER: This would be a good time	9	A. Yes.
10	to take a break for lunch.	10	Q. Now, with respect to Serfontein and
11	VIDEOGRAPHER: Here ends video	11	the pharmaceutical preparations that it purports to
12	recording number 1. The time is 12:11. We are off	12	disclose, they essentially cover all forms of
13	the record.	13	folate, correct?
14	(Luncheon recess: 12:11 p.m.)	14	A. Um not necessarily.
15		15	Q. Well, it covers the salt forms,
16		16	correct?
17		17	A. Yes.
18		18	Q. Free acid form?
19		19	A. Yes.
20		20	Q. And the various reduced folates that
21 22		21	have various glutamate linkages?  A. Yes.
23		23	Q. Now, you'll agree that Serfontein does
23 24		24	not indicate any preference with respect to any
25		25	particular reduced folate, correct?
Z ()		2	paracular reduced idiate, correct:

	126	128
1	Miller - confidential	
2	A. That's correct.	
3	Q. In fact, Serfontein provides no	
4	definition as to what the meant by "suitable active	
5	metabolite of folate," correct?	
6	A. I don't believe so.	
7	Q. And in Serfontein, there are no	
8	working examples of any pharmaceutical preparation	
9	consisting of a specific reduced folate; correct?	•
10	A. I believe that's the case, yes.	
11	Q. Now, in fact, example 2 in Serfontein,	
12	you may refer to it if you have to, that example	
13	specifically is directed to folic acid, correct?	
14	A. That's what is specifically said in	
15	the box describing the contents of that.	
16	Q. Right. And in example 3, the contents	
17	of the pharmaceutical preparation that's revealed	
18	there contains folic acid, correct?	
19	A. That's correct.	
20	Q. The same is true for example 4?	
21	A. Yes.	
22	Q. And is the same true for example 5?	
23	A. Yes.	
24	Q. The same is true for example 6?	
25	A. Yes.	
	127	
1	Miller - confidential	
2	Q. And the same is true for example 7,	
3	correct?	
4	A. Yes.	_
5	Q. Now, example 8 refers to folate,	
6	correct?	
7	A. Correct.	
8	Q. But folate's not defined in this	
9	document as being, or corresponding to folic acid,	
10	correct?	
11	A. It hasn't explicitly stated by using	
12	the term "folate," it's unclear just looking at	
13	that table.	
14	Q. So it's unclear looking at this table	
15	what compound is being included?	
16	A. Yes.	L
<u> </u>	11. 100.	Q. Okay. But there's no embodiment
Ì		well, let me back up.
		19 With respect to the as you refer to
		20 it as embodiment on page 11 of your report, doesn't
		21 give you the amounts of vitamin B-6 or folate or
		22 B-12 or any other ingredient, right?
		A. That's correct, yeah.
		Q. And you'll agree, right, that there's
		25 no specific mention of either 6(S)-5-MTHF, or
		2. 25 Specific mention of either o(5)-5-111111, 01

