

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

3
4 MOM ENTERPRISES, LLC,)
5 Petitioner,)
6 vs.) Case IPR2023-00726
7 ELAINE AND REINHOLD W.) Patent 9,066,958 B2
8 VIETH,)
9 Patent Owner.)

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13 CONFIDENTIAL – ATTORNEYS' EYES ONLY

14 SUBJECT TO THE PROTECTIVE ORDER

15

16

17 Oral deposition of REINHOLD VIETH, Ph.D.

18 called by the petitioner for examination

19 pursuant to agreement and pursuant to the rules,

20 taken stenographically by Lisa M. Barrett, RPR, CRR,

21 CSR, at the Marriott Hotel Toronto, 1 Blue Jays Way,

22 Toronto, Ontario, Canada on Tuesday the 2nd day

23 of April, 2024, at 9:00 a.m. (EDT)

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VIETH DEPOSITION EXHIBIT

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Exhibit 2071 Article "VMC Public Health" 151
Title "Very High Vitamin D
Supplementation Rates Among
Infants Aged Two Months in
Vancouver and Richmond,
British Columbia, Canada. "

* * * * *

1 REINHOLD VIETH, Ph.D.: Affirmed

2 DIRECT EXAMINATION BY MR. CONRAD:

09:05:38 3 Q. Good morning, Dr. Vieth. How are you?

09:05:41 4 A. Good.

09:05:42 5 Q. Is this your first deposition that you've
09:05:44 6 given or have you given other — given testimony in
09:05:48 7 other depositions before?

09:05:50 8 A. Not in this case.

09:05:51 9 Q. So you've been deposed before?

09:05:53 10 A. In something different, yeah.

09:05:55 11 Q. Okay. About how many times have you been
09:05:57 12 deposed?

09:06:02 13 A. I would say twice.

09:06:11 14 Q. You said twice? When was the last time
09:06:15 15 you were deposed?

09:06:17 16 A. Around 2017.

09:06:19 17 Q. What was the subject of that action?

09:06:22 18 A. Employment.

09:06:24 19 Q. What about before that?

09:06:26 20 A. I was an expert witness.

09:06:31 21 Q. And what was the subject matter of the
09:06:32 22 case?

09:06:35 23 A. It -- can I name the -- the subject matter
09:06:38 24 was I was on the side of a company that was
09:06:46 25 infringing on a patent.

09:06:49 1 Q. Which company was that?

09:06:51 2 A. The name of the company was Apotex, a

09:06:57 3 generic drug manufacturer.

09:06:59 4 Q. How do you spell that?

09:07:00 5 A. A-P-O-T-E-X.

09:07:02 6 Q. And you were working for Apotex or you

09:07:04 7 were an expert witness on behalf of them?

09:07:07 8 A. I was asked to review documents and be an

09:07:09 9 expert witness, yes.

09:07:10 10 Q. Was Apotex a plaintiff or a defendant?

09:07:18 11 A. I think they were defendant.

09:07:20 12 Q. They were accused of infringing?

09:07:21 13 A. Yes.

09:07:22 14 Q. What sort of testimony -- did you provide

09:07:25 15 an expert report in that case?

09:07:27 16 A. Did I ...?

09:07:29 17 Q. Did you provide an expert report in that

09:07:31 18 case?

09:07:31 19 A. Oh yes.

09:07:32 20 Q. And what -- what were the conclusions --

09:07:34 21 let me ask you a different question. Were you

09:07:39 22 providing an opinion as to whether the patent was

09:07:42 23 not infringed or whether the patent was invalid?

09:07:49 24 MR. ANDERSON: Object to the form of the

09:07:50 25 question.

09:07:50 1 BY MR. CONRAD::

09:07:52 2 Q. Or both?

09:07:52 3 MR. ANDERSON: You can answer, if you
09:07:54 4 understand the question.

09:07:58 5 THE WITNESS: I guess as a witness, I
09:07:59 6 don't always know the legal context, but
09:08:04 7 basically I provided an opinion that the patent
09:08:06 8 was not valid.

09:08:08 9 BY MR. CONRAD::

09:08:12 10 Q. What kind of patent was at issue? Do you
09:08:15 11 remember what the supposed invention was?

09:08:17 12 A. The supposed what?

09:08:19 13 Q. Invention?

09:08:20 14 A. Well, you know, basically, you don't want
09:08:26 15 to reveal technical details, although I can, but I
09:08:30 16 mean, it was an out-of-court settlement.

09:08:34 17 It was an osteoporosis drug that a
09:08:38 18 brand name drug company had, and Apotex being, I
09:08:43 19 guess, a company that makes generic drugs said:
09:08:47 20 This patent's not valid and we'll make our own
09:08:49 21 version of it. And I was defending on the Apotex
09:08:52 22 side.

09:08:57 23 Q. How often have you -- or how many times
09:08:59 24 have you served as an expert witness in a patent
09:09:01 25 infringement case?

09:09:05 1 A. Just that one.

09:09:06 2 Q. Okay. Right, well, since you haven't done
09:09:10 3 this a whole bunch I'm going to go over a couple of
09:09:14 4 ground rules. I'm sure your counsel has gone over
09:09:18 5 some of this before but I just felt like we could go
09:09:20 6 over them again today.

09:09:22 7 So the first thing I'd like to point
09:09:24 8 out is that, as you notice, all of this is being
09:09:27 9 transcribed and that means that we need to have
09:09:35 10 audible testimony, no nods or shakes of the heads,
09:09:38 11 and I'll do my best not to talk over you and let you
09:09:41 12 finish your answer and if you can do the same, to
09:09:44 13 wait for my question to finish, that would be great.

09:09:49 14 We can take a break whenever you
09:09:50 15 need -- just let us know -- and I will try to take a
09:09:58 16 break about every hour or so, but if you need to
09:10:02 17 stop to take a break for whatever reason, just let
09:10:05 18 me know. Okay?

09:10:11 19 All right. Do you understand today
09:10:16 20 that your testimony here is under oath, just as if
09:10:19 21 you were in a court of law on a witness stand
09:10:22 22 testifying in front of a judge and jury?

09:10:24 23 A. Yes.

09:10:26 24 Q. Is there anything that would prevent you
09:10:28 25 from giving truthful and accurate testimony today?

09:10:31 1 A. No.

09:10:33 2 Q. I understand the -- it seems to me that

09:10:37 3 the acoustics in the room are a little challenging

09:10:40 4 so if you have any trouble hearing my question or

09:10:43 5 you can't understand my question, will you let me

09:10:48 6 know?

09:10:48 7 A. Yes.

09:10:51 8 Q. Okay. Dr. Vieth, I'm going to hand you

09:10:56 9 what's been marked as Exhibit 2008, which is

09:11:01 10 declaration of Reinhold Vieth dated June 28, 2023.

09:11:10 11 (R. VIETH Exhibit 2008 was marked for

09:11:10 12 identification.)

09:11:11 13 THE WITNESS: Okay.

09:12:45 14 (Pause)

09:12:53 15 BY MR. CONRAD::

09:12:54 16 Q. And Dr. Vieth, I'm also handing you

09:12:56 17 Exhibit 2068 which is a declaration of Reinhold

09:13:04 18 Vieth dated February 3rd, 2024.

09:14:24 19 (R. VIETH Exhibit 2068 was marked for

09:14:24 20 identification.)

09:13:19 21 BY MR. CONRAD:

09:13:19 22 Q. Are these both declarations that you

09:13:21 23 submitted in this IPR proceeding?

09:13:26 24 MR. ANDERSON: Object to the form of the

09:13:27 25 question.

09:13:31 1 You may answer.

09:13:36 2 THE WITNESS: I'm trying to figure out
09:13:37 3 what the form of the question objection is. I
09:13:38 4 don't know.

09:13:39 5 MR. ANDERSON: You don't need to worry
09:13:40 6 about that. Unless I tell you not to answer,
09:13:42 7 you go ahead and answer if you understand the
09:13:44 8 question.

09:13:45 9 BY MR. CONRAD::

09:13:45 10 Q. He's making an objection that he doesn't
09:13:47 11 like the question, it's a bad question, for whatever
09:13:49 12 reason. So unless he tells you not to answer
09:13:52 13 because --

09:13:54 14 A. Yes, I submitted these.

09:14:00 15 Q. Were you involved in the preparation of
09:14:03 16 these declarations?

09:14:04 17 A. Yes.

09:14:14 18 Q. I'm going to first turn to Exhibit 2068.
09:14:17 19 This is the February 2024 declaration.

09:14:28 20 You start off in this declarations
09:14:31 21 talking a little bit about your background, so I am
09:14:34 22 going to ask you a couple more questions about that.
09:14:36 23 Okay?

09:14:36 24 A. Mm-hmm.

09:14:37 25 Q. Sorry, Dr. Vieth, if you could give a

09:14:39 1 "yes" or a "no" --

09:14:39 2 A. You said "okay. "

09:14:40 3 Q. And you "mm-hmm. "

09:14:42 4 A. Okay. Yeah, what are you getting at?

09:14:43 5 Q. Sorry, sorry.

09:14:44 6 So in order to get the testimony down

09:14:46 7 accurately I'll need you to give audible responses,

09:14:49 8 "yes" or "no," not "mm-hmm" or --

09:14:54 9 A. Okay, when I get a question I'll answer

09:14:55 10 that way.

09:14:57 11 Q. Okay.

09:14:57 12 A. Yes.

09:15:08 13 Q. I notice that you were educated in

09:15:12 14 Toronto; is that right?

09:15:13 15 A. Yes.

09:15:15 16 Q. Did you live in Toronto all your life?

09:15:18 17 A. Since I was two. Would I say "no" to that

09:15:23 18 because I didn't live here all my life?

09:15:25 19 Q. Where were you born?

09:15:27 20 A. Germany.

09:15:29 21 Q. Oh, your parents were German?

09:15:30 22 A. Yes.

09:15:31 23 Q. And they came over when you were two?

09:15:33 24 A. Correct.

09:15:34 25 Q. And your family moved to Toronto?

09:15:36 1 A. Yes.

09:15:37 2 Q. And you've lived in Toronto ever since?

09:15:40 3 A. Correct, yes.

09:15:45 4 Q. When -- what did your parents do for a

09:15:52 5 living?

09:15:58 6 A. My mother was a cleaning lady. My dad had

09:16:05 7 several jobs. Initially, I guess, the first one was

09:16:09 8 as a plumber, and then we had rooming houses.

09:16:19 9 Q. What led you into the field of medicine?

09:16:21 10 A. I'm sorry?

09:16:22 11 Q. What led you into the field of medicine?

09:16:27 12 A. Why did I take the path that I took? I

09:16:35 13 enjoyed the undergraduate science courses I took. I

09:16:41 14 guess one key is I took an undergraduate project

09:16:45 15 course. The people that oversaw that thought I was

09:16:50 16 pretty good at it. After my undergraduate, the

09:16:54 17 intent was to take an MBA, but they called me in the

09:17:00 18 summer and said come on in and talk to a couple of

09:17:03 19 people that need graduate students.

09:17:07 20 I talked to a couple and the ones

09:17:10 21 that I liked were -- I talked to Sang Whay Kooh and

09:17:14 22 Donald Fraser at Hospital for Sick Children. They

09:17:17 23 had recently published in New England Journal about

09:17:22 24 vitamin D and rickets and they got a grant that

09:17:25 25 supported a graduate student which was me.

09:17:27 1 And I followed that river to here.

09:17:47 2 Q. So in the -- as a graduate student you
09:17:50 3 were researching rickets?

09:17:58 4 A. My project was to understand the
09:18:00 5 metabolism of vitamin D. At that time, that early
09:18:07 6 1970s era, it was discovered that vitamin D itself
09:18:14 7 is metabolized into a hormone called 1,25-dihydroxy
09:18:20 8 vitamin D. And it was my job to understand how the
09:18:26 9 kidney and the liver and the body produced that
09:18:31 10 hormone and under what circumstances.

09:18:41 11 Q. Has your focus in medicine been in the
09:18:47 12 field of vitamin D ever since?

09:18:53 13 A. Yes.

09:18:55 14 Q. Are there other subject matters in which
09:18:57 15 you also conducted research in your career?

09:19:03 16 MR. ANDERSON: Object to the form of the
09:19:03 17 question.

09:19:12 18 THE WITNESS: I'm trying to understand how
09:19:14 19 I should answer that question.

09:19:16 20 BY MR. CONRAD::

09:19:16 21 Q. It's not a trick question.

09:19:18 22 A. Can you ask the question, again?

09:19:20 23 Q. Sure. It's not a trick question.

09:19:22 24 Besides vitamin D, what other subject
09:19:24 25 matters have you conducted research into?

09:19:26 1 A. Okay. Bone drugs, bisphosphonates. In
09:19:31 2 other words, if you were to search PubMed for
09:19:34 3 articles that I've written, or look through the CV,
09:19:36 4 you will find a minority of my publications related
09:19:39 5 to non-vitamin D items.

09:19:54 6 Q. Okay. Let's turn to paragraph 6 of
09:19:59 7 Exhibit 2068.

09:20:08 8 A. Mm-hmm.

09:20:08 9 Q. In paragraph 6 you note that there is a
09:20:10 10 problem of vitamin D deficiency, right?

09:20:13 11 A. Yes.

09:20:18 12 Q. And that's something that's been known for
09:20:20 13 a long time, right?

09:20:22 14 MR. ANDERSON: Object to the form of the
09:20:23 15 question.

09:20:25 16 THE WITNESS: Yes, it's been known that
09:20:27 17 vitamin D deficiency has existed for some --
09:20:29 18 well, for a hundred years anyway.

09:20:32 19 BY MR. CONRAD::

09:20:38 20 Q. In paragraph 8 you point out that the need
09:20:40 21 for supplemental vitamin D goes back hundreds of
09:20:44 22 years. Scandinavian countries started using cod
09:20:51 23 liver oil in the 1700s; do you see that?

09:20:54 24 A. Yes.

09:20:58 25 Q. You point out, "They referred to cod liver

09:21:01 1 oil as a means to help children thrive. "

09:21:05 2 Do you see that?

09:21:05 3 A. Yes.

09:21:07 4 Q. So, for hundreds of years there have
09:21:16 5 already been solutions for providing supplemental
09:21:19 6 vitamin D to children, right?

09:21:22 7 MR. ANDERSON: Object to the form of the
09:21:23 8 question.

09:21:30 9 THE WITNESS: It's not a straightforward
09:21:31 10 answer there.

09:21:36 11 BY MR. CONRAD:

09:21:36 12 Q. Okay.

09:21:36 13 A. Simply because Scandinavians knew you
09:21:41 14 needed something in fish oils to help infants thrive
09:21:44 15 was the point of it, and in the early 1900s, between
09:21:49 16 1910 and 1920, people started realizing that there
09:21:53 17 was -- should I go into this?

09:21:57 18 Q. Sure.

09:21:58 19 A. Okay.

09:21:59 20 MR. ANDERSON: Well, answer the questions
09:22:00 21 that are posed to you.

09:22:02 22 THE WITNESS: Well, no, but you said for
09:22:03 23 hundreds of years we've known that we need
09:22:06 24 vitamin D, and that's not true.

09:22:07 25 What we knew was to help infants thrive

09:22:11 1 you needed some agent in cod liver oil.

09:22:15 2 So the reason vitamin A is called A, it
09:22:20 3 was called "fat-soluble A," agents within the
09:22:24 4 fats that helped with regard to health.

09:22:27 5 The reason vitamin B is called vitamin B,
09:22:30 6 it was called water-soluble B, and that's why
09:22:35 7 you have B1, B2. Like, they're arbitrary. So
09:22:39 8 there was a breakdown initially of you got a
09:22:41 9 fat-soluble vitamins A, and you had the
09:22:45 10 water-soluble vitamins B, as in Bill.

09:22:49 11 So, A was the anti-ricketic, but it took
09:22:57 12 until around 1920 before people realized, hey,
09:23:04 13 this A stuff has got the stuff that prevents
09:23:07 14 rickets, but that's not exactly the A. So they
09:23:11 15 called it D because you had the B vitamin, the
09:23:15 16 C vitamin which is from oranges, and then D is
09:23:17 17 the next one in the alphabet.

09:23:19 18 So they realized that the fish oil which
09:23:22 19 helped infants to thrive had fat-soluble A but
09:23:27 20 fat-soluble A was actually two components, what
09:23:31 21 we now regard as vitamin A as well as what we
09:23:35 22 now regard as vitamin D.

09:23:37 23 That's the way that -- you know, so you
09:23:40 24 knew that people needed fat-soluble agents
09:23:42 25 within cod liver oil and they helped with

09:23:45 1 regard to thriving.

09:23:51 2 BY MR. CONRAD::

09:23:51 3 Q. Okay, I think I understand. So the point
09:23:54 4 you're making is that they started using vitamin D
09:24:07 5 supplementation to help children thrive but didn't
09:24:10 6 realize that it was specifically vitamin D that was
09:24:12 7 giving the effect they were looking for?

09:24:15 8 MR. ANDERSON: Object to the form of the
09:24:16 9 question.

09:24:19 10 THE WITNESS: Up to around the 1920s
09:24:22 11 that's probably the case. They were working in
09:24:24 12 the dark but they knew something was needed,
09:24:28 13 yeah.