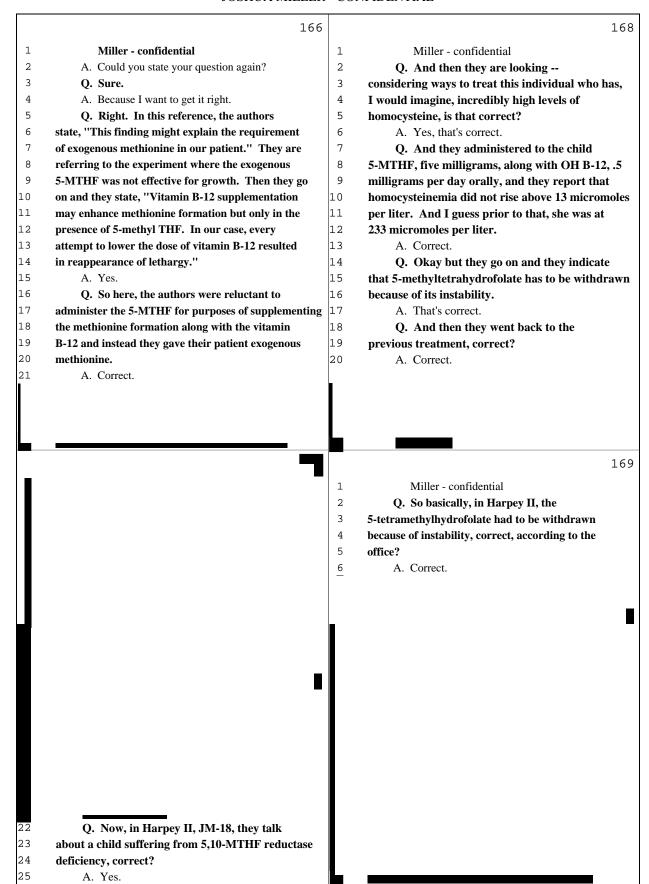


34 (Pages 130 to 133)

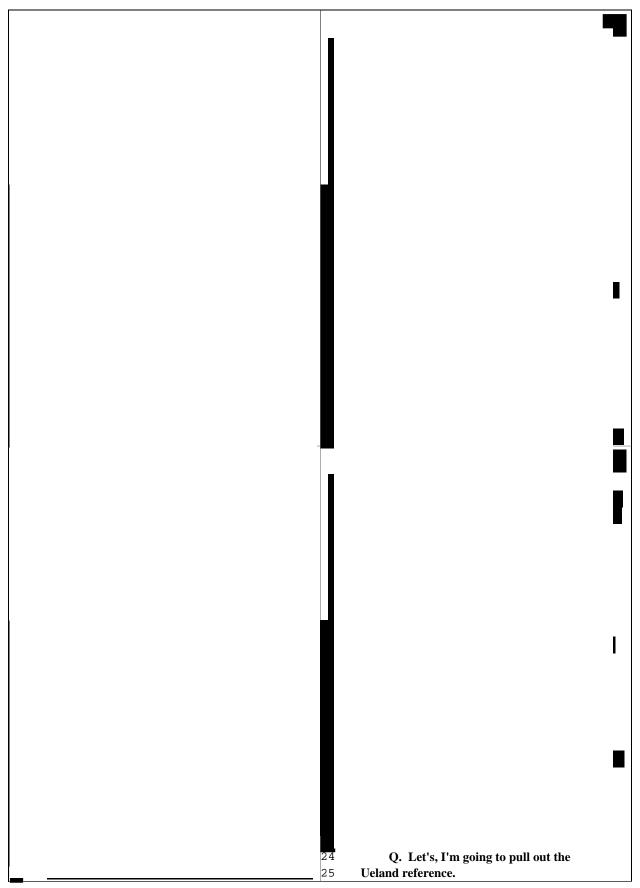




40 (Pages 154 to 157)

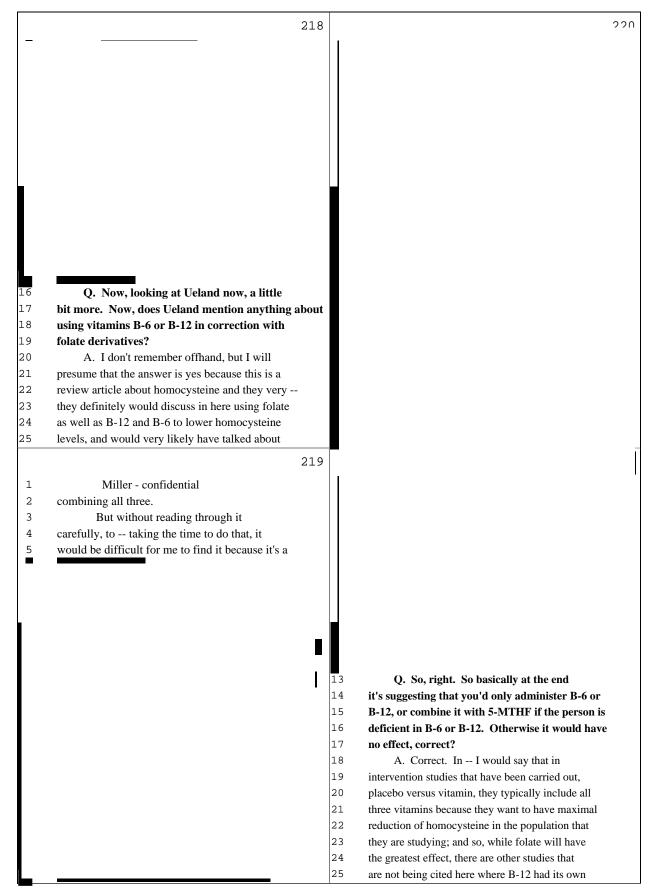


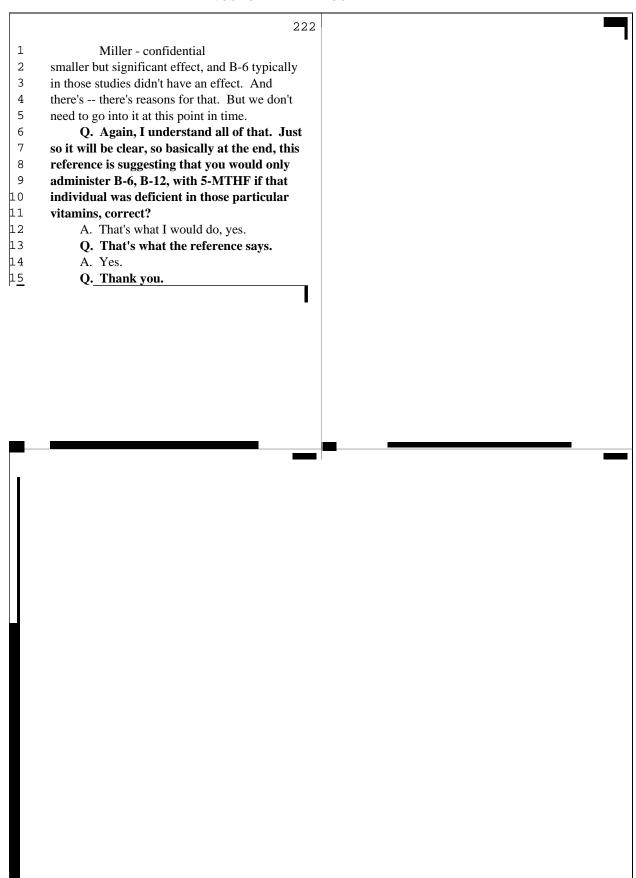
	198		2	00
	150	1		
		1	Miller - confidential	
		2	A. Yes.	
		3 4	Q. And basically, Marazza is really directed to a separation technique for mixtures	
		5	that contain the two diastereoisomers?	
		6	A. That's correct.	
		7		
			Q. And the diastereoisomers of 5 is it	
		8	5-MTHF, right? It's basically directed to a	
		9	separation technique, correct?  A. Correct.	
		11		
		12	Q. And then on the first page, first	.1
		13	column, column 1, "Background of the invention,"	a
			you see that, it says, "There exists an increasing	
		14 15	interest in the application of this natural metabolite as at least one active compound in a	
		16		
		17	therapeutic agent, for example, as vitamin and	
			folate deficiencies," it states. Correct?	
		18 19	A. Correct.	
		20	Q. Now, it uses the phrase, "There exists	
			and increasing interest," okay?	
		21	A. Um-hum.	
	-			_
L	D4 24			
	ce, JM-24			Į
21 <b>EXH</b>	(Deposition Exhibit 24, copy			
	patent, Marazza, et al, marked for			
	cation, as of this date.)			
	which is Marazza. Now, you've made			
25 this ref	erence, correct?	25	Q. So when you say "reasonable	