09:24:35 14 BY MR. CONRAD::

09:24:35 15 Q. What happened in the 1920s?

09:24:39 16 MR. ANDERSON: Object to the form of the
09:24:40 17 question.

09:24:51 18 THE WITNESS: In the 1920s -- how can I
09:24:54 19 say it? It was essentially discovered that if
09:25:00 20 you irradiated certain compounds with
09:25:08 21 ultraviolet light, then it would help to
09:25:13 22 prevent rickets in rats, in terms of the
09:25:15 23 laboratory, so foods that were irradiated with
09:25:24 24 light would become active in terms of an agent
09:25:33 25 called vitamin D.

09:25:33 1 An interesting collection of experiments
09:25:37 2 with regards to rats happened around the 1920s.
09:25:40 3 Initially they thought rats didn't need
09:25:43 4 too much vitamin D because they were nocturnal,
09:25:44 5 but, indeed, they do need it. And the
09:25:48 6 experiment that I like is a classic one, where
09:25:52 7 it was discovered that if you eradicate rat
09:26:01 8 cages without the rat in it with ultraviolet
09:26:05 9 light, and then put the rat back in the cage,
09:26:06 10 the rat would be protected against rickets.

09:26:10 11 And as somebody who works with rats, and
09:26:17 12 you know these animals -- you know that rat
09:26:21 13 cages get oily just from the fur, you know,
09:26:23 14 they're rubbing against the walls of it and the
09:26:25 15 lanolin from the skin rubbed onto the walls of
09:26:28 16 the rat cages, you'd expose that skin oil,
09:26:31 17 lanolin, to ultraviolet light, and that then
09:26:35 18 contained effectively vitamin D. And the rats
09:26:39 19 would lick the walls of the cage and voila.

09:26:42 20 BY MR. CONRAD::

09:26:44 21 Q. Mm-hmm.

09:26:44 22 A. It is kind of a neat kind of model, but
09:26:50 23 that's the sort of experiments that went on.

09:26:53 24 In Madison, Wisconsin they
09:26:57 25 effectively found that a different kind of agent,

09:26:59 1 certain yeast-type products produced an
09:27:06 2 anti-ricketic agent. That turned out to be what we
09:27:12 3 now regard as vitamin D2, which is a similar
09:27:17 4 molecule, but not identical to the molecule that we
09:27:19 5 call vitamin D3 -- again, you have to give subscript
09:27:24 6 numbers and things -- that were discovered largely
09:27:32 7 through the 1920s.

09:27:34 8 Q. And so vitamin D2, forgive me if I'm
09:27:39 9 mispronouncing this, is an agent called
09:27:43 10 Ergocalciferol; did I get that right?

09:27:47 11 A. Correct.

09:27:47 12 Q. And that is derived from a form of yeast,
09:27:51 13 did you say that?

09:27:52 14 A. Correct.

09:27:55 15 Q. Okay. Vitamin D3 is an agent called
09:28:00 16 cholecalciferol?

09:28:03 17 A. C-H-O-L-E-C-A-L-I-F-E-R-O-L.

09:28:09 18 Q. Cholecalciferol?

09:28:12 19 A. Yes.

09:28:13 20 Q. And that's derived from lanolin --

09:28:20 21 A. Yes.

09:28:20 22 Q. -- which is an oil found in skin or wool?

09:28:26 23 A. That's correct.

09:28:31 24 Q. And then rickets, which we've been talking
09:28:33 25 about -- I'm not a doctor so if you can explain to

09:28:36 1 me what the disease rickets is?

09:28:38 2 A. You'd like me to explain rickets?

09:28:40 3 Q. Yes -- just a concise explanation, not
09:28:43 4 a long one.

09:28:44 5 A. Sure. All right. Before I explain
09:28:48 6 rickets I'll say what vitamin D does. So, vitamin D
09:28:54 7 is a raw material, just like cholesterol is a raw
09:28:59 8 material, to make a hormone. For example,
09:29:02 9 cholesterol is the raw material to make
09:29:05 10 testosterone, estrogen, cortisol, et cetera, okay,
09:29:09 11 so you get the molecule altered.

09:29:12 12 Vitamin D has a structure similar to
09:29:14 13 cholesterol, but it's different, and it is used by
09:29:17 14 the kidney to make a hormone called 1,25-dihydroxy
09:29:24 15 vitamin D, also known as calcitriol.

09:29:30 16 It's a very potent molecule that, in
09:29:34 17 it's classic sense, serves as a signal to turn on
09:29:42 18 the active absorption of calcium from your
09:29:47 19 intestines.

09:29:49 20 Calcium, the stuff that you eat, is
09:29:53 21 not soluble, not very soluble, and for example, you
09:29:57 22 know, the recommended amount of calcium for you and
09:30:01 23 me as adults is around 1,000 milligrams of calcium
09:30:06 24 per day, but you only absorb around 2 to
09:30:14 25 400 milligrams of that and about 200 milligrams gets

09:30:20 1 excreted into your urine, so your body needs around
09:30:23 2 200 milligrams, but what if you only eat
09:30:27 3 400 milligrams of calcium?

09:30:30 4 The calcium, yeah, it gets dissolved
09:30:33 5 to some degree by the hydrochloric acid that's in
09:30:37 6 your stomach, but you have to increase your ability
09:30:42 7 to absorb the calcium, if you are not eating much
09:30:47 8 calcium. And the means by which that happens is
09:30:50 9 with this vitamin D derived hormone. If you don't
09:30:53 10 have enough vitamin D you have a hormone deficiency.

09:30:58 11 So calcium. You need calcium to
09:31:00 12 pull -- sorry, you need vitamin D to pull calcium
09:31:03 13 out of your food.

09:31:05 14 You're -- you are getting on an easy
09:31:13 15 lecture that I am literally doing at a pharmacy
09:31:18 16 tomorrow, so I've got it in my head.

09:31:19 17 Do you mind?

09:31:20 18 Q. No, this is free education, so go ahead.

09:31:22 19 A. Now, about getting back to the way bones
09:31:25 20 grow, long bones grow almost like the cartilage in
09:31:31 21 your ear. Long -- you get a collagen matrix like a
09:31:35 22 net of collagen placed down into the long bones. As
09:31:40 23 your bones grow, that collagen gets laid down and
09:31:45 24 gets longer. Like, a child that's growing, on the
09:31:48 25 long bones it has epiphyseal growth plates. In

09:31:53 1 other words, towards the end of the shaft of each
09:31:55 2 bone, you have a region where the collagen is being
09:31:57 3 laid down, at this end and at this end. That
09:32:01 4 collagen is going to bend and if you don't do -- if
09:32:08 5 you don't have enough calcium your bones will bend,
09:32:11 6 physically bend.

09:32:14 7 If you have sufficient calcium
09:32:17 8 flowing into your circulation, the bones will
09:32:20 9 acquire calcium and phosphate. Phosphorus is not
09:32:25 10 the key nutrient like calcium is. You get a lot of
09:32:29 11 phosphorus in meats and things like that. So
09:32:32 12 calcium phosphate crystals deposit into the collagen
09:32:34 13 matrix that's laid down at the ends of the shafts of
09:32:37 14 your long bones.

09:32:39 15 Now, rickets is a disease that
09:32:42 16 happens when calcium is not deposited into the bones
09:32:46 17 and that soft bone bends and, classically, you
09:32:52 18 recognize people with bowed legs as having rickets,
09:32:55 19 but that said, one of the -- well, the mechanism by
09:33:03 20 which -- you know, I contend that skin color
09:33:05 21 changes, as people migrated northward. Like, skin
09:33:08 22 pigmentation acts as a natural sun screen. In
09:33:12 23 Nigeria they don't sell Coppertone suntan lotion or
09:33:14 24 sun block, but nobody worries about skin cancer
09:33:15 25 because black skin blocks the sun; it's the nature.

09:33:18 1 And the reason you and I have white skin is our
09:33:22 2 ancestors died away if their skin was too black, as
09:33:26 3 they migrated out of Africa.

09:33:28 4 Why would you die as you're migrating
09:33:33 5 out of Africa? Well, too little vitamin D results
09:33:37 6 in softer bones, not just the long bones, but also
09:33:43 7 the pelvis. And I've got, you know, publications
09:33:46 8 where I've written on this, even in anthropology
09:33:49 9 journals.

09:33:50 10 A women's pelvis, if she has grown up
09:33:54 11 with rickets is not shaped properly. And she has
09:33:58 12 what's called cephalopelvic disproportion. In other
09:34:02 13 words, the vaginal opening, the bones don't allow a
09:34:05 14 baby to be born, and women that were vitamin D
09:34:08 15 deficient a thousand years ago died in child birth.

09:34:12 16 So you had a mechanism for natural
09:34:14 17 selecting for lighter skin color because lighter
09:34:19 18 skin color made it possible to have more vitamin D
09:34:22 19 as you migrated northward, more vitamin D because
09:34:25 20 the lighter skin color allowed for production of
09:34:28 21 vitamin D.

09:34:32 22 Yeah, that's rickets.

09:34:34 23 Q. Okay. I did appreciate that explanation.
09:34:37 24 So thank you very much.

09:34:58 25 So let's talk about the potency of

09:35:00 1 vitamin D. It can be toxic; correct?

09:35:03 2 A. Mm-hmm. Yes.

09:35:07 3 Q. What effect would too much vitamin D have

09:35:11 4 on a human?

09:35:20 5 A. Well, I published what I think was a

09:35:24 6 really good and accepted article, I mean around

09:35:28 7 1990, "The mechanisms of vitamin D toxicity".

09:35:34 8 Do you want me to go into detail on

09:35:35 9 it?

09:35:37 10 No. Actually --

09:35:38 11 (Simultaneous speakers - unclear)

09:35:40 12 A. I'll give you a short answer.

09:35:41 13 Q. Yes.

09:35:42 14 A. Too much vitamin D overrides the controls

09:35:46 15 that you have on the vitamin D hormone which is

09:35:47 16 potent.

09:35:49 17 Too much action of the vitamin D

09:35:50 18 hormone at the intestines means you are pulling in

09:35:55 19 too much calcium from your food which you do not

09:35:57 20 want. You become hypercalcemic.

09:36:00 21 Calcium is the most tightly regulated

09:36:03 22 thing in your bloodstream. It's got a coefficient

09:36:06 23 of variation of just 3 per cent. Why? Because it

09:36:08 24 is essential for neuromuscular function. Too low a

09:36:13 25 calcium means you become twitchy; too high a calcium

09:36:17 1 means, you know, your neuromuscular system becomes
09:36:24 2 less excitable.

09:36:25 3 Q. Okay.

09:36:26 4 A. And it can be fatal either way.

09:36:30 5 Q. Now, the traditional cod liver oil means
09:36:37 6 of providing vitamin D to children was through a
09:36:42 7 dose of approximately 1 teaspoon, right?

09:36:48 8 A. That's correct.

09:36:49 9 Q. And by the nature of that composition if
09:36:50 10 you provide a dose of 1 teaspoon of cod liver oil
09:36:55 11 you were not going to give a toxic dose to the
09:36:59 12 infant or child, right?

09:37:01 13 A. That's right.

09:37:02 14 MR. ANDERSON: Object to the form of the
09:37:02 15 question.

09:37:04 16 BY MR. CONRAD::

09:37:04 17 Q. Sorry, what was your answer?

09:37:05 18 A. I agree with you.

09:37:38 19 Q. In paragraph 21 you discuss how, in the
09:37:44 20 1940s and 1950s, tablets were developed to provide
09:37:49 21 vitamin D.

09:37:51 22 Do you see that?

09:37:52 23 A. Through -- which paragraph, please?

09:37:54 24 Q. Paragraph 21.

09:37:55 25 A. 21. Right.

09:38:03 1 Q. And then in the next paragraph you mention
09:38:07 2 that in the 1950s a solution, particularly for
09:38:11 3 children, was a liquid concoction often administered
09:38:14 4 by a teaspoon or an eye dropper; do you see that?

09:38:20 5 A. Yes.

09:38:22 6 Q. What -- what brand name or common name
09:38:28 7 were given to these tablets or this solution that
09:38:32 8 you are referring to?

09:38:34 9 MR. ANDERSON: Object to the form of the
09:38:34 10 question. No foundation.

09:38:37 11 THE WITNESS: I know the one I took. It
09:38:38 12 was called Paradec liquid, at that time, but
09:38:44 13 that's all I know.

09:38:45 14 BY MR. CONRAD::

09:38:46 15 Q. What was the one you took?

09:38:49 16 A. P-A-R-A-D-E-C, when I was little.

09:38:53 17 Q. How old were you when you were taking that
09:38:56 18 supplement?

09:38:57 19 A. Oh, under ten.

09:38:59 20 Q. So you remember this?

09:39:01 21 A. Of course.

09:39:02 22 Q. What form did it come in, a tablet or a
09:39:05 23 solution?

09:39:06 24 A. It was a syrup.

09:39:10 25 Q. And about how large was the dose or

09:39:13 1 serving size?

09:39:15 2 A. It was a teaspoon.

09:39:17 3 Q. And do you remember what the dosage of

09:39:19 4 vitamin D was?

09:39:20 5 A. No.

09:39:49 6 Q. Were you familiar with a product called

09:39:55 7 Vigantol Oil?

09:40:00 8 MR. ANDERSON: Object to the form of the

09:40:01 9 question. Vague. Are you talking about in the

09:40:11 10 1950s or -- you said ...

09:40:14 11 BY MR. CONRAD::

09:40:15 12 Q. Sorry, let me phrase the question

09:40:16 13 differently.

09:40:16 14 You are familiar with a product

09:40:18 15 called Vigantol, correct?

09:40:20 16 A. At this moment, yes.

09:40:21 17 MR. ANDERSON: Object to the form of the

09:40:21 18 question.

09:40:23 19 BY MR. CONRAD::

09:40:24 20 Q. Sorry, could you repeat your answer?

09:40:25 21 A. At this time, yes.

09:40:26 22 Q. And if you can take a quick pause between

09:40:30 23 my question and your answer, that will help us out

09:40:33 24 with a clear transcript because your counsel may

09:40:34 25 object.

09:40:34 1 A. Yes, sure.

09:40:35 2 MR. ANDERSON: Yeah, you need to give
09:40:36 3 me — give everyone time to put in their two
09:40:40 4 cents' worth.

09:40:42 5 BY MR. CONRAD::

09:40:42 6 Q. Thank you.

09:40:44 7 When did you first learn about
09:40:46 8 Vigantol?

09:40:50 9 A. Around the year 2000.

09:40:53 10 Q. And how did you encounter it first?

09:40:56 11 A. How? The circumstance was I was asked to
09:41:02 12 present for Merck at a conference they held in
09:41:14 13 Cairo, Egypt. And there was the sales rep, who said
09:41:20 14 just as an aside, "Oh, we have this product that was
09:41:24 15 in the desert for a year and it stayed stable."

09:41:31 16 And he showed me the product but I
09:41:33 17 never paid attention at that time to what it was.
09:41:41 18 But in retrospect, that product was Vigantol at that
09:41:45 19 time.

09:41:45 20 Q. Why were you presenting to Merck? Why did
09:41:48 21 they invite you to that conference?

09:41:50 22 A. Around 1998 I was trying to get them to
09:42:02 23 introduce a product of tricalcium phosphate powder
09:42:08 24 with vitamin D in it, a product that you could add
09:42:14 25 to food to fortify it with calcium and vitamin D.

09:42:20 1 So I had a product idea I had pitched to them and
09:42:23 2 they I had invited me to Darmstadt and it was just
09:42:27 3 related to tricalcium phosphate.

09:42:29 4 Q. So this -- so you had -- in the 1990s you
09:42:35 5 came up with the idea for a form of powder that
09:42:37 6 could be used to supplement food with vitamin D?

09:42:41 7 A. To -- it was a combination product,
09:42:46 8 tricalcium phosphate powder and vitamin D. I was
09:42:50 9 trying to pitch that to them as a product idea.

09:43:03 10 Q. And I take it they didn't move forward
09:43:06 11 with you on that pitch?

09:43:07 12 A. That's correct.

09:43:08 13 Q. Were you successful in getting any other
09:43:10 14 investors in that idea or purchasers or ...?

09:43:14 15 MR. ANDERSON: Object to the form of the
09:43:14 16 question.

09:43:18 17 THE WITNESS: Answer: No, I was not
09:43:19 18 successful.

09:43:20 19 BY MR. CONRAD::

09:43:23 20 Q. I'm curious why not.

09:43:25 21 A. I'm sorry?

09:43:25 22 Q. Were there any reasons why you were not
09:43:28 23 able to commercialize that idea?

09:43:32 24 A. At that time I learned the way large
09:43:35 25 companies function. The -- my contacts at Merck,

09:43:45 1 they liked me and my ideas but they brought in
09:43:48 2 another guy, the devil's advocate, and he just sort
09:43:52 3 of was a devil's advocate about my idea so it didn't
09:43:57 4 go anywhere.

09:44:03 5 Q. Why did you -- did you select Merck to
09:44:06 6 pitch this idea?