54 (Pages 210 to 213)

	214
1	Miller - confidential
2	Now, the Ueland reference is also
3	directed to the use of folic acid, right?
4	A. No, there is a a statement in
5	there, statement or paragraph, talking about the
6	intracellular pool of 5-methyl 6(S)
7	Q. Right, so the intracellular pool is
8	what's happening in vivo after administration of
9	folic acid, correct?
10	A. Exactly, yes.
11	Q. It's not talking about administering
12	the 6(S)-5-MTHF exogenously, correct?
13	A. Yes.
14 15	Q. Let me just identify, that is JM-28.
	And can you just identify what that document is for
16	the record?
17	EXH (Deposition Exhibit 28, review
18	article by Ueland and Refsum, "Plasma
19	homocysteine, a risk factor for vascular disease;
20	Plasma levels in health, disease, and drug
21	therapy" marked for identification, as of this
22	date.)
23	A. That's the Ueland reference.
24	(A pause in the proceedings.)
25	Q. Okay, now, Ueland knew, I guess, as
	215
1	Miller - confidential
2	you pointed out, that it talks about increasing the
3	pool of 6(S)-5-MTHF after administration of folic
4	acid, is that correct?
5	A. That's correct.
	A. That's correct.  Q. Now, you understand that the Bailey
6 7	- ''
	patent, as well as the '040 patent, they are not
8	directed to use of folic acid, correct?
9	A. Correct.
10	Q. In fact, is it fair to say that what
11	they were trying to do was develop supplements
12	other than folic acid?
13	A. Correct.



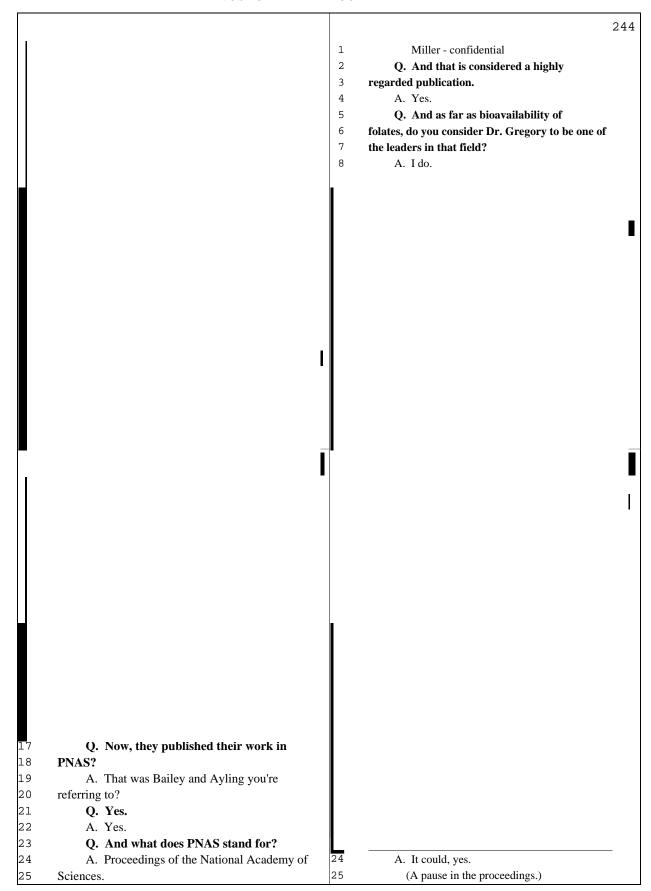


Q. Okay. Now, if I could just direct your attention to paragraph 127 of your opening report, okay, and in this paragraph, you state, "I agree that Dr. Ayling, and a co-inventor of the Bailey patents, Mr. Steven Bailey, discovered a subpopulation of individuals for whom DHFR activity varied more than was known or would have been espected by one of ordinary skill in the art, and that "AMTHF and/or 6(S)-5-MTHF should be more uniformly bioavailable to such individuals."  Do you see that? A. 1-do. Would say that, since I wrote this report, I've seen Dr. Shane's report with a reference to the Whitchead reference, and I have changed my opinion on that.  Q. Okay. But now, just sticking with what s' in your report, okay, so again, I understand what you just said with respect to the Whitchead reference and Dr. Shane's report and you've now changed oyur opinion. But at the time you wrote your report, ou considered Dr. Ayling and Dr. Bailey to have discovered that subpopulation, correct?	1	
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Dr. Bailey to have discovered that subpopulation,	22	
	23	your report, you considered Dr. Ayling and
25	24	Dr. Bailey to have discovered that subpopulation,
	 25	correct?