09:44:08 7 A. Okay. Okay, now. The reason Merck was
09:44:17 8 interesting -- this is the German Merck, not the US
09:44:20 9 one -- was that -- I'm trying to remember the
09:44:24 10 year -- well, regardless of the year, Merck had
09:44:29 11 supported research using a product they had called
09:44:33 12 "Ostram" [phon.] tablets which was tricalcium
09:44:39 13 phosphate with vitamin -- no, sorry, Ostram was just
09:44:43 14 a tricalcium phosphate product, and the
09:44:53 15 investigator, Pierre Meunier, had also told me that
09:44:57 16 he had arbitrarily decided to add vitamin D to this
09:45:02 17 clinical trial that Merck was sponsoring with regard
09:45:11 18 to tricalcium phosphate.

09:45:13 19 So Merck in Germany sponsored a study
09:45:17 20 in France to look into the use of tricalcium
09:45:23 21 phosphate -- I think it was a powder at that time --
09:45:25 22 along with 800 units of vitamin D pills, as a
09:45:30 23 prophylactic treatment for people in senior citizens
09:45:36 24 homes in France. And it turned out that that
09:45:38 25 composition of product reduced the prospective,

09:45:43 1 subsequently followed, rate of fractures by about
09:45:49 2 one-third.

09:45:50 3 So that was the classic study that's
09:45:54 4 widely taken as evidence that vitamin D and calcium
09:45:58 5 are useful with regard to osteoporosis, preventing
09:46:06 6 fractures.

09:46:16 7 Q. What were the downsides that this devil's
09:46:22 8 advocate raised to the idea of tricalcium phosphate
09:46:26 9 powder with vitamin D?

09:46:27 10 A. Sorry, at that time I think my brain shut
09:46:31 11 down when he was playing devil's advocate and I did
09:46:34 12 not -- I just accepted whatever it was and I did not
09:46:38 13 make note of why they declined.

09:46:42 14 Q. Okay, but that is how you were introduced
09:46:49 15 to Merck and then ultimately it led to you being
09:46:52 16 invited to a conference in Cairo, right?

09:46:56 17 A. That's correct.

09:46:58 18 Q. And there, that's where Merck introduced
09:47:03 19 to you a product that they said could survive the
09:47:07 20 desert; did I hear you correctly?

09:47:09 21 A. That's correct.

09:47:09 22 Q. And what do you mean by that?

09:47:13 23 A. He just gave me an anecdote. The
09:47:18 24 conference was for sales and marketing reps of Merck
09:47:23 25 Germany that were through the Middle East, like

09:47:31 1 Iran, Pakistan, Egypt obviously, and the anecdote
09:47:37 2 was, hey, you know, talking to your -- because he
09:47:40 3 invited -- the reason I was invited, basically it
09:47:42 4 was almost like a continuing education for sales
09:47:46 5 reps and the topic of the conference was product --
09:47:53 6 product life cycle, product life cycle. That was
09:47:57 7 the name of it and going into it I thought, oh,
09:48:01 8 vitamin D, you need it through your life cycle but I
09:48:04 9 was wrong.

09:48:05 10 It was related to the concept you
09:48:06 11 have product life cycle, it builds up and goes down
09:48:09 12 as sales change over time but I was, like, the
09:48:12 13 continuing education entertainment of it, like, FYI
09:48:16 14 here's vitamin D.

09:48:16 15 And just as an FYI, his statement to
09:48:22 16 me was, oh, you know, we had a shipment of this
09:48:27 17 product and by mistake it was left out in the desert
09:48:31 18 in I think Pakistan and we thought it had broken
09:48:35 19 down and it didn't. That's the extent of it.

09:48:39 20 Q. Were you aware at that time that that
09:48:43 21 product was named Vigantol?

09:48:46 22 A. No.

09:48:46 23 Q. But you were aware at that time that it as
09:48:49 24 a vitamin D product, right?

09:48:51 25 A. Yeah, I knew they had a product that was

09:48:53 1 stable. That was it.

09:49:11 2 Q. After that conference, what was the next
09:49:13 3 time that you encountered Vigantol?

09:49:22 4 A. Well, I can't remember the year but let's
09:49:26 5 see. Can I give you plus-minus a year? It was
09:49:29 6 around 2001. I was at the American Society for Bone
09:49:34 7 and Mineral Research conference, and I was standing
09:49:39 8 in the poster hall -- I don't know whose poster.
09:49:42 9 But beside me was a fellow named Michael Parfitt,
09:49:47 10 who was Director of Osteoporosis in Detroit, and a
09:49:52 11 lady named Ghada El-Hajj Fuleihan, who is a really
09:49:59 12 bright Lebanese, American-trained internal medical
09:50:05 13 specialist. And she said to Michael Parfitt, "You
09:50:08 14 know, I'd like to do a vitamin D study, can you give
09:50:11 15 me some help with that?" And, you know, to my
09:50:16 16 surprise, Michael Parfitt goes to her, "Here, talk
09:50:20 17 to Reinhold," and that's how I connected up with
09:50:28 18 Ghada El-Hajj Fuleihan from Lebanon and the issue
09:50:36 19 was how can we get an appropriately, I guess,
09:50:41 20 internationally-licensed product for a clinical
09:50:44 21 trial. And at that point I said, well, you know
09:50:51 22 because I knew Merck had a product for the Middle
09:50:56 23 Eastern countries, I connected her to the people in
09:51:01 24 Merck in Germany, and that was it.

09:51:07 25 Sorry, what was the rest of it? Your

09:51:08 1 question, have I answered it?

09:51:11 2 Q. Yes. So because you were aware that Merck

09:51:18 3 had this vitamin D product that was stable in the

09:51:21 4 desert in the early 2000s, Dr. Fuleihan --

09:51:27 5 A. Yes.

09:51:28 6 Q. -- when you met her you suggested

09:51:31 7 connecting her with Merck, to use Vigantol in -- or

09:51:37 8 Merck's product in her studies?

09:51:40 9 MR. ANDERSON: Object to the form of the

09:51:40 10 question.

09:51:42 11 THE WITNESS: That's what I said, yes.

09:51:43 12 BY MR. CONRAD::

09:51:45 13 Q. And did you help out with that effort?

09:51:48 14 MR. ANDERSON: Object to the form of the

09:51:48 15 question.

09:51:50 16 THE WITNESS: "That effort" meaning

09:51:53 17 connecting to Germany, no. I gave her the

09:51:57 18 contact and she pursued it from there.

09:52:01 19 BY MR. CONRAD::

09:52:01 20 Q. Were you involved in that study with her?

09:52:05 21 A. The -- I was involved in aspects of it.

09:52:08 22 Yes.

09:52:31 23 Q. I'm handing you what's been marked as

09:52:32 24 Exhibit 1015.

09:52:34 25 (R. VIETH Exhibit 1015 was marked for

09:52:34 1 identification.)

09:52:37 2 MR. ANDERSON: Thank you.

09:52:55 3 BY MR. CONRAD::

09:52:56 4 Q. Exhibit 1015 is a journal article titled

09:53:01 5 "Effect of vitamin D Replacement on Musculoskeletal

09:53:09 6 Parameters in School Children, a Randomized

09:53:12 7 Controlled Trial."

09:53:13 8 This is a study that you participated

09:53:16 9 in with Dr. Fuleihan, isn't it?

09:53:21 10 MR. ANDERSON: Object to the form of the

09:53:21 11 question.

09:53:23 12 THE WITNESS: Of course, yes.

09:53:24 13 BY MR. CONRAD::

09:53:25 14 Q. She's listed as the first named author and

09:53:28 15 your name is in the list of authors as well, right?

09:53:33 16 A. It's an honorable position to be the last

09:53:37 17 author, yes.

09:53:38 18 Q. I believe so. Now, is this the study that

09:53:48 19 you are referring to that you helped out

09:53:50 20 Dr. Fuleihan get connected with Merck?

09:53:55 21 MR. ANDERSON: Object to the form of the

09:53:55 22 question.

09:53:56 23 THE WITNESS: Yes.

09:54:05 24 BY MR. CONRAD::

09:54:06 25 Q. I see on the first page of the article

09:54:08 1 under "Subjects and methods" that it says that
09:54:14 2 children and adolescents were recruited between
09:54:18 3 December 2001 and June 2002.
09:54:24 4 And then it was from the Greater Beirut
09:54:29 5 area in Lebanon; do you recall that?
09:54:33 6 MR. ANDERSON: Object to the form of the
09:54:33 7 question. No foundation.
09:54:39 8 THE WITNESS: I didn't pay attention as to
09:54:41 9 where they were recruited.
09:54:42 10 BY MR. CONRAD::
09:54:42 11 Q. Okay. Down near the bottom of the first
09:54:48 12 page there is a header called "Intervention".
09:54:51 13 It says:
09:54:52 14 "The subjects were randomly assigned in a
09:54:54 15 double-blind manner to receive weekly placebo oil
09:54:59 16 or a vitamin D3 preparation given as low dose
09:55:03 17 vitamin D."
09:55:04 18 Do you see that?
09:55:05 19 THE WITNESS: Yes.
09:55:06 20 BY MR. CONRAD::
09:55:06 21 Q. And you see that after it describes the
09:55:16 22 preparations, it indicates in parentheses on the
09:55:20 23 next page:
09:55:21 24 "Vigantol Oil, Merck KGaA, Darmstadt, Germany."
09:55:29 25 Do you see that?

09:55:30 1 A. Yes.

09:55:36 2 Q. Then below, in the next section, on the
09:55:38 3 second page, it says:

09:55:39 4 "Quality assurance. The samples of oil
09:55:43 5 solution prepared for the three treatment groups
09:55:46 6 were assayed at the clinical pathology laboratory at
09:55:52 7 Mount Sinai Hospital, (Toronto, Canada) by R.V.). "

09:55:56 8 Do you see that?

09:55:56 9 A. Yes.

09:55:58 10 Q. And that's referring to you?

09:55:59 11 A. Correct.

09:56:02 12 Q. It says in the next sentence:

09:56:03 13 "The vitamin D concentration in the three
09:56:06 14 solutions was within 10 per cent of that anticipated
09:56:09 15 based on the label on the bottles and the dilution
09:56:13 16 protocol. "

09:56:13 17 Do you see that?

09:56:14 18 A. Yes.

09:56:16 19 Q. Okay. So your participation in this study
09:56:19 20 involved preparing the solutions that were given to
09:56:23 21 these subjects?

09:56:24 22 A. No.

09:56:25 23 MR. ANDERSON: Object to the form of the
09:56:25 24 question.

09:56:26 25 BY MR. CONRAD::

09:56:27 1 Q. Okay. Then what was your role that's
09:56:29 2 being described here in the study?
09:56:35 3 A. At that -- my role was more than just this
09:56:38 4 part.
09:56:38 5 Q. Okay. Well, then, let me ask you a better
09:56:40 6 question.
09:56:40 7 A. Yeah.
09:56:41 8 Q. So what was your role related to this
09:56:43 9 study?
09:56:44 10 A. My role was with regard to the designing
09:56:47 11 of the trial, the dose, the interpretation. I did
09:57:02 12 not have direct contact with any subject in it.
09:57:05 13 Intellectual.
09:57:08 14 Q. You mean your role was intellectual? I'm
09:57:11 15 sorry, what did you just say?
09:57:13 16 A. Yeah, thinking about it, working on it,
09:57:15 17 yeah.
09:57:23 18 Q. What does it mean when it says the samples
09:57:24 19 of oil solution were assayed by you?
09:57:28 20 MR. ANDERSON: Object to the form of the
09:57:28 21 question.
09:57:32 22 THE WITNESS: I was sent three vials and
09:57:37 23 asked to measure how much vitamin D there was
09:57:42 24 in those vials and I handed it off to somebody
09:57:45 25 else in the lab to measure. I didn't

09:57:47 1 personally deal with it.

09:57:51 2 BY MR. CONRAD::

09:57:52 3 Q. What were these vials?

09:57:54 4 A. Pardon?

09:57:55 5 Q. What were the vials that you were

09:57:56 6 referring to?

09:57:56 7 A. Just amber glass vials.

09:57:59 8 Q. Were these solutions that other members of

09:58:02 9 the study had prepared?

09:58:05 10 MR. ANDERSON: Objection, no foundation.

09:58:08 11 THE WITNESS: I have no knowledge as to

09:58:09 12 who exactly prepared those vials.

09:58:12 13 BY MR. CONRAD::

09:58:15 14 Q. What was the -- it says here there was a

09:58:18 15 label on the bottles. What was the label?

09:58:26 16 A. I'm trying to remember. It was definitely

09:58:28 17 not the product label. It was something along the

09:58:32 18 lines of vial 1, 2, 3.

09:58:42 19 Q. At that point did you know that Vigantol

09:58:44 20 Oil was being used in the study?

09:58:49 21 A. One of them came along with an oil-stained

09:58:53 22 package of the Vigantol, just the -- in a small box

09:58:58 23 that contained the bottle.

09:59:00 24 Q. Mm-hmm. Do you -- what did you do with

09:59:04 25 that package?

09:59:06 1 A. Don't know.

09:59:10 2 Q. And by package, you mean the

09:59:12 3 manufacturer's packaging that Vigantol Oil came in?

09:59:17 4 A. Yes.

09:59:23 5 Q. Do you remember what was on that

09:59:24 6 packaging?

09:59:30 7 A. It was a shockingly minimal description --

09:59:32 8 essentially, the dose, I think.

09:59:37 9 Q. What language was it in?

09:59:39 10 A. I honestly don't remember.

10:00:01 11 Q. What did you know at the time of the

10:00:06 12 compositions in the solutions that you assayed?

10:00:13 13 MR. ANDERSON: Object to the form of the

10:00:13 14 question. Mischaracterizes testimony, no

10:00:18 15 foundation.

10:00:19 16 THE WITNESS: All I knew was it was an oil

10:00:22 17 and it had vitamin D in it.

10:00:24 18 BY MR. CONRAD::

10:00:33 19 Q. Were each of those vials a different

10:00:35 20 concentration of vitamin D?

10:00:37 21 A. Yes.

10:00:39 22 Q. You didn't know what the oil was?

10:00:42 23 A. No.

10:00:56 24 Q. After you analyzed those samples, what

10:01:07 25 else did you do for this study?

10:01:09 1 MR. ANDERSON: Object to the form of the
10:01:09 2 question. Mischaracterizes his testimony.
10:01:17 3 THE WITNESS: Beyond that, I carried on
10:01:20 4 discussion and analysis with the other authors.
10:01:24 5 BY MR. CONRAD::
10:01:34 6 Q. What was the next time that you
10:01:35 7 encountered Vigantol?
10:01:40 8 MR. ANDERSON: Object to the form of the
10:01:40 9 question.
10:01:40 10 THE WITNESS: Vigantol [pron.].
10:01:41 11 BY MR. CONRAD::
10:01:43 12 Q. Vigantol.
10:01:47 13 A. I never encountered it again.
10:01:50 14 Q. You never --
10:01:52 15 A. Honestly. I'm serious.
10:01:55 16 Q. Till when -- you've never since then?
10:02:00 17 A. Firstly, I don't know what you mean by the
10:02:01 18 word "encounter."
10:02:04 19 Q. Sure. Encountered in the broadest sense,
10:02:07 20 meaning that you used it, saw it, received it, since
10:02:14 21 this study --
10:02:15 22 A. Mm-hmm. Okay.
10:02:18 23 Q. -- in Exhibit 1015, when's the next time
10:02:22 24 that you encountered Vigantol?
10:02:24 25 A. I'm smiling because I tried.

10:02:26 1 Q. What do you mean?

10:02:27 2 A. When we were in Germany one time I went

10:02:29 3 into a pharmacy to try and buy it. They refused. I

10:02:33 4 never had a prescription for it.

10:02:35 5 I never, ever had any other Vigantol

10:02:40 6 than that 2001 or whatever, delivery.

10:02:45 7 Q. When -- why were you trying to buy it in

10:02:47 8 Germany?

10:02:49 9 A. It just seemed interesting.

10:02:53 10 Q. And it was available in Germany at the

10:02:55 11 time but it was not -- you were not able to buy it?

10:02:58 12 MR. ANDERSON: Object to the form of the

10:02:58 13 question.

10:03:01 14 BY MR. CONRAD::

10:03:01 15 Q. Because you didn't have a prescription?

10:03:03 16 A. Correct.

10:03:07 17 Q. Did you try any other ways to obtain a

10:03:09 18 sample of Vigantol?

10:03:12 19 A. No.

10:03:13 20 Q. When -- what was the -- excuse me, what

10:03:16 21 timeframe were you -- was the event in Germany that

10:03:22 22 you were talking about at the pharmacy?

10:03:27 23 A. I don't recall.

10:03:28 24 Q. Was it the early 2000s?

10:03:30 25 MR. ANDERSON: Objection, calls for

10:03:32 1 speculation.

10:03:33 2 THE WITNESS: It would have been,

10:03:33 3 probably.

10:04:09 4 BY MR. CONRAD::

10:04:09 5 Q. Okay, let's turn to your declaration,

10:04:12 6 Exhibit 2068, paragraph 29 -- I'm sorry, paragraph

10:04:25 7 27.

10:04:26 8 A. Okay.

10:04:26 9 Q. Here you're describing a syrup-based

10:04:33 10 product called D-Vi-Sol, right?

10:04:37 11 A. That's right.

10:04:38 12 Q. That's a product that has been available

10:04:40 13 in the Americas for a few decades.

10:04:45 14 A. Yes.

10:04:45 15 Q. It's a vitamin D product, right?

10:04:51 16 A. Correct.

10:04:58 17 Q. Was that the most common product,

10:05:01 18 vitamin D supplementation product in the Americas

10:05:06 19 that you were aware of in the early 2000s?

10:05:08 20 MR. ANDERSON: Object to the form of the

10:05:08 21 question.

10:05:10 22 THE WITNESS: I had no idea of what was

10:05:12 23 most common or not.

10:05:13 24 BY MR. CONRAD::

10:05:17 25 Q. You were a -- your practice doesn't

10:05:19 1 involve general pediatric care, right?

10:05:26 2 A. Correct.

10:05:27 3 Q. So it's not -- it wouldn't have been a

10:05:30 4 typical thing for you to be aware of and prescribe

10:05:35 5 vitamin D supplementations for children in a

10:05:39 6 pediatric setting, right?

10:05:44 7 A. D-Vi-Sol is what I used on my own -- or we

10:05:48 8 gave our own children. So we have a lot of

10:05:50 9 experience with that product.

10:05:51 10 Q. So you had experience as a parent, right?

10:05:53 11 A. Yes.

10:05:58 12 Q. In paragraph 29 you talk about -- you say

10:06:02 13 this -- you say:

10:06:03 14 "The problem my wife and I sought to address in

10:06:06 15 the early 2000s was..."

10:06:08 16 And then you pose a question.

10:06:11 17 So, let's talk about -- let's talk about

10:06:14 18 your family.

10:06:18 19 Elaine Vieth, the named co-inventor, is

10:06:21 20 your wife; is that right?

10:06:23 21 A. Yes.

10:06:27 22 Q. And you have several children?

10:06:28 23 A. Yes.

10:06:29 24 Q. When were they born -- approximately?

10:06:36 25 A. Between the years 1980 and 1988.

10:06:51 1 Q. And you provided them, or you and your
10:06:53 2 wife provided them vitamin D supplementation when
10:06:57 3 they were children?
10:06:59 4 A. Yes.
10:06:59 5 Q. And the product was D-Vi-Sol?
10:07:01 6 A. Yes, usually.
10:07:03 7 Q. You said "weekly"?
10:07:06 8 A. I said "usually".
10:07:08 9 Q. Was there another product that you used?
10:07:13 10 A. If -- I don't know exactly whether my wife
10:07:16 11 gave additional multi-vitamins and things but I
10:07:20 12 wouldn't put it past her.
10:07:22 13 Q. What is Ms. Vieth's occupation -- or was
10:07:29 14 at the time?
10:07:32 15 A. Well, in the 1980s, at that time she was
10:07:38 16 a -- at that time she was a part-time nurse.
10:07:43 17 Q. Was she a registered nurse?
10:07:45 18 A. Yes.
10:07:48 19 Q. And what hospital did she work at or
10:07:50 20 hospitals?
10:07:51 21 A. She worked at the local medical clinic.
10:07:57 22 Q. How long did she work as a nurse?
10:08:04 23 A. Number of years? Until -- until around
10:08:16 24 2005, I guess. Like, in other words, from when she
10:08:21 25 graduated, she was full-time for a few years. She

10:08:27 1 was a largely stay-at-home mom with a part-time job,
10:08:30 2 all related to nursing -- oh, yes, and then for a
10:08:34 3 while she was a clinical trial assistant.

10:08:38 4 Q. She was a clinical trial assistant. Where
10:08:41 5 at?

10:08:42 6 A. At a cancer hospital.

10:08:45 7 Q. What was the name of the hospital?

10:08:47 8 A. Princess Margaret Hospital.

10:08:49 9 Q. Is that in Toronto?

10:08:50 10 A. Yes.

10:08:54 11 Q. Okay. What departments did she work in
10:08:56 12 when she was a nurse?

10:08:58 13 MR. ANDERSON: Objection, no foundation.

10:09:03 14 THE WITNESS: When she was a nurse there
10:09:05 15 are a number of departments that went through.
10:09:09 16 She was in, for some years, the Hospital for
10:09:14 17 Sick Children in Toronto. And that was
10:09:17 18 multiple departments. And then worked in a,
10:09:25 19 you know, as a nurse in a medical clinic. Like
10:09:28 20 a department in a medical clinic means the
10:09:31 21 nurse at the end of the hall, give you your
10:09:35 22 allergy shots, they give you your medicines,
10:09:38 23 things like that.

10:09:39 24 BY MR. CONRAD::

10:09:41 25 Q. Why were you and her trying to address the

10:09:46 1 problem about how to reliably deliver vitamin D to
10:09:50 2 an infant?

10:09:52 3 A. The why is, I had kind of a policy that if
10:09:57 4 at all possible, Elaine would come along to
10:10:00 5 conferences. She was interested. And I don't
10:10:05 6 have -- didn't make note of the specific conferences
10:10:10 7 at which the question was posed but it was a very
10:10:12 8 common question and, you know, as you see in my
10:10:16 9 statement in there, people would regularly ask: How
10:10:22 10 do you give vitamin D to a baby? And the answer was
10:10:28 11 either none or give D-Vi-Sol, and a common method,
10:10:41 12 give formula.

10:10:46 13 Q. So put vitamin D supplementation in the
10:10:47 14 formula or the formula itself?

10:10:48 15 A. All infant formulas are fortified with
10:10:55 16 vitamin D. It wasn't cool to breast feed for many
10:10:58 17 years. It's kind of a more contemporary thing, but
10:11:01 18 my wife was always interested in breast feeding, so
10:11:05 19 the issue was -- and at that time, if you were to
10:11:06 20 look, you know, even YouTube videos, you'll see
10:11:07 21 people giving a joke almost, like, here is the
10:11:11 22 D-Vi-Sol, and it would drip down the baby's cheek.

10:11:17 23 So it was a common question and
10:11:22 24 Elaine was always like, "Reinhold, they don't have
10:11:25 25 any answer. "

10:11:32 1 Q. Did you or her provide vitamin D to your
10:11:36 2 children when they were infants?

10:11:38 3 A. Yes.

10:11:40 4 Q. And it was using the D-Vi-Sol method?

10:11:44 5 A. Yes.

10:11:48 6 Q. Were you aware of any other products in
10:11:50 7 the 1980s that were available to you that provided
10:11:55 8 vitamin D in one drop?

10:11:58 9 A. No.

10:12:16 10 Q. Let's go to paragraph 32. You say:

10:12:19 11 "In the early 2000s I was conducting research
10:12:22 12 on the use of high doses of vitamin D for clinical
10:12:25 13 trials of prostate cancer and multiple sclerosis.
10:12:32 14 At that time I became aware of medium-chain
10:12:33 15 triglycerides (MCT), which I obtained as a chemical
10:12:42 16 agent. "

10:12:43 17 Do you see that?

10:12:44 18 A. Yes.

10:12:46 19 Q. Why did you -- what led you to become
10:12:46 20 aware of MCT?

10:12:52 21 A. For the prostate cancer studies that we
10:12:55 22 were working on and for the Multiple Sclerosis
10:13:00 23 study, I was using, what to me, was a conventional
10:13:05 24 manner of preparing doses, that people seemed to
10:13:08 25 like which was preparing in an ethanol solution.

10:13:12 1 But the concentrations to my shock, in a way, was
10:13:18 2 that they tended to break down over time and that's
10:13:25 3 when I started to wonder, is there some way of, you
10:13:27 4 know, giving the dose without breaking down, and at
10:13:33 5 that point I kind of tried to connect with Merck
10:13:36 6 because they had given me that anecdote from some
10:13:39 7 years before.

10:13:41 8 Q. So why did you reach out to Merck?

10:13:43 9 A. Because the guy had told me that they had
10:13:45 10 a product that seemed to be stable.

10:13:49 11 Q. So you were -- you reached out to Merck
10:13:51 12 because you remember the Vigantol product was stable
10:13:57 13 and you were trying to find a solution for how to
10:14:01 14 make a stable solution for this prostate cancer
10:14:04 15 study?

10:14:05 16 MR. ANDERSON: Object to the form of the
10:14:05 17 question.

10:14:07 18 THE WITNESS: I didn't know the name
10:14:08 19 Vigantol actually.

10:14:10 20 I just asked, can you tell me about it?

10:14:13 21 BY MR. CONRAD::

10:14:14 22 Q. Right. Yeah. I think we've got that.

10:14:16 23 So you weren't aware it was called
10:14:18 24 Vigantol Oil but you were looking for a stable
10:14:24 25 solution to use in your clinical trials of prostate

10:14:29 1 cancer and Multiple Sclerosis and you reached out to
10:14:33 2 Merck to find out more about their product to know
10:14:36 3 why it was stable, right?

10:14:39 4 MR. ANDERSON: Object to the form of the
10:14:39 5 question.

10:14:41 6 THE WITNESS: I -- I reached out to them
10:14:46 7 to find out why it was stable?

10:14:49 8 BY MR. CONRAD::

10:14:49 9 Q. Yeah, apologies. I'm not trying to put
10:14:52 10 words in your mouth. I'm trying to understand why
10:14:55 11 you were reaching out to Merck, why them?

10:14:58 12 A. Because of the anecdote that I had been
10:15:01 13 told earlier I was asking: How can I prepare this
10:15:04 14 material in a liquid? He gave me, you know, the
10:15:09 15 usual statement it's vitamin D in a -- I can't
10:15:14 16 remember the technical word he used, the oil of
10:15:17 17 cocos nucifera, something like that.

10:15:23 18 Q. Sorry, could you --

10:15:23 19 A. I'm mashing up the technical word. Cocos
10:15:31 20 nucifera, I guess is some Latin word for palm oil,
10:15:37 21 coconut oil.

10:15:38 22 Q. Ah, okay.

10:15:38 23 A. So that's, you know, what he gave me.
10:15:42 24 What I did, I tried to connect with the Canadian
10:15:50 25 representative, like, Merck in Germany has a kind of

10:15:53 1 Canadian company and even the -- my email contact in
10:16:02 2 Germany tried to connect and the email says to my --
10:16:06 3 to none of my surprise, the Canadian guy never
10:16:10 4 responded, and he never did. So I never got
10:16:13 5 anything from the Canadian version of Merck and so
10:16:20 6 I -- I went after a product from a company called
10:16:24 7 Sasol, S-A-S-O-L.

10:16:29 8 And then, again, I was faced with
10:16:32 9 five options for what they called medium-chain
10:16:39 10 triglycerides and I thought, wait a minute, what
10:16:45 11 would they be using? I didn't know.

10:16:47 12 Q. So let me make sure I got this right.

10:16:50 13 So you wanted to know what made --
10:16:54 14 what you could use for a stable product so you
10:16:56 15 reached out to Merck and he gave you some
10:16:59 16 information, right?

10:17:00 17 A. Yeah.

10:17:00 18 Q. And he told you something about cocos
10:17:02 19 nucifera?

10:17:09 20 A. It was like -- like I'm not giving you --
10:17:11 21 I'm not conversant in the exact word, but it's
10:17:14 22 pretty close to that.

10:17:15 23 Q. Okay. And why -- what did he tell you
10:17:19 24 about that?

10:17:25 25 A. I -- off the top of my head I can't recall

10:17:27 1 the words exactly.

10:17:29 2 Q. Well, what was the information that he
10:17:30 3 gave you?

10:17:34 4 A. Umm... I guess that's the information and
10:17:41 5 then I tried looking up, you know, whatever I
10:17:49 6 implied from this cocos nucifera, which was probably
10:17:54 7 medium-chain triglycerides oil. It wasn't actually
10:17:58 8 that, but like I said, I went to this company called
10:18:01 9 Sasol, which seemed to have a good-quality
10:18:05 10 medium-chain triglyceride and they gave me five
10:18:09 11 options. And I still didn't know because I got
10:18:11 12 really frustrated.

10:18:15 13 Q. Okay, so -- sorry, I'm still trying to
10:18:24 14 piece this together.

10:18:25 15 So you were trying to figure out what
10:18:26 16 made Merck's products stable. You asked them. How
10:18:29 17 did you learn that it was medium-chain
10:18:33 18 triglycerides?

10:18:35 19 A. It was mostly from inference. Like, I
10:18:43 20 went to the Sasol catalog. It had several different
10:18:50 21 options.

10:18:52 22 Q. Mm-hmm.

10:18:53 23 A. And you will find probably there's one
10:18:55 24 email and -- because the German guy was kind of
10:19:01 25 cagey, he didn't tell me, but he wrote down -- and

10:19:05 1 the number is, I think it was 812. 812. Wait a
10:19:10 2 minute. So I went back to the Sasol company page on
10:19:24 3 medium-chain triglycerides and I figured 812 was the
10:19:28 4 version of the oil that would be suitable.

10:19:31 5 Q. Okay.

10:19:32 6 A. It was kind of, like, I think he told me
10:19:34 7 something that was a bit of a trade secret.

10:19:39 8 Q. So the product that you found at Sasol was
10:19:45 9 called Miglyol, right?

10:19:49 10 A. Correct.

10:19:50 11 Q. And there are different forms of Miglyol
10:19:52 12 but Merck led you to Miglyol 812?

10:19:57 13 MR. ANDERSON: Object to the form of the
10:19:57 14 question. Mischaracterizes testimony.

10:20:00 15 THE WITNESS: I was given a hint.

10:20:02 16 BY MR. CONRAD::

10:20:03 17 Q. Okay.

10:20:04 18 A. And the rest I inferred -- because they
10:20:07 19 are not going to tell you their secrets.

10:20:10 20 Q. Okay.

10:20:10 21 A. They were nice because I was trying to
10:20:12 22 make things for clinical trials. It is not like I
10:20:15 23 was trying to copy their product.

10:20:17 24 Q. Okay.

10:20:17 25 A. I wanted stable for my experiments.

10:20:25 1 If you look in my lab notebook that
10:20:30 2 you have, I scanned a PDF, I have -- I put the
10:20:34 3 bottle on a photocopier, the Miglyol, and you will
10:20:38 4 see the exact product that I was using.

10:20:41 5 Q. Okay. So you obtained Miglyol 812, which
10:20:53 6 is a medium-chain triglyceride; is that right?

10:21:02 7 A. A very specific one.

10:21:04 8 Q. And you prepared solutions of vitamin D
10:21:06 9 using Miglyol to use in your study for prostate
10:21:15 10 cancer and MS?

10:21:16 11 A. We evaluated it for that, yes.

10:21:29 12 Q. Your declaration says this was the early
10:21:32 13 2000s; approximately what timeframe was this when
10:21:36 14 you obtained Miglyol --

10:21:39 15 A. Around 2002. I'd have to check my
10:21:43 16 notebook.

10:21:44 17 Q. Did you -- you said you tested it. Did
10:21:46 18 you ultimately use it in the study?

10:21:49 19 A. Umm ...

10:21:51 20 MR. ANDERSON: You mean the study for the
10:21:53 21 prostate --

10:21:54 22 BY MR. CONRAD::

10:21:56 23 Q. The prostate cancer study.

10:21:57 24 A. I'd have to check, but I don't think I did
10:21:58 25 in the end.

10:21:59 1 Q. Do you recall what you used?

10:22:00 2 A. I used the ethanol preparation that we had

10:22:04 3 been working on largely because we used it fast

10:22:10 4 before the stuff broke down and that kind of

10:22:13 5 obviated the stability issue.

10:22:15 6 Q. Why were you looking at stability in the

10:22:16 7 first place for that study?

10:22:19 8 A. For all studies, if it's research you have

10:22:22 9 to prove that you've got the right dose and if the

10:22:24 10 dose breaks down, you are in trouble.

10:22:34 11 Q. Can you turn to your declaration on the

10:22:37 12 bottom right, page number 76.

10:22:54 13 A. Page 76?

10:22:54 14 Q. Page 76.

10:22:54 15 MR. ANDERSON: Page 76?

10:22:54 16 MR. CONRAD: Yes, the numbering is on the

10:22:54 17 bottom right.

10:22:57 18 MR. ANDERSON: So you are -- just to make

10:22:58 19 it easier for him, you are in his -- the

10:22:59 20 exhibit which is his lab notebook?

10:23:02 21 MR. CONRAD: Yes.

10:23:02 22 BY MR. CONRAD:

10:23:02 23 Q. This is the first page of the excerpt of

10:23:04 24 your lab notebook.

10:23:05 25 A. Right. Okay.

10:23:08 1 Q. You see in the top right of that notebook
10:23:09 2 there is a date of **Redacted** ?

10:23:11 3 A. Mm-hmm.

10:23:13 4 MR. ANDERSON: You need to answer audibly,
10:23:14 5 sir.

10:23:15 6 THE WITNESS: Oh, yes.

10:23:16 7 BY MR. CONRAD::

10:23:16 8 Q. Approximately -- or I'm sorry, what --
10:23:19 9 what were you doing that's reflected in this lab
10:23:22 10 notebook on that date?

10:23:28 11 A. You have to give me time to look through
10:23:29 12 this because that is sort of an out-of-context page.

10:23:32 13 Q. Go ahead.

10:23:37 14 A. Oh gee, that's one page.

10:23:56 15 The context is the pages that you are
10:23:57 16 not showing me which are the ones before that.

10:24:01 17 Q. I apologize. This is all we were
10:24:04 18 provided.

10:24:50 19 A. So, just to be clear, you are asking me
10:24:52 20 what was I doing for that **Redacted** date?

10:24:57 21 Q. Yes.

10:25:09 22 A. The context there is you see two people's
10:25:12 23 names down at the bottom.

10:25:13 24 Q. Okay.

10:25:16 25 A. Those were patients whose doctors knew

10:25:24 1 that I was providing those patients with higher

10:25:28 2 doses of vitamin D.

10:25:29 3 Q. I see those names next to -- or near the
10:25:33 4 box that says Redacted

10:25:41 5 A. Yeah.

10:25:41 6 Q. Do you know what that refers to?

10:25:42 7 A. That was a code number that I had for the
10:25:44 8 files.

10:25:47 9

Redacted

10:25:47 10

Redacted

10:25:47 11

Redacted

10:25:47 12

Redacted

10:25:57 13 MR. ANDERSON: And, by the way, I think
10:25:58 14 you should be cautious of using a patient's
10:26:01 15 name.

10:26:03 16 THE WITNESS: Fair enough. He's asking,
10:26:03 17 though.

10:26:04 18 MR. ANDERSON: I understand, but for
10:26:05 19 purposes of, at least in the US, the HIPAA
10:26:09 20 Rules. I don't want you to get you cross ways
10:26:13 21 with any of that.

10:26:13 22 THE WITNESS: All right.

10:26:14 23 MR. ANDERSON: So, just for the record,
10:26:14 24 we'll designate the transcript as
10:26:16 25 "Confidential, Attorneys' Eyes Only." We'll

10:26:20 1 address that later --

10:26:22 2 [REDACTED]

10:26:22 3 MR. ANDERSON: Will you please wait for me

10:26:22 4 to finish.

10:26:22 5 THE WITNESS: Sorry.

10:26:22 6 MR. ANDERSON: Sorry. Thank you.

10:26:22 7 Did you get what I said?

10:26:22 8 COURT REPORTER. Yes.

10:26:22 9 MR. ANDERSON: Thank you.

10:26:26 10 THE WITNESS: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

10:27:07 20 BY MR. CONRAD::

10:27:10 21 Q. [REDACTED]

[REDACTED]

10:27:20 23 A. I can't remember. Most of the time, yes.

10:27:25 24 Q. What other kinds of solutions would there

10:27:27 25 have been at that time that you used?

10:27:31 1 A. None. They had nothing else available.

10:27:35 2 Q. Were these solutions that you prepared?

10:27:40 3 A. Did I prepare them?

10:27:47 4 Well, it -- I can't remember whether

10:27:51 5 it was me or one of the lab people at that point.

10:27:57 6 Q. Okay. Let's turn to the next page in your

10:27:59 7 lab notebook that's in here.

10:28:01 8 MR. ANDERSON: Counsel, before you do

10:28:02 9 that, we've been going about an hour and some.

10:28:04 10 Can we take a short break?

10:28:07 11 MR. CONRAD: Yes, that's fine.

10:28:08 12 --- Recess taken at 10:28 a.m.

10:28:12 13 --- Upon resuming at 10:37

10:37:42 14 BY MR. CONRAD::

10:37:45 15 Q. Dr. Vieth, were we were looking at page 77

10:37:52 16 of Exhibit 2068.

10:38:00 17 This is the second page of the lab

10:38:01 18 notebook excerpt.

10:38:04 19 A. Uh-huh.

10:38:05 20 Q. Do you see at the top right there is a

10:38:07 21 date of Redacted?

10:38:10 22 A. Is that the page?

10:38:11 23 Q. Yes. Yes.

10:38:13 24 I'm looking at it --

10:38:15 25 A. Got it.

10:38:15 1 Q. Okay. There's a date of [Redacted]
[Redacted]; do you see that?

10:38:22 3 A. Yes.

10:38:23 4 Q. And then on the first line on the left
10:38:25 5 there is [Redacted]
[Redacted]

10:38:35 7 Do you see that?

10:38:35 8 A. Yes.

10:38:36 9 Q. Okay. So what's going on on this page?

10:38:45 10 MR. ANDERSON: Object to the form of the
10:38:45 11 question.

10:38:47 12 THE WITNESS: My general protocol for
10:38:51 13 vitamin D, and I've published it in the past,
10:38:53 14 is that an appropriate adult dose for vitamin D
10:38:59 15 is 4,000 units per day. [Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
10:39:38 24 Obviously I, you know, had both the
10:39:42 25 oil-based and the ethanol-based forms of

10:39:47 1 vitamin D kind of going in parallel for a bit.

10:39:52 2 BY MR. CONRAD::

10:39:52 3 Q. So these were various solutions that you
10:39:55 4 were preparing, Redacted

Redacted 5 Redacted?

10:40:02 6 A. That's right.

10:40:03 7 Q. Were these being used for a study?

10:40:10 8 A. I -- Redacted

Redacted 9 Redacted

Redacted 10 Redacted

10:40:45 11 Q. What were you testing in this comparison?

10:40:48 12 What were you looking at?

10:40:49 13 A. I don't remember exactly there, at this
10:40:55 14 time, I don't think.

10:40:57 15 Q. Off to the side on that page, there is a
10:41:01 16 chart that's not exactly the clearest reproduction
10:41:05 17 but underneath it has a couple of different lines.

10:41:15 18 Redacted

Redacted 19 Redacted

Redacted 20 Redacted

Redacted 21 Redacted

Redacted 22 Do you know what this chart is
10:41:30 23 showing?

10:41:32 24 A. So, on the X axis, the horizontal axis of
10:41:36 25 the graph, you see the wave length.

10:41:38 1 Q. Yes.
10:41:39 2 A. On the Y axis, you see the [Redacted].
10:41:40 3 The line that kind of goes up with the first arrow
10:41:50 4 there, is a line that shows you the [Redacted]
[REDACTED] [REDACTED].

10:42:04 6 The other lines are just [Redacted]

10:42:16 8 Q. What properties does [Redacted] indicate
10:42:20 9 for a substance?

10:42:25 10 A. [Redacted]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]

10:42:50 17 Q. Why would you have been looking at that?

10:42:55 18 [Redacted]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

10:43:29 24 Q. I'm sorry. Continue.

10:43:30 25 MR. ANDERSON: Have you finished your

10:45:15 1 microliter is a thousandth of a milliliter. A

10:45:21 2 milliliter is a thousandth of a liter, so ...

10:45:22 3 Q. What device were you measuring here?

10:45:26 4 A. I was using -- I can't remember what it

10:45:28 5 was. It certainly was not a dropper bottle or

10:45:33 6 anything like that. It was just using the kind of

10:45:36 7 droppers that I had available in the lab.

10:45:40 8 Q. And when you say one drop equals [Redacted]

[Redacted] [Redacted]

[Redacted] [Redacted] [Redacted]

[Redacted] [Redacted] [Redacted]

[Redacted] [Redacted] [Redacted]

[Redacted] [Redacted] [Redacted]

[Redacted] [Redacted] [Redacted]

[Redacted] [Redacted] [Redacted]

[Redacted] [Redacted] [Redacted]

[Redacted] [Redacted] [Redacted]

[Redacted] [Redacted] [Redacted]

[Redacted] [Redacted] [Redacted].

10:46:27 20 Q. Why were you trying to measure the volume

10:46:29 21 of a drop of [Redacted]?

10:46:36 22 A. I don't have that clear a recollection of

10:46:37 23 that moment.

10:46:42 24 Q. Beneath that box on that page, there is an

10:46:49 25 arrow pointing down and the next --

10:46:52 1 A. Yes.

10:46:53 2 Q. -- words are "Vigantol 600 IU per drop";

10:47:00 3 do you see that?

10:47:01 4 A. Yes.

10:47:02 5 Q. And then there's some calculations beneath

10:47:04 6 that.

10:47:04 7 What are you doing there?

10:47:11 8 A. I was trying to just sort of do a

10:47:13 9 reference from something that is -- that was a kind

10:47:19 10 of a reference material.

10:47:21 11 Q. What do you mean by that?

10:47:25 12 A. Well, if this, then that. It was kind of

10:47:26 13 a comparison.

10:47:29 14 Q. Right, but what are you doing comparing?

10:47:41 15 A. Okay, so Redacted

Redacted.

10:47:52 17 Q. Mm-hmm.

10:47:53 18 A. Redacted

Redacted

Redacted

Redacted

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10:48:31

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10:49:33

13

MR. ANDERSON: Object to the form of the

10:49:34

14

question. Mischaracterizes his testimony.

10:49:38

15

THE WITNESS: I don't think I discovered

10:49:39

16

anything.

10:49:40

17

I was just sort of comparing. It's not --

10:49:41

18

and those are theoretical numbers because I

10:49:43

19

didn't actually use Redacted there. I kind

10:49:45

20

of took a labeled number. I didn't use it as

10:49:48

21

such.

10:49:48

22

BY MR. CONRAD::

10:49:48

23

Q. Right, I'm not saying you are Redacted

Redacted

Redacted

here. I'm trying to understand what it

10:49:52

25

means.

10:49:52 1 A. Mm-hmm.

10:49:52 2 Q. And that's why I'm trying to ask the

10:49:54 3 question to make sure I understand it. Okay?

10:49:57 4 [Redacted]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

10:50:30 11 MR. ANDERSON: Object to the form of the

10:50:30 12 question. Mischaracterizes testimony.

10:50:33 13 THE WITNESS: I'm not sure how I should

10:50:35 14 answer that. I don't quite understand it.

10:50:37 15 BY MR. CONRAD::

10:50:37 16 Q. Okay. Then maybe you can rephrase it in a

10:50:40 17 way that does make sense for you, and explain to me

10:50:44 18 what your goal was here with all of this.

10:50:51 19 A. Well, [Redacted]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

10:51:21 1 [Redacted]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
10:52:20 6 Q. Can you turn to page number 80 of the
10:52:25 7 exhibit.
10:52:34 8 A. Page 80, okay.
10:52:35 9 Q. At the top of this page there is a date of
10:52:37 10 [Redacted] ?
10:52:38 11 A. Yes.
10:52:39 12 Q. And this is the lab notebook page 97?
10:52:44 13 A. Yes.
10:52:46 14 Q. It starts off at the top referring to
10:52:49 15 Miglyol. What is this page describing?
10:52:58 16 A. Well, the handwriting is not mine. It's
10:53:01 17 one of the lab graduate students, actually.
10:53:05 18 It is preparing some [Redacted]
[REDACTED] [REDACTED].
10:53:15 20 Q. What was the purpose on this day for that?
10:53:17 21 A. The purpose I can't -- the context on that
10:53:26 22 date as to why that was done, I cannot give you the
10:53:30 23 background at this moment.
10:53:52 24 Q. There is a lot of text on this page on the
10:53:53 25 bottom right that's really small. Is that your

10:53:57 1 handwriting?

10:54:01 2 A. The small writing, yes. I think most of

10:54:06 3 it is, yes.

10:54:07 4 Q. Do you know what you were describing here

10:54:09 5 in the bottom right?

10:54:31 6 A. Some of the writing is not readable.

10:54:35 7 To what was -- to the amount --

10:54:40 8 (sotto voce) -- it was a calculation of a

10:54:59 9 preparation of vitamin D. That was all that was.

10:55:03 10 It's nothing else.

10:55:09 11 Q. At the very bottom, there's a line that

10:55:12 12 begins [Redacted] do you see that?

10:55:17 13 A. Yes.

10:55:18 14 Q. What is that describing there?

10:55:21 15 A. [Redacted]

[REDACTED]

[REDACTED]

[REDACTED]

10:55:37 19 A. Like a -- I can't read the number exactly

10:55:39 20 but it was just sort of referencing back to old

10:55:42 21 data.

10:55:43 22 Q. Right. Without knowing what those numbers

10:55:46 23 are, what do you mean by "[Redacted]"? What does

10:55:51 24 that phrase mean?

10:55:53 25 A. Previous result was what we recall when we

10:55:59 1 tested [Redacted], that was

10:56:02 2 the dose.

10:56:04 3 Q. So a [Redacted]

10:56:04 4 [Redacted]?

10:56:15 5 MR. ANDERSON: Object to the form of the

10:56:17 6 question. Mischaracterizes his testimony.

10:56:20 7 BY MR. CONRAD::

10:56:21 8 Q. Is that right?

10:56:21 9 A. Of course.

10:56:22 10 Q. And what was he testing?

10:56:26 11 A. The material tested were the three samples

10:56:30 12 that had been sent [Redacted]

10:56:32 13 Q. Okay. So that's the individual who

10:56:35 14 assayed the samples?

10:56:37 15 A. Yeah, it's just remembering from the past,

10:56:40 16 yes.

10:56:51 17 Q. Why was this noted down here?

10:56:53 18 A. Why?

10:56:54 19 Q. Yes. Why did it matter to what you were

10:56:57 20 doing on this day, on [Redacted]?

10:57:08 21 A. I don't know my thinking at that time.

10:57:27 22 Q. On the next page, around the middle,

10:57:29 23 there's a line and a dated section that says [Redacted]

10:57:29 24 [Redacted]. Do you see that?

10:57:38 25 A. Yes.

10:57:39 1 Q. And it starts off Redacted
[REDACTED] Do you see that?
10:57:47 3 A. Yes.
10:57:48 4 Q. What is this section describing?
10:57:51 5 A. I was trying to Redacted
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
10:58:25 10 A. That's correct.
10:58:26 11 Q. Can you turn to the next page.
10:58:31 12 This is a date of Redacted.
10:58:38 13 What's being described on this page?
10:58:41 14 A. Redacted
[REDACTED] –
10:58:47 16 (sotto voce)
10:58:50 17 MR. ANDERSON: You need to read to
10:58:50 18 yourself. Anything you say out loud, she's
10:58:50 19 taking it down.
10:58:50 20 THE WITNESS: You asked what it said.
10:58:50 21 MR. ANDERSON: Well, if that's your
10:58:51 22 answer, then say it loud enough so everyone can
10:58:54 23 hear it. You are kind of mumbling, sir.
10:58:57 24 THE WITNESS: Oh.
10:59:19 25 You have there some technical notes with

10:59:22 1 regard to preparing samples that would be run
10:59:24 2 on an analyzer.
10:59:27 3 BY MR. CONRAD::
10:59:30 4 Q. To analyze what?
10:59:34 5 A. Redacted.
10:59:37 6 Q. And what were the samples being analyzed?
10:59:46 7 A. I can only infer some of it. I had a
10:59:58 8 reference sample from Redacted
Redacted.
11:00:06 10 Redacted
Redacted
Redacted
Redacted
Redacted
Redacted.
11:00:28 15 Redacted
Redacted
Redacted
11:00:35 18 And then below that, I guess two days
11:00:38 19 later, I also did a health food store purchased
11:00:44 20 product called Redacted
Redacted that I was measuring things in. So
11:00:50 22 that's that. Preparation notes.
11:01:23 23 Q. Redacted
Redacted?
11:01:29 25 A. It was Redacted

11:01:38 1 Q. Redacted
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
11:01:59 6 MR. ANDERSON: Object to the form of the
11:01:59 7 question.
11:02:00 8 THE WITNESS: I can't remember the volume
11:02:01 9 of dose that Redacted was instructing to
11:02:05 10 take.
11:02:06 11 BY MR. CONRAD::
11:02:15 12 Q. But that was one of the products that you
11:02:17 13 were comparing with the other samples, here in your
11:02:20 14 analysis, right?
11:02:21 15 A. Correct.
11:02:22 16 Q. Why did you include that product?
11:02:31 17 A. It was an alternative liquid product that
11:02:40 18 contained a relatively high concentration of
11:02:43 19 vitamin D.
11:02:43 20 Q. What was the goal of this analysis? What
11:02:46 21 were you trying to determine?
11:02:50 22 A. I did not write this into my notebook
11:02:54 23 here.
11:02:56 24 Q. You don't recall?
11:02:57 25 A. It's 18 years ago, or whatever.

11:03:12 1 Q. Let's turn to the next page which has a
11:03:14 2 date of [Redacted] ?
11:03:21 3 A. Page 83?
11:03:24 4 Q. Yes. It's describing some study samples.
11:03:31 5 Do you know what this is referring
11:03:32 6 to?
11:03:40 7 A. They were samples, A, et cetera, A, B, C,
11:03:47 8 et cetera, were test samples before and after
11:03:57 9 sucking vitamin D solution from pacifier.
11:04:03 10 Q. Okay.
11:04:03 11 A. It doesn't say that but that's ...
11:04:07 12 Q. And that's one of the studies that you
11:04:10 13 referred to ultimately in your patent application?
11:04:13 14 A. That's correct.
11:04:15 15 Q. So by this date, [Redacted], you
11:04:21 16 and your wife had already posed the question of how
11:04:24 17 do you solve this problem and here you are
11:04:27 18 conducting some studies directed at that problem?
11:04:32 19 A. Yes.
11:04:36 20 Q. When -- when did you begin working on the
11:04:45 21 problem that you describe that ultimately led to
11:04:47 22 your patent application?
11:04:51 23 A. I'd have to go to my notebook carefully to
11:04:54 24 go through it and see that history.
11:04:57 25 Q. So we've looked at some of the pages in

11:04:58 1 your notebook leading up to this date in Redacted

11:04:58 2 [REDACTED].

11:05:03 3 Was there any point in time during

11:05:05 4 there that you were working on the problem that you

11:05:12 5 ultimately filed a patent application for?

11:05:18 6 I guess, let me ask you a different

11:05:20 7 question. That is kind of a weird question: Were

11:05:23 8 any of the pages of the lab notebook that we have

11:05:26 9 looked at so far directed to you trying to solve the

11:05:29 10 problem that you and your wife were facing about

11:05:32 11 delivering vitamin D to an infant?

11:05:37 12 MR. ANDERSON: Object to the form of the

11:05:37 13 question.

11:05:43 14 THE WITNESS: I would have to say yes,

11:05:45 15 some work, yes.

11:05:47 16 BY MR. CONRAD::

11:05:49 17 Q. Which of what we've seen so far was

11:05:51 18 related to that problem?

11:05:56 19 A. Do you want me to try and walk through the

11:05:59 20 notebook?

11:06:00 21 Q. Sure. Yes.

11:06:35 22 A. Around Redacted.

11:06:37 23 Q. Mm-hmm.

11:06:38 24 A. Your page 78.

11:06:41 25 Just working with Redacted.

11:06:45 1 Q. Mm-hmm.

11:06:49 2 A. At that time, you know, I didn't have any

11:06:51 3 particularly -- particular interest. Recognize that

11:06:55 4 Redacted

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] And at that point I started

11:07:31 12 thinking about it and talking to my wife about it.

11:07:34 13 Those are not in the notebook, but

11:07:38 14 it's physically working with this material and

11:07:42 15 realizing that it's not the conventional type of

11:07:48 16 material.

11:07:48 17 Q. Redacted

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

11:08:23 1 [Redacted]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED].
11:08:38 5 Q. So did you actually -- did you actually
11:08:45 6 try it out, test it out on yourself?
11:08:51 7 MR. ANDERSON: Object to the form of the
11:08:51 8 question.
11:08:52 9 THE WITNESS: Not in January.
11:08:53 10 BY MR. CONRAD::
11:08:53 11 Q. Okay.
11:08:54 12 A. [Redacted]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
11:09:37 22 Q. What did you -- you and her talk about at
11:09:40 23 this time?
11:09:52 24 A. "What if?"
11:09:54 25 Q. What if what?

11:12:03

1

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11:12:22

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11:13:32

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Q. Redacted

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11:13:44

24

MR. ANDERSON: Object to the form of the

11:13:44

25

question.

11:13:50 1 THE WITNESS: What was it?

11:13:51 2 BY MR. CONRAD::

11:13:51 3 Q. Yeah, what led you in the direction to
11:13:53 4 take that step?

11:13:54 5 A. It was part of a what if. There is no per
11:14:00 6 se something led me to it. You just, you know, come
11:14:06 7 up with a question.

11:14:07 8 It is not that you've got some raw
11:14:10 9 clue. You just ask yourself and then see whether it
11:14:15 10 works.

11:14:16 11 Like, my job is to do research in
11:14:20 12 which you pose questions and often as not the
11:14:26 13 question is a piece of garbage, you know, even
11:14:30 14 extracting the vitamin D off of the pacifier,
11:14:33 15 whether Redacted

11:14:40 18 And why? Because you think of it.

11:14:46 19 Q. So you thought of the idea of putting one
11:14:50 20 drop on a surface and then you figured you would try
11:14:53 21 it and see if it worked?

11:14:55 22 MR. ANDERSON: Object to the form of the
11:14:55 23 question. Mischaracterizes his testimony.

11:14:59 24 THE WITNESS: You are kind of telling me
11:15:01 25 something. I'm not sure what I'm supposed to

11:15:03 1 answer here.

11:15:03 2 BY MR. CONRAD::

11:15:04 3 Q. I'm trying to figure out what that step
11:15:05 4 is. And I think, if I got it right, correct me if
11:15:08 5 I'm wrong, you saw there was something different
11:15:11 6 about Miglyol. You got an idea that you should try
11:15:19 7 to see if, when you put it on a surface, that it can
11:15:25 8 be removed effectively.

11:15:32 9 A. I got the impression that Miglyol oil
11:15:37 10 could come off of a surface more easily than other
11:15:41 11 oils.

11:15:44 12 Q. What -- what gave you that impression?

11:15:48 13 A. By working with it, actually having it in
11:15:53 14 my hands, on my hands, noting it was different.

11:16:01 15 There is nothing in books that says
11:16:04 16 it is.

11:16:08 17 Q. What other approaches besides putting it
11:16:11 18 on the surface did you try?

11:16:18 19 A. I -- can you suggest other ones I might
11:16:20 20 have tried?

11:16:21 21 Q. I don't know. I'm just --

11:16:23 22 A. I don't either. I -- in the back of our
11:16:28 23 minds was a problem and, you know, as you are going
11:16:34 24 through life you look at the information that you
11:16:37 25 acquire either from reading or observing and I would

11:16:41 1 argue in this case it is more observing, an unusual
11:16:47 2 behavior of a liquid and you come up with ideas and
11:16:53 3 one of the ideas was "Maybe this would work." The
11:17:00 4 "this" being that you could suck this off reasonably
11:17:03 5 well.

11:17:03 6 And the thing that's easily
11:17:06 7 overlooked is the legal requirement that if you have
11:17:10 8 a product, you have to have that product do what you
11:17:14 9 say it does.

11:17:15 10 In other words, it's not sufficient
11:17:16 11 to pull half of it off. It has to be absolute.

11:17:22 12 Q. Mm-hmm.

11:17:23 13 A. So just sticking it in your mouth and
11:17:25 14 pulling it out is not good enough. I know -- you
11:17:27 15 know, like, we tested it. You know, I am
11:17:30 16 fundamentally skeptical about new ideas but I try
11:17:35 17 new ideas out.

11:17:39 18 Q. So once you get this idea then you spend
11:17:46 19 most of this time conducting these tests and these
11:17:51 20 analyses to confirm that it does, in fact, work the
11:17:55 21 way you had hoped?

11:17:59 22 A. I evaluated or I -- I did experiments to
11:18:02 23 confirm likely gaps in the -- or -- experiments were
11:18:09 24 done to address questions that I had about the
11:18:13 25 viability of the idea.

11:18:19 1 Q. And the viability meaning is the -- is
11:18:23 2 enough of the dose going to be removed when it's
11:18:26 3 sucked off?

11:18:28 4 MR. ANDERSON: Object to the form of the
11:18:28 5 question.

11:18:30 6 THE WITNESS: Well, firstly, does it stick
11:18:33 7 to something. Secondly, can you quantitatively
11:18:38 8 pull it off and how would you do that?

11:18:43 9 BY MR. CONRAD::

11:18:44 10 Q. So you devised some experiments to figure
11:18:46 11 out how to quantitatively test how this method
11:18:49 12 worked?

11:18:50 13 A. Yes.

11:19:02 14 Q. What gave you the idea of a pacifier?

11:19:08 15 A. Umm ...

11:19:09 16 Q. Was it your idea or was it your wife's
11:19:11 17 idea?

11:19:13 18 A. I didn't want to suck nipples on babies
11:19:19 19 and a pacifier is a reasonable parental alternative
11:19:24 20 for people to give to a baby, a common one.

11:19:31 21 Q. So why were nipples in the question?

11:19:35 22 A. Because that's how a baby is breast
11:19:37 23 feeding.

11:19:38 24 Q. So was the original idea to put a drop on
11:19:41 25 a nipple?

11:19:44 1 A. Yes, that's my wife's version of it, yes.

11:19:46 2 Q. So that was her idea?

11:19:49 3 A. Yes.

11:19:50 4 Q. Where did she come up with that idea?

11:19:55 5 MR. ANDERSON: Objection, no foundation.

11:19:56 6 THE WITNESS: Where did -- that was her
11:19:58 7 idea.

11:19:58 8 BY MR. CONRAD::

11:20:00 9 Q. Do you know what led her to that idea?

11:20:02 10 A. Her mind.

11:20:04 11 Q. Well, I mean, I know that we've talked
11:20:06 12 about some ideas -- some ways in which you came to
11:20:13 13 using Miglyol oil, medium-chain triglycerides for
11:20:18 14 example?

11:20:19 15 A. Mm-hmm.

11:20:19 16 Q. Did you ever talk with her where her idea
11:20:22 17 came from, what led her to that?

11:20:24 18 A. No.

11:20:29 19 Q. So that using a pacifier was an
11:20:33 20 alternative to putting a drop on a nipple and you
11:20:39 21 tested the pacifier?

11:20:41 22 A. That's correct.

11:20:42 23 Q. What made you think of a pacifier as an
11:20:44 24 alternative?

11:20:46 25 MR. ANDERSON: Asked and answered.

11:20:48 1 You can go ahead, again.

11:20:50 2 THE WITNESS: Because it is. It's a -- an
11:20:56 3 alternative to a pacifier is a baby bottle
11:20:59 4 nipple.

11:20:59 5 Like, it's just the way babies eat by
11:21:03 6 sucking things, pacifiers, nipples, baby
11:21:08 7 bottles; it is all part of the equation.

11:21:10 8 BY MR. CONRAD::

11:21:23 9 Q. Part of the testing that you did was to
11:21:27 10 confirm how long it would take to suck on the
11:21:33 11 surface in order to remove enough of the vitamin D
11:21:36 12 composition?

11:21:37 13 A. That's right.

11:21:40 14 Q. And so until doing those tests you didn't
11:21:45 15 know if the method was effective?

11:21:51 16 MR. ANDERSON: Object to the form of the
11:21:51 17 question.

11:21:53 18 THE WITNESS: That's right, I didn't. I
11:21:56 19 was skeptical, and you have to try it.

11:22:01 20 BY MR. CONRAD:

11:22:01 21 Q. And so you conducted tests to determine
11:22:13 22 whether, in fact, it was effective?

11:22:14 23 A. We conducted tests to confirm that after
11:22:17 24 sucking over the object for at least 30 seconds, you
11:22:21 25 would pull off at least 90 per cent of the material

11:22:25 1 that you applied to it.

11:22:32 2 If you only pulled off 75 per cent,
11:22:35 3 problem.

11:22:51 4 Q. In your declaration you criticize the idea
11:22:54 5 of putting a drop on the tip of a spoon and
11:22:59 6 providing that to an infant. Have you ever tested
11:23:04 7 using a spoon and whether or not that method is
11:23:06 8 effective?

11:23:08 9 A. Can you show me the paragraph you are
11:23:09 10 referring to? What number?

11:24:04 11 Q. Paragraph 46.

11:24:15 12 A. Okay. What's the question?

11:24:23 13 Q. In paragraph 46 you are criticizing the
11:24:25 14 idea of using a spoon as the surface to put the drop
11:24:28 15 on. Did you -- have you ever tested putting one
11:24:33 16 drop of the composition on a spoon and then giving
11:24:37 17 that to an infant?

11:24:40 18 MR. ANDERSON: Object to the form of the
11:24:43 19 question.

11:24:45 20 THE WITNESS: No, we never tested that.

11:24:47 21 BY MR. CONRAD::

11:25:11 22 Q. At what point did you think that maybe you
11:25:13 23 should file a patent application?

11:25:30 24 MR. ANDERSON: I assume you mean date?

11:25:32 25 MR. CONRAD: Yes.

11:25:32 1 BY MR. CONRAD::

11:25:33 2 Q. Well, approximately.

11:26:10 3 A. Do you want to know the month?

11:26:12 4 Q. Yes, approximately.

11:26:19 5 A. Late 2006.

11:26:23 6 Q. What happened then that gave you the idea
11:26:25 7 of filing a patent application?

11:26:30 8 MR. ANDERSON: Object to the form of the
11:26:30 9 question.

11:26:42 10 THE WITNESS: By late 2006 I didn't see
11:26:48 11 any gaps in the idea. In other words, my
11:26:54 12 skepticism about the concept was overcome.

11:27:02 13 In other words, you know, I could come up
11:27:05 14 with a liquid product where a single drop would
11:27:15 15 go onto a surface and stay there long enough to
11:27:18 16 put it into a person's mouth and to pull it off
11:27:24 17 with reasonable efficiency and then finally to
11:27:28 18 demonstrate that actually your blood level went
11:27:31 19 up as a result.

11:27:33 20 There are a lot of different pieces in
11:27:34 21 there.

11:27:35 22 The pieces came together and then what I
11:27:40 23 also do, you know, one reason I've been pretty
11:27:42 24 successful with research is, you know, I cover
11:27:44 25 my bases by making sure that this is reasonably

11:27:50 1 original and I know from having previous
11:27:52 2 contacts with companies, that if this just sits
11:27:58 3 in the water in a lab notebook it's not going
11:28:01 4 to go anywhere.

11:28:02 5 You need some proprietary protection to
11:28:05 6 justify development of a product into a real
11:28:10 7 commercial product and to get people to buy it.
11:28:13 8 Like, by itself it sits there. Dead,
11:28:15 9 unvalidated, uninteresting.

11:28:22 10 BY MR. CONRAD::

11:28:22 11 Q. So by late 2006 you had the idea of
11:28:24 12 commercializing this and you decided you would need
11:28:28 13 patent protection to move forward?

11:28:31 14 A. That's right.

11:28:52 15 Q. I'm handing you Exhibit 1017, which is the
11:29:02 16 Canadian Patent Application number 2,558,202 that
11:29:07 17 led to the challenged patent here.

11:29:13 18 Were you involved in preparing this
11:29:16 19 application?

11:28:54 20 (R. VIETH Exhibit 1017 was marked for
11:28:54 21 identification.)

11:29:16 22 MR. ANDERSON: Object to the form of the
11:29:16 23 question.

11:29:20 24 THE WITNESS: Was I involved in preparing
11:29:21 25 it? Yes.

11:29:33 1 BY MR. CONRAD::

11:29:33 2 Q. Had you conducted any search prior to
11:29:37 3 filing this patent application as to what other
11:29:41 4 products or methods for delivering vitamin D might
11:29:44 5 have been out there?

11:29:45 6 MR. ANDERSON: Object to the form of the
11:29:45 7 question.

11:29:49 8 THE WITNESS: Like I said, I did. Yes.

11:29:51 9 BY MR. CONRAD::

11:29:53 10 Q. Let's turn to page -- well, the
11:30:05 11 bottom-most number, page 5 of the exhibit.

11:30:23 12 You see around line 8, it says:

11:30:26 13 "Existing products, approved in Canada and the
11:30:28 14 United States for the purpose of infant vitamin D
11:30:31 15 nutrition, require the use of one-half to one mL of
11:30:35 16 a detergent-solubilized aqueous liquid emulsion."

11:30:39 17 Do you see that?

11:30:41 18 A. Yes.

11:30:42 19 Q. That's referring to D-Vi-Sol, that you
11:30:47 20 were familiar with, right?

11:30:48 21 A. Yes.

11:30:48 22 Q. You see:

11:30:54 23 "The liquid is either given directly into the
11:30:56 24 mouth, or mixed into milk or to other food consumed
11:30:59 25 by the infant."

11:31:08 1 Where did you get that from, the
11:31:10 2 instructions for D-Vi-Sol?
11:31:13 3 A. I referenced it with the website.
11:31:14 4 Q. And then at line 15 there is a reference
11:31:17 5 to:
11:31:17 6 "... Vigantol dosing instruction for rickets,
11:31:23 7 as translated from the German ..."
11:31:25 8 And then a web page. Do you see that?
11:31:28 9 A. Yes.
11:31:31 10 Q. Was that something that you had
11:31:32 11 discovered?
11:31:35 12 MR. ANDERSON: Object to the form of the
11:31:35 13 question.
11:31:38 14 THE WITNESS: Yes.
11:31:39 15 BY MR. CONRAD::
11:31:40 16 Q. So you had researched dosing instructions
11:31:43 17 for Vigantol on the internet?
11:31:47 18 A. Yes.
11:31:48 19 Q. And one of the instructions you found was
11:31:50 20 this web page here that says it was accessed on
11:31:54 21 August 30th, 2006; correct?
11:31:57 22 A. Yes.
11:31:58 23 Q. And did you use the -- it says it's
11:32:03 24 translated. How did you translate that page?
11:32:10 25 A. I don't recall.

11:32:10 1 Q. Is it possible you used the translation
11:32:14 2 tool that the web browser offered?
11:32:17 3 MR. ANDERSON: Object to the form of the
11:32:17 4 question, calls for speculation.
11:32:20 5 THE WITNESS: It's likely, yes.
11:32:21 6 BY MR. CONRAD::
11:32:21 7 Q. Do you speak any German?
11:32:25 8 A. I was born in Germany and, yes, to some
11:32:28 9 degree.
11:32:30 10 Q. You spoke it when you were -- did you
11:32:33 11 speak it with your parents at all?
11:32:35 12 A. Household German, yes.
11:32:37 13 Q. Can you read German?
11:32:40 14 A. No.
11:33:01 15 Q. Can you turn to the page with the
11:33:04 16 number -- excuse me -- page number 6 of the exhibit,
11:33:08 17 bottom number.
11:33:19 18 You see page number -- I'm sorry,
11:33:22 19 line number 8 says:
11:33:24 20 "One prescription product contains vitamin D in
11:33:28 21 an unspecified oil (20,000 IU (500mcg) per mL of
11:33:38 22 oil)."
11:33:38 23 Do you see that?
11:33:39 24 A. Yes.
11:33:40 25 Q. And that's referring to Vigantol, right?

11:33:42 1 A. Apparently, yes.

11:33:43 2 Q. And other than the web page cited there,
11:33:50 3 what else did you look at to identify what the
11:33:55 4 Vigantol dosing instructions would be?

11:33:58 5 MR. ANDERSON: Objection, assumes facts
11:33:59 6 not in evidence.

11:34:03 7 THE WITNESS: What other -- I'm trying to
11:34:05 8 figure out your question. Do you mean, have I
11:34:08 9 done things beyond what's written there?

11:34:10 10 BY MR. CONRAD::

11:34:11 11 Q. Yes, yes. So it looks like you tried to
11:34:13 12 research what Vigantol dosing instructions were.
11:34:19 13 You encountered at least the web page that's cited
11:34:23 14 here in this Canadian patent application.

11:34:27 15 What else did you find about the
11:34:30 16 Vigantol dosing instructions?

11:34:34 17 MR. ANDERSON: Objection, assumes facts
11:34:37 18 not in evidence.

11:34:39 19 THE WITNESS: I'm not aware of anything
11:34:40 20 else at this moment.

11:34:44 21 BY MR. CONRAD::

11:34:44 22 Q. And what is that website listed there?
11:34:47 23 What did you find?

11:34:49 24 MR. ANDERSON: Object to the form of the
11:34:49 25 question.

11:34:53 1 THE WITNESS: My findings were essentially
11:34:55 2 paraphrased in the paragraph you're looking at.
11:35:03 3 BY MR. CONRAD::
11:35:03 4 Q. Was that an official product page for
11:35:09 5 Vigantol?
11:35:10 6 MR. ANDERSON: Objection, no foundation.
11:35:12 7 Calls for speculation. Also the form of the
11:35:17 8 question.
11:35:18 9 THE WITNESS: So should I answer it?
11:35:20 10 MR. ANDERSON: If you understand the
11:35:21 11 question and you can do so --
11:35:23 12 THE WITNESS: Was it an official web page?
11:35:26 13 I doubt it.
11:35:26 14 BY MR. CONRAD::
11:35:34 15 Q. So you doubt it was an official
11:35:36 16 Merck-authorized page, right?
11:35:38 17 A. That's correct.
11:35:39 18 MR. ANDERSON: Same objections.
11:35:40 19 THE WITNESS: Sorry.
11:35:45 20 BY MR. CONRAD::
11:35:45 21 Q. But you did see from that page that the --
11:35:50 22 strike that.
11:36:16 23 Can you turn to page 8 of the
11:36:19 24 exhibit, starting at line 28. You see there
11:36:47 25 there's:

11:36:48 1 "Medium-chain triglycerides are obtained from
11:36:52 2 the oil extracted from the hard, dried fraction of
11:36:55 3 the endosperm of Cocos nucifera L. or from the dried
11:37:01 4 endosperm of Elaeis guineensis Jacq ..."
11:37:14 5 What does that mean in more plain
11:37:17 6 English?
11:37:21 7 MR. ANDERSON: Object to the form of the
11:37:21 8 question.
11:37:23 9 THE WITNESS: I'm supposed to interpret
11:37:24 10 that?
11:37:25 11 BY MR. CONRAD::
11:37:25 12 Q. If you can. Is this something that you
11:37:27 13 wrote?
11:37:29 14 A. I took it as kind of a definition. For
11:37:36 15 example, that evidently means coconut oil. And I
11:37:41 16 don't know the other species of plant there.
11:37:44 17 Q. Okay. So is this a definition that you
11:37:48 18 took from somewhere?
11:37:52 19 A. Yes.
11:38:04 20 Q. Let's go to page 14 of the exhibit where
11:38:12 21 the claims begin. You see the first claim is for a
11:38:27 22 composition. Do you see that?
11:38:31 23 A. Yes.
11:38:32 24 Q. And then if you go down to claim number
11:38:39 25 11, it says:

11:38:40 1 "... use of a composition as claimed in any one
11:38:43 2 of claims 1 to 11. "

11:38:46 3 Do you see that?

11:38:47 4 A. Yes, I see it.

11:38:48 5 Q. Okay. So here there are attempts to claim
11:38:51 6 both a composition and a method of use, right?

11:38:57 7 MR. ANDERSON: Object to the form of the
11:38:57 8 question to the extent it calls for a legal
11:39:00 9 conclusion.

11:39:07 10 THE WITNESS: It says "use of a
11:39:09 11 composition," that's correct.

11:39:11 12 BY MR. CONRAD::

11:39:12 13 Q. And there is also an attempt to claim the
11:39:14 14 composition itself in claim 1, right?

11:39:17 15 MR. ANDERSON: Same objection.

11:39:22 16 THE WITNESS: Correct.

11:39:33 17 BY MR. CONRAD::

11:39:34 18 Q. I'm handing you what's been marked as
11:39:35 19 Exhibit 1001, which is the '958 Patent.

11:39:37 20 (R. VIETH Exhibit 1001 was marked for
11:39:37 21 identification.)

11:39:53 22 BY MR. CONRAD:

11:39:53 23 Q. If you can turn to the last page, where
11:39:59 24 the claims begin, do you see that claim 1 and all
11:40:05 25 the other claims are a method of delivering a

11:40:11 1 composition -- or sorry, a method of delivering a
11:40:16 2 nutritional or therapeutic amount of vitamin D, but
11:40:20 3 there is no claim that simply claims a composition
11:40:23 4 itself; right?

11:40:26 5 MR. ANDERSON: Object to the form of the
11:40:26 6 question.

11:40:28 7 THE WITNESS: Right.

11:40:28 8 BY MR. CONRAD::

11:40:32 9 Q. Why -- why in the US application did you
11:40:35 10 not try to claim the composition?

11:40:39 11 MR. ANDERSON: I'm going to object and
11:40:40 12 instruct the witness not to answer to the
11:40:42 13 extent the answer would call for the disclosure
11:40:44 14 of an attorney-client communication between
11:40:47 15 Dr. Vieth and his patent attorney.

11:40:48 16 If you can answer the question without
11:40:50 17 disclosing any of your conversations with your
11:40:53 18 patent attorney regarding what was to be
11:40:56 19 claimed or not claimed, you may answer.

11:41:02 20 THE WITNESS: I don't think I can answer
11:41:02 21 that.

11:41:03 22 BY MR. CONRAD::

11:41:06 23 Q. Because of a discussion with your
11:41:07 24 attorney?

11:41:09 25 A. It's discussions that were almost 20 years

11:41:11 1 ago and I don't have a clear recollection of that.

11:41:16 2 Q. Okay.

11:41:29 3 In Exhibit 1001, if you can turn to
11:41:33 4 column --

11:41:36 5 THE WITNESS: Maybe -- could I have a
11:41:37 6 washroom break or something?

11:41:39 7 MR. CONRAD: Yes, let's take a break.

11:41:42 8 --- Recess taken at 11:41 a.m.

11:41:42 9 --- Upon resuming at 11:47 a.m.

11:41:42 10 BY MR. CONRAD::

11:47:26 11 Q. So we were looking at Exhibit 1001 which
11:47:29 12 is the '958 Patent. If you can turn to column 3,
11:47:34 13 around line 8., that paragraph begins:

11:47:42 14 "One prescription product contains vitamin D in
11:47:45 15 an unspecified oil."

11:47:47 16 Do you see that?

11:47:47 17 A. Yes.

11:47:48 18 Q. And that's also referring to Vigantol,
11:47:51 19 right?

11:47:54 20 A. Probably. Yes.

11:47:57 21 Q. There's no link to the web page that you
11:48:00 22 had located; do you know why that is?

11:48:06 23 MR. ANDERSON: Object to the form of the
11:48:06 24 question and instruct you not to answer to the
11:48:08 25 extent it calls for an attorney-client

11:48:10 1 communication. You may answer to the extent
11:48:12 2 you can do so without disclosing any
11:48:17 3 attorney-client communications.

11:48:19 4 THE WITNESS: I don't know the answer.

11:48:19 5 BY MR. CONRAD::

11:48:24 6 Q. When you were researching dosing
11:48:30 7 instructions for Vigantol, did you encounter any
11:48:33 8 description of its contents, of its composition?

11:48:37 9 A. No.

11:48:46 10 Q. Did you do any research to identify what
11:48:48 11 the contents of its composition is?

11:48:58 12 A. Did I do research to try to understand
11:49:00 13 that product?

11:49:06 14 MR. ANDERSON: Object to the form of the
11:49:06 15 question.

11:49:10 16 THE WITNESS: I think we discussed that
11:49:11 17 earlier this morning.

11:49:12 18 BY MR. CONRAD::

11:49:13 19 Q. When you were conducting tests on
11:49:16 20 Vigantol?

11:49:17 21 MR. ANDERSON: Object to the form of the
11:49:17 22 question, mischaracterizes his testimony --

11:49:23 23 (Simultaneous speakers – unclear)

11:49:23 24 (Court reporter clarification)

11:49:24 25 THE WITNESS: No, during that time when I

11:49:24 1 --

11:49:31 2 COURT REPORTER: Sorry, repeat your

11:49:31 3 answer, please, Doctor.

11:49:31 4 THE WITNESS: Pardon me?

11:49:31 5 COURT REPORTER: Could you repeat your

11:49:31 6 answer, please, Doctor?

11:49:31 7 THE WITNESS: Could I have the question

11:49:32 8 again.

11:49:33 9 BY MR. CONRAD::

11:49:34 10 Q. I'll ask a different question.

11:49:35 11 I asked you: Did do you any research

11:49:37 12 to identify what the contents of the composition of

11:49:41 13 Vigantol Oil is and you said, "We discussed that

11:49:44 14 earlier this morning."

11:49:45 15 So my question for you now is: What

11:49:48 16 was it that we were discussing earlier this morning

11:49:51 17 that you were referring to?

11:49:53 18 A. No, I did not do research to understand

11:49:55 19 the contents.

11:49:56 20 Q. The patent application says that it's

11:49:58 21 an -- in an unspecified oil. So you are saying you

11:50:02 22 didn't do any research to identify what that oil

11:50:05 23 would be?

11:50:09 24 A. The reason --

11:50:11 25 MR. ANDERSON: Object to the form of the

11:50:11 1 question.

11:50:11 2 THE WITNESS: I did not do research to

11:50:13 3 understand that oil.

11:50:23 4 (Off-record discussion)

11:50:27 5 BY MR. CONRAD::

11:50:28 6 Q. Why did you not -- sorry, why did you not

11:50:31 7 do any research to figure out what that oil was?

11:50:37 8 A. It was not in the public domain to know.

11:50:43 9 Q. What made you think that?

11:50:44 10 A. Because I tried to find out.

11:50:51 11 Q. And you were unable to find out what it

11:50:53 12 was?

11:50:58 13 A. Not in the public domain.

11:51:10 14 Q. Why did you want to find out what the

11:51:10 15 composition was? What was your goal?

11:51:15 16 MR. ANDERSON: Object to the form of the

11:51:15 17 question. Assumes facts not in evidence.

11:51:18 18 THE WITNESS: You are referring to that

11:51:19 19 second paragraph on column 3, right?

11:51:22 20 BY MR. CONRAD::

11:51:23 21 Q. No, this is just a more general question.

11:51:26 22 You testified that you tried to find out what the

11:51:30 23 composition of Vigantol Oil was but you couldn't

11:51:32 24 because, you said, it's in the public domain. So my

11:51:35 25 question is: What was your goal? What were you --

11:51:39 1 why were you trying to find out what the composition
11:51:42 2 of Vigantol was?

11:51:42 3 MR. ANDERSON: I'm going to object to the
11:51:43 4 form of the question. You said, "Because it is
11:51:45 5 in the public domain." You missed the word
11:51:48 6 "not", I think.

11:51:50 7 BY MR. CONRAD::

11:51:51 8 Q. Correct, yeah, I'll rephrase that. Sorry.
11:51:53 9 You testified that you tried to find
11:51:55 10 out what the composition of Vigantol Oil was but you
11:51:58 11 couldn't because you said it's not in the public
11:52:00 12 domain.

11:52:01 13 So my question is: What was your
11:52:04 14 goal? What were you trying to find out? Why were
11:52:08 15 you trying to find out what the composition of
11:52:10 16 Vigantol was?

11:52:11 17 MR. ANDERSON: Object to the form of the
11:52:11 18 question.

11:52:19 19 THE WITNESS: I was not trying to
11:52:20 20 understand the composition of Vigantol -- I
11:52:24 21 wasn't.

11:52:24 22 BY MR. CONRAD::

11:52:25 23 Q. Okay. So you never -- you weren't trying
11:52:29 24 to understand what the composition of Vigantol Oil
11:52:33 25 was and you didn't try to find out?

11:52:36 1 MR. ANDERSON: Object to the form of the
11:52:36 2 question. Mischaracterizes testimony.
11:52:40 3 THE WITNESS: I did not chase down
11:52:41 4 Vigantol per se.
11:52:43 5 BY MR. CONRAD::
11:52:45 6 Q. What do you mean "per se." I'm trying to
11:52:48 7 understand what you did do.
11:52:50 8 A. Like I said earlier, I tried to get it. I
11:52:52 9 didn't.
11:52:53 10 I had one sample from 2002 and that's
11:52:55 11 it.
11:52:58 12 Q. Was that sample an original formulation of
11:53:05 13 Vigantol Oil or was it a diluted formulation?
11:53:10 14 MR. ANDERSON: Object to the form of the
11:53:10 15 question.
11:53:10 16 THE WITNESS: Honestly I don't know. They
11:53:16 17 were two samples -- three samples, high, low,
11:53:18 18 and placebo sent to me: "Reinhold, what's
11:53:22 19 their composition" -- "What's their vitamin D
11:53:25 20 content?" That was the -- that was the extent
11:53:26 21 of it.
11:53:27 22 BY MR. CONRAD:
11:53:27 23 Q. Let's go back to your declaration, 2068,
11:54:54 24 paragraph 47. There you state that:
11:55:20 25 "An infant has not developed the ability to

11:55:22 1 lick in the adult sense of it; infants do not lick.
11:55:26 2 With four children -- and observing others -- I have
11:55:28 3 never seen an infant link to take in anything
11:55:31 4 extraneous to their body."
11:55:33 5 Do you see that?
11:55:34 6 A. Yes.
11:55:35 7 Q. So when you used the word "lick" in your
11:55:39 8 declaration, are you using it in the adult sense of
11:55:42 9 licking, like licking a lollipop?
11:55:46 10 MR. ANDERSON: Object to the form of the
11:55:46 11 question.
11:55:53 12 THE WITNESS: The adult sense of licking?
11:55:55 13 BY MR. CONRAD::
11:55:56 14 Q. Yes, what do you mean by the adult sense
11:55:57 15 of licking?
11:56:00 16 A. It means to suck a lollipop, yes.
11:56:09 17 Q. You're not using the word "lick" in a
11:56:11 18 broad sense meaning touching a tongue to a surface
11:56:17 19 regardless of whether you're moving the tongue or
11:56:21 20 not, right?
11:56:24 21 MR. ANDERSON: Object to the form of the
11:56:24 22 question.
11:56:24 23 THE WITNESS: You are telling me something
11:56:25 24 I'm not saying?
11:56:26 25 BY MR. CONRAD::

11:56:27 1 Q. I'm asking you.

11:56:29 2 A. I still don't understand your question.

11:56:31 3 Q. You're not -- you've got a lot of

11:56:34 4 statements in your declaration that say that infants

11:56:36 5 do not lick in the same way an adult might.

11:56:40 6 My question for you is: You're not

11:56:46 7 trying to say that an infant can't touch its tongue

11:56:52 8 to a surface, right?

11:56:55 9 MR. ANDERSON: Object to the form of the

11:56:55 10 question.

11:56:57 11 THE WITNESS: A double negative in there.

11:57:04 12 BY MR. CONRAD::

11:57:04 13 Q. Sorry?

11:57:04 14 A. I still don't understand.

11:57:08 15 Q. Well, in paragraph 49 you talk about

11:57:11 16 licking movements, right?

11:57:16 17 A. 49?

11:57:17 18 Q. Paragraph 49.

11:57:20 19 A. Correct.

11:57:24 20 Q. Let me -- let me short circuit this,

11:57:28 21 maybe.

11:57:29 22 You are not a pediatric clinician,

11:57:34 23 right?

11:57:34 24 A. Right.

11:57:35 25 MR. ANDERSON: Object to the form of the

11:57:35 1 question.

11:57:35 2 BY MR. CONRAD:

11:57:36 3 Q. Your experience with babies is primarily

11:57:40 4 through your own experience as a father, right?

11:57:44 5 MR. ANDERSON: Object to the form of the

11:57:44 6 question.

11:57:49 7 THE WITNESS: Yes.

11:57:49 8 BY MR. CONRAD::

11:57:49 9 Q. It's not part of your research or practice

11:57:53 10 to observe or research infants licking surfaces,

11:58:02 11 right?

11:58:03 12 MR. ANDERSON: Object to the form of the

11:58:03 13 question.

11:58:08 14 THE WITNESS: It's -- part of my

11:58:12 15 scientific approach is to read the

11:58:15 16 peer-reviewed literature.

11:58:17 17 BY MR. CONRAD::

11:58:19 18 Q. My point is that you wouldn't consider

11:58:20 19 yourself an expert on how or whether infants can

11:58:25 20 lick, right?

11:58:27 21 MR. ANDERSON: Object to the form of the

11:58:27 22 question.

11:58:30 23 THE WITNESS: I consider myself an expert

11:58:32 24 on watching babies breast feed.

11:58:34 25 BY MR. CONRAD::

11:58:35 1 Q. And that's because of your experience as a
11:58:38 2 father of four children, right?

11:58:40 3 A. Yes.

11:58:57 4 Q. Okay. I'm handing you what's been marked
11:59:42 5 as Exhibit 1007.

11:59:43 6 (R. VIETH Exhibit 1007 was marked for
11:59:43 7 identification.)

11:59:45 8 BY MR. CONRAD:

11:59:45 9 Q. This is the declaration of translation by
11:59:49 10 David Joshua Sherman from February 28, 2023.

11:59:56 11 And you reviewed this as part of
11:59:59 12 preparing your declaration in this matter; correct?

12:00:03 13 A. Yes.

12:00:41 14 Q. I'm handing you Exhibit 1006, which is the
12:00:56 15 excerpt of textbook from Ulrike Harder.

11:59:43 16 (R. VIETH Exhibit 1006 was marked for
11:59:43 17 identification.)

18 BY MR. CONRAD:

12:01:03 19 Q. And you also reviewed this in preparing
12:01:05 20 your declaration, right?

12:01:07 21 A. Yes. Not in German, though.

12:01:12 22 COURT REPORTER: Sorry?

12:01:12 23

12:01:12 24 THE WITNESS: Not in German. This is
12:01:12 25 German.

12:01:12 1 BY MR. CONRAD:

12:01:18 2 Q. So, first off, do you know what the German

12:01:25 3 phrase "zum Ablecken" means in English?

12:01:31 4 MR. ANDERSON: Object to the form of the

12:01:31 5 question.

12:01:35 6 THE WITNESS: Do I know? Is this in

12:01:37 7 retrospect or prospectively?

12:01:41 8 BY MR. CONRAD::

12:01:41 9 Q. This is with -- from your experience,

12:01:42 10 being raised in a German household?

12:01:46 11 MR. ANDERSON: Object to the form of the

12:01:46 12 question. No foundation.

12:01:56 13 THE WITNESS: "I reviewed the German

12:01:58 14 translation (sotto voce)."

12:02:06 15 I go with the Tinworth translation of it.

12:02:11 16 BY MR. CONRAD::

12:02:11 17 Q. So my question for you is different: Would

12:02:15 18 you disagree that the German phrase "zum Ablecken"

12:02:18 19 means to be licked off in English?

12:02:24 20 MR. ANDERSON: Object to the form of the

12:02:24 21 question. Calls for speculation. No

12:02:26 22 foundation.

12:02:26 23 THE WITNESS: I agree with him.

12:02:29 24 BY MR. CONRAD::

12:02:30 25 Q. You agree with your attorney?

12:02:34 1 A. Yes.

12:02:36 2 Q. So having been raised in a German
12:02:40 3 household to German parents and speaking
12:02:44 4 conversational household English -- German with your
12:02:47 5 parents growing up, do you have an understanding of
12:02:50 6 the German phrase, "zum Ablecken"?

12:02:57 7 MR. ANDERSON: Object to the form of the
12:02:57 8 question, no foundation, calls for speculation.

12:03:01 9 THE WITNESS: This is one part that kind
12:03:03 10 of annoys me here. Because the statement says,
12:03:11 11 "Here you go, lick it off". That's what that
12:03:15 12 means.

12:03:15 13 It doesn't mean to be licked off. It
12:03:18 14 means, at least in my view, "Here you go, lick
12:03:21 15 it off."

12:03:22 16 BY MR. CONRAD::

12:03:23 17 Q. Okay.

12:03:23 18 A. Is your baby going to respond to that? No
12:03:26 19 way.

12:03:28 20 It's a nonsense statement.

12:03:30 21 Q. Okay. So you --

12:03:32 22 A. And I would also argue here, you have
12:03:37 23 David Sherman, a man, criticizing Rebecca Tinworth
12:03:42 24 in her translation. And I would argue her
12:03:44 25 translation is the correct one because she's a

12:03:47 1 mother or probably a mother.

12:03:52 2 Q. So let me make sure I have your testimony
12:03:58 3 here.

12:04:00 4 So you would agree that the key text
12:04:04 5 in Harder that we've been discussing means something
12:04:10 6 to the effect of "Here you go. Lick it off."

12:04:13 7 A. Yes.

12:04:14 8 MR. ANDERSON: Object to the form of the
12:04:14 9 question, calls for speculation, no foundation.

12:04:18 10 THE WITNESS: That's -- it implies that
12:04:21 11 you're offering it to a baby to do something
12:04:27 12 active, to which a baby has no ability to
12:04:29 13 respond. That's what it is.

12:04:47 14 If I get -- sorry, I won't talk.

12:05:14 15 BY MR. CONRAD::

12:05:15 16 Q. Is your understanding that a baby has no
12:05:18 17 ability to actively lick, are you assuming that the
12:05:25 18 baby is a newborn?

12:05:27 19 MR. ANDERSON: Object to the form of the
12:05:27 20 question.

12:05:31 21 THE WITNESS: I'm not making any
12:05:33 22 inferences on the author of the paragraph that
12:05:37 23 you're asking about.

12:05:41 24 BY MR. CONRAD::

12:05:42 25 Q. What you mean by that answer?

12:05:44 1 A. Well, that lady, Harder, is a midwife.

12:05:47 2 Q. Mm-hmm.

12:05:49 3 A. And the context of her chapter is in the

12:05:52 4 context of the ages during which a midwife might

12:05:59 5 deal with a mother and a baby.

12:06:01 6 Q. And to your understanding what role does a

12:06:03 7 midwife play?

12:06:05 8 A. She helps you have a baby and maybe a

12:06:07 9 little bit after baby care.

12:06:44 10 Q. Can you go to page 6 of Exhibit 1007.

12:07:17 11 Okay, it is actually highlighted,

12:07:18 12 sort of, but on page 4 -- I'm sorry, page 6, what we

12:07:25 13 were just discussing, the highlighted sentence,

12:07:33 14 about two-thirds of the way down says:

12:07:34 15 "Use of the oil is simple. One drop of

12:07:38 16 Vigantol Oil is given to the baby to be licked off

12:07:41 17 from the tip of a spoon once a day before a

12:07:45 18 breastfeed or a meal."

12:07:47 19 So you would understand that that is

12:07:51 20 describing putting one drop of a composition

12:07:55 21 onto the exterior surface of an object, right?

12:07:59 22 A. No.

12:08:00 23 MR. ANDERSON: Object to the form of the

12:08:00 24 question.

12:08:01 25 BY MR. CONRAD::

12:08:03 1 Q. No?

12:08:03 2 A. No.

12:08:05 3 Q. You don't consider the tip of a spoon, the

12:08:07 4 surface, the exterior surface of an object?

12:08:18 5 A. Could you illustrate for me how you would

12:08:20 6 do this?

12:08:21 7 Q. I mean, I did it at home.

12:08:23 8 A. Well ...

12:08:23 9 Q. You put one drop on the tip of a spoon.

12:08:29 10 A. How did you hold the spoon?

12:08:30 11 Q. Just naturally.

12:08:31 12 A. And that means?

12:08:33 13 Q. Just whatever made it work, so that a tip

12:08:33 14 -- one drop would stay at the tip.

12:08:39 15 A. So concave up or concave down?

12:08:42 16 Q. I've tried it both ways.

12:08:44 17 A. Hm-hmm.

12:08:45 18 Q. And have you tried it?

12:08:45 19 A. Hm-hmm.

12:08:45 20 Q. Did you try to put one drop on the tip of

12:08:48 21 a spoon?

12:08:49 22 A. Hm-hmm -- well, recently.

12:08:50 23 Q. Recently?

12:08:51 24 A. Yeah.

12:08:51 25 Q. And were you able to -- and when did you

12:08:54 1 that, did any of that drop fall off of the spoon?

12:08:58 2 A. If you put a drop of oil on to a piece of

12:09:01 3 metal, especially if it's the concave side, that oil

12:09:06 4 is not going to stay there at the tip. It will

12:09:09 5 go (sound), roll into it.

12:09:13 6 Q. What if it's not metal; what if it's

12:09:16 7 plastic?

12:09:17 8 MR. ANDERSON: Objection, calls for

12:09:17 9 speculation.

12:09:19 10 THE WITNESS: It is speculation.

12:09:19 11 BY MR. CONRAD::

12:09:20 12 Q. So have you tested a plastic spoon to see

12:09:22 13 how it behaves?

12:09:24 14 A. No. How about a wood spoon?

12:09:30 15 Q. Did you test a wooden spoon?

12:09:32 16 A. Yes.

12:09:32 17 Q. But not a plastic spoon?

12:09:34 18 A. That's right.

12:09:35 19 Q. What other kinds of spoons did you test?

12:09:38 20 A. Wooden -- wood is obvious -- or paper. It

12:09:42 21 absorbs into it.

12:09:47 22 Q. Okay, so you tried wood. You tried paper.

12:09:49 23 You tried --

12:09:49 24 A. Recently.

12:09:51 25 Q. You tried metal. You didn't try plastic.

12:09:57 1 What else did you try?

12:10:00 2 A. Nothing.

12:10:01 3 MR. ANDERSON: Object to the form of the

12:10:03 4 question.

12:10:03 5 THE WITNESS: Didn't try other things.

12:10:08 6 BY MR. CONRAD::

12:10:09 7 Q. And in the test on -- with the metal

12:10:12 8 spoon, did any of that drop fall off of the spoon?

12:10:19 9 A. You know that if you put a drop onto the

12:10:21 10 spoon, the drop will role toward the centre of the

12:10:25 11 spoon and not off of it.

12:10:27 12 Q. Did you try turning the spoon over to see

12:10:29 13 if it fell off?

12:10:31 14 A. No, I did not try that.

12:10:46 15 Q. I think you would agree that Harder

12:10:53 16 doesn't provide any testing to show that her method

12:10:57 17 is effective, right?

12:10:58 18 A. That's correct.

12:11:02 19 MR. ANDERSON: Object to the form of the

12:11:02 20 question.

12:11:02 21 THE WITNESS: Sorry right.

12:11:06 22 MR. ANDERSON: Go ahead.

12:11:07 23 THE WITNESS: She didn't validate

12:11:08 24 anything.

12:11:10 25 BY MR. CONRAD::

12:11:10 1 Q. And that's part of the problem you have
12:11:11 2 with this, right, that she didn't confirm that her
12:11:16 3 test was -- her method was actually effective,
12:11:20 4 right?

12:11:24 5 MR. ANDERSON: Object to the form of the
12:11:24 6 question.

12:11:24 7 THE WITNESS: That's a repeat of the
12:11:25 8 previous question. Yes.

12:11:33 9 BY MR. CONRAD::

12:11:33 10 Q. But the difference between you and Harder
12:11:35 11 in your mind, would it be because you actually
12:11:38 12 conducted the scientific test to confirm that this
12:11:41 13 was, in fact, effective?

12:11:50 14 MR. ANDERSON: Object to the form of the
12:11:50 15 question.

12:11:51 16 THE WITNESS: Can you ask that question
12:11:52 17 again?

12:11:53 18 BY MR. CONRAD::

12:11:54 19 Q. Sure. I mean -- it's fair to say, reading
12:11:56 20 your declaration, that you don't believe that the
12:12:02 21 Harder text demonstrates a scientifically rigorous
12:12:07 22 approach to administering a supplement to a baby,
12:12:15 23 right?

12:12:16 24 MR. ANDERSON: Object to the form of the
12:12:16 25 question.

12:12:19 1 THE WITNESS: It's a ridiculous approach.

12:12:21 2 BY MR. CONRAD::

12:12:21 3 Q. Ridiculous meaning because it's not
12:12:24 4 scientific in any way?

12:12:26 5 MR. ANDERSON: Object to the form of the
12:12:26 6 question.

12:12:26 7 THE WITNESS: That's one way of putting
12:12:28 8 it.

12:12:29 9 BY MR. CONRAD::

12:12:33 10 Q. Is it your opinion that in order for a
12:12:37 11 method to teach someone how to practice that method
12:12:42 12 that it must have been scientifically tested first?

12:12:49 13 MR. ANDERSON: Object to the form of the
12:12:49 14 question. Also object to the extent it calls
12:12:51 15 for a legal conclusion.

12:12:54 16 THE WITNESS: As a scientist you have to
12:12:56 17 validate what you are suggesting.

12:12:58 18 BY MR. CONRAD::

12:13:00 19 Q. And your belief is that Harder didn't do
12:13:01 20 the necessary validation for this method, right?

12:13:05 21 MR. ANDERSON: Object to the form of the
12:13:05 22 question.

12:13:10 23 THE WITNESS: I can hardly start to
12:13:12 24 criticize that Harder paper. Like, there is
12:13:14 25 such a long list of problems with it. It's

12:13:16 1 ridiculous. It's a joke.

12:13:19 2 BY MR. CONRAD::

12:13:19 3 Q. Why is that?

12:13:22 4 A. Firstly, putting a single drop onto a
12:13:27 5 spoon means you are putting it onto the concave
12:13:30 6 surface and you know that if you put a drop of oil
12:13:32 7 on a piece of metal, that oil spreads. That's why
12:13:37 8 you lubricate a bike chain, or whatever, with oil.
12:13:41 9 So oil spreads. It doesn't stay as a drop. You put
12:13:43 10 -- if you -- you know, her instruction is "Here,
12:13:48 11 baby, lick this off."

12:13:51 12 Like a six-week old baby is going to
12:13:54 13 look at the spoon and go "nothing." The reason a
12:13:57 14 baby licks is to seek the mother's nipple and that
12:14:03 15 happens with skin-to-skin contact, as shown in
12:14:06 16 several of these publications that I've cited.

12:14:09 17 So her premises are absurd,
12:14:10 18 technically, with regard to the spoon, technically
12:14:14 19 with regard to how a baby breast feeds. And then,
12:14:17 20 lastly, like there's no way ever that a baby could
12:14:21 21 lick a drop off a spoon. It's not going to happen.

12:14:25 22 Are you going to shove this spoon at
12:14:27 23 the baby's mouth? In practicality, you wouldn't do
12:14:32 24 it, I wouldn't do it, and if anybody ever were to
12:14:36 25 preach it, they would be open to a lawsuit for, you

12:14:39 1 know, improper medical care.

12:14:51 2 Q. Are you saying that if you put one drop of
12:14:57 3 the claimed product onto a spoon and then make
12:15:06 4 contact with what's on the surface of that product
12:15:10 5 with the baby's tongue, that none of it would be
12:15:14 6 removed?

12:15:15 7 MR. ANDERSON: Object to the form of the
12:15:15 8 question.

12:15:21 9 THE WITNESS: You are implying that --
12:15:22 10 none is an absolute term and I'm not going to
12:15:26 11 answer absolute or probability questions like
12:15:30 12 that.

12:15:30 13 BY MR. CONRAD::

12:15:31 14 Q. I take it you would agree by your -- by
12:15:36 15 how you're talking about Harder, that there's no way
12:15:39 16 that this method is going to effectively remove all
12:15:46 17 of the dose that's on the spoon; is that your
12:15:50 18 viewpoint?

12:15:51 19 MR. ANDERSON: Object to the form of the
12:15:51 20 question.

12:15:55 21 THE WITNESS: It might get some, you might
12:15:57 22 contaminate the mouth with a little vitamin D,
12:16:00 23 but that is nothing, incidental, incidental
12:16:04 24 delivery.

12:16:05 25 BY MR. CONRAD::

12:16:19 1 Q. She says in the last sentence of the
12:16:21 2 paragraph:
12:16:22 3 "I have also now been able to convince some
12:16:27 4 pediatricians of the advantages of the oil."
12:16:32 5 I mean, that applies that some
12:16:35 6 pediatricians understand it, doesn't it?
12:16:37 7 MR. ANDERSON: Objection, calls for
12:16:37 8 speculation.
12:16:39 9 THE WITNESS: That's right. You are
12:16:40 10 asking me to speculate. And my speculation is
12:16:45 11 she chatted with a pediatrician at a cocktail
12:16:49 12 party and they said, yeah, that sounds
12:16:51 13 interesting.
12:16:52 14 BY MR. CONRAD::
12:16:52 15 Q. She also says that:
12:16:53 16 "Should two drops fall onto the spoon, the
12:16:56 17 spoon should be washed and the process started
12:16:59 18 again."
12:16:59 19 What does that tell you?
12:17:00 20 A. It tells me one has to be very careful
12:17:03 21 with the dose.
12:17:04 22 Q. And she's making that point here, right?
12:17:07 23 A. A silly dose -- in other words, it's very
12:17:11 24 easy to miscount? Like, let's say you blinked when
12:17:16 25 a drop fell. You put two drops