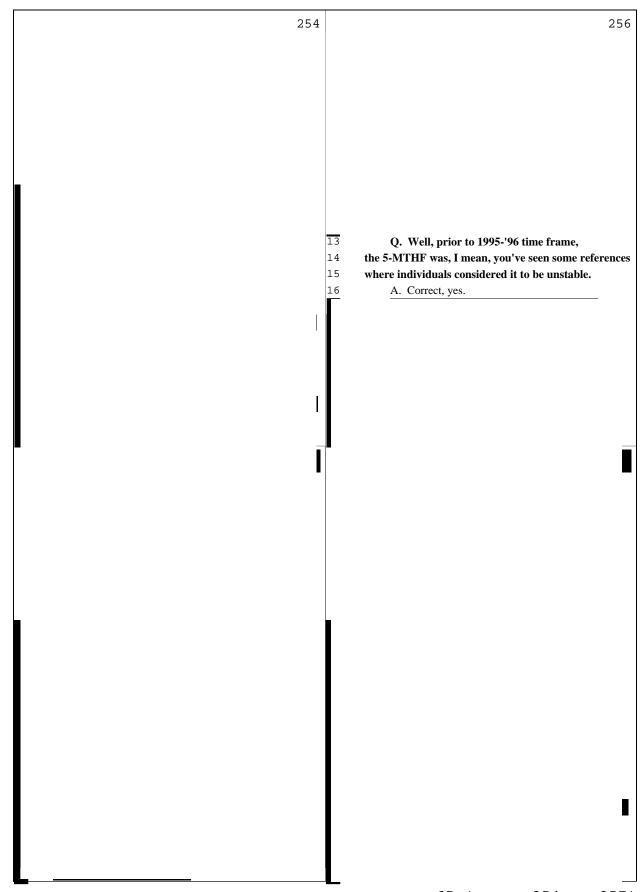


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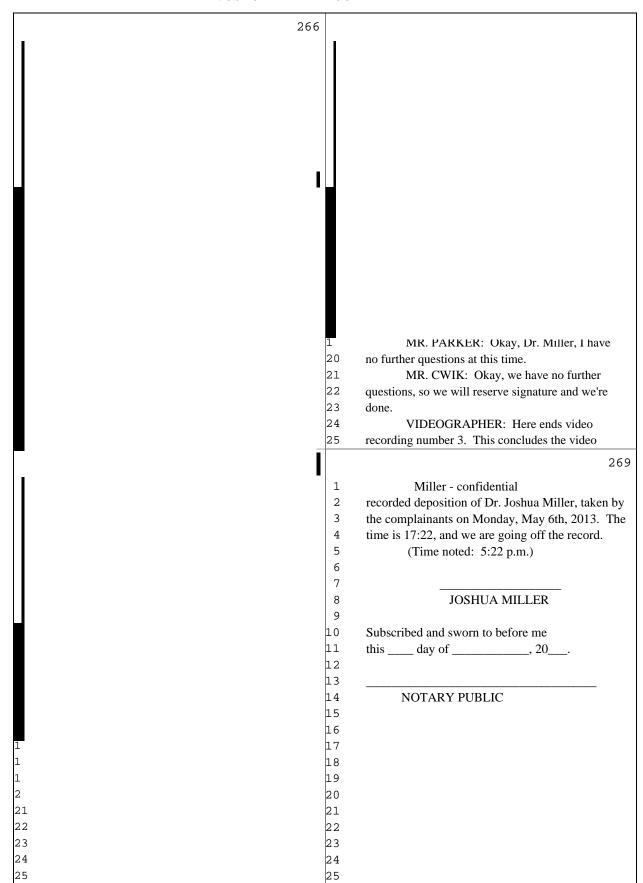
	238	240
	<u>.</u>	1 Miller - confidential
	I	2 A. Sure, yes.
		1
20	Q. So folate metabolism is a complicated	1
21	system, correct?	
22	A. Yes.	
23	Q. And there are multiple steps involved,	
24	and there are multiple enzymes.	
25	A. Um-hum.	_
	239	
1	Miller - confidential	_
2	Q. So if you had a population, people may	
3	have defects in various steps, but not the same	
4	steps.	
5	A. Um-hum.	
6	Q. And so because of that, if I	
7	understand it correctly, the inference or the	
8	extending the logic further is that, well,	
9	obviously, you're not going to have a balanced and	
10 11	uniform level of bioavailability among the population because people could have varying	
12	defects in the genes responsible for the enzymes,	
13	whether they were severe, slight, moderate, but	
14	that can contribute to having various levels of	
15	bioavailability.	
16	A. Not just the enzymes but the	
17	transporters and receptors and that are also	
18	involved in getting the folates to where they are	
19	supposed to go.	L
20	Q. And that, too, is somewhat of a	Q. So when you mentioned that, in your
21	complicated process, correct?	response, because I do want to just kind of just
22 23	A. Sure, yes.	focus on one thing, just to, for my sake get it shorter, you said, I would I mean, that you
24	Q. And all the various substrates or the compounds involved in that process, they all have	23 snorter, you said, I would I mean, that you acknowledged that Dr. Green and Dr. Gregory have
25	different physiological properties.	25 talked about the complexity of folate metabolism,
	annot our bullatorogreus brober step.	- Toute members, or route membership



62 (Pages 242 to 245)



65 (Pages 254 to 257)



68 (Pages 266 to 269)

<ul> <li>Reporter and Notary Pub</li> <li>State of New Jersey, do h</li> <li>That JOSHUA MIL</li> </ul>	Certified Shorthand olic within and for the nereby certify: LER, the witness whose we set forth, was duly ch deposition is a true	1 2 3 4 5 6 7 8		272
2 CERTIFICA 3 4 I, DAVID LEVY, a 5 Reporter and Notary Pub 6 State of New Jersey, do b 7 That JOSHUA MIL	Certified Shorthand olic within and for the nereby certify: LER, the witness whose we set forth, was duly ch deposition is a true	2 3 4 5 6 7 8	DEPOSITION EXHIBITS (JM) FOR IDENT. Exhibit 7 Excerpt from Green expert 75 report  Exhibit 8 List of folate compounds 79 Exhibit 9 Report of Dr. Barry Shane 100 Exhibit 10 European patent application, 106	
3 I, DAVID LEVY, a 5 Reporter and Notary Pub 6 State of New Jersey, do b 7 That JOSHUA MIL	Certified Shorthand olic within and for the nereby certify: LER, the witness whose we set forth, was duly ch deposition is a true	3 4 5 6 7 8	DEPOSITION EXHIBITS (JM) FOR IDENT. Exhibit 7 Excerpt from Green expert 75 report  Exhibit 8 List of folate compounds 79 Exhibit 9 Report of Dr. Barry Shane 100 Exhibit 10 European patent application, 106	
<ul> <li>I, DAVID LEVY, a</li> <li>Reporter and Notary Pub</li> <li>State of New Jersey, do h</li> <li>That JOSHUA MIL</li> </ul>	olic within and for the nereby certify:  LER, the witness whose e set forth, was duly ch deposition is a true	5 6 7 8	Exhibit 7 Excerpt from Green expert 75 report  Exhibit 8 List of folate compounds 79 Exhibit 9 Report of Dr. Barry Shane 100 Exhibit 10 European patent application, 106	
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7 That JOSHUA MIL	LER, the witness whose e set forth, was duly ch deposition is a true	8	Exhibit 10 European patent application, 106	
	e set forth, was duly ch deposition is a true	9		
8 deposition is hereinbefore set forth, was duly		9	Schonich, et al	
9 sworn by me and that such deposition is a true		10	Exhibit 11 Declaration of Joshua S. 109	
record of the testimony given by the witness.			Miller, Ph.D.	
11 I further certify that I am not		11	F 177 10 F	
related to any of the parties to this		12	Exhibit 12 Excerpt from Goodman & 153 Gilman textbook	
action by blood or marriage, and that I		13	Gillian CAUDOOK	
am in no way interested in the outcome		14	Exhibit 13 Excerpt from Goodman & 155	
•	in the outcome	15	Gilman, 1986	
of this matter.  IN WITNESS WHEREOF, I have hereunto set my		16	Exhibit 14 Excerpt from Goodman & 155	
	,		Gilman, 1985	
hand this 7th day of May	, 2013.	17 18	Exhibit 15 Various definitions from New 157	
L8	W COD DED CLE	10	American Medical Dictionary	
	Y, CSR, RPR, CLR	19	•	
20		20	Exhibit 16 Excerpt from Goodman & 159 Gilman, 2001	
21		21	Gillian, 2001	
22		22	Exhibit 17 Harpey I reference 162	
23		23	Exhibit 18 Harpey II reference 162	
24		24	Exhibit 19 Article, "Folic Acid and 174 L-5-Methyltetrahydrofolate,"	
25		25	Shane, et al	
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17 Willier, 1 ii.D.			Marginal Vitamin Deficiency,"	
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19		19	a risk factor for vascular	
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2	I N D E X (Cont'd.)	2 ERRATA	
3	DEPOSITION EXHIBITS (JM) FOR IDENT.	3	
4	Exhibit 31 Article from New England 251		
_	Journal of Medicine,		
5	Czeizel, et al	5 the following reasons:	
6	Exhibit 32 Article, "Folic acid - an 265 innocuous means to reduce	6	
7	plasma homocysteine,"	7 PAGE LINE	
'	Brattstrom, et al	8 CHANGE	
8	,	9 REASON:	
9	Exhibit 33 Article, "Moderate 265	10 CHANGE	
	homocysteine - a possible	11 REASON:	
10	risk factor for arteriosclerotic	12 CHANGE	
11	cerebrovascular disease,"	13 REASON:	
	Brattstrom, et al	14 CHANGE	
12	, · · ·	15 REASON:	
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15		17 REASON:	
16 17		18 CHANGE	
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23 24		24 WITNESS' SIGNATURE DATE	
25		25	
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3	INSTRUCTIONS TO WITNESS		
4			
5	Please read your deposition over carefully and		
6	make any necessary corrections. You should state		
7	the reason in the appropriate space on the errata		
	sheet for any corrections that are made.		
8	•		
9	After doing so, please sign the errata sheet and		
10	date it.		
11	You are signing same subject to the changes you		
12	have noted on the errata sheet, which will be		
13	attached to your deposition.		
14	It is imperative that you return the original		
15	errata sheet to the deposing attorney within thirty		
16	(30) days of receipt of the deposition transcript		
17	by you. If you fail to do so, the deposition		
18	transcript may be deemed to be accurate and may be		
19	used in court.		
20	asoa in court.		
21			
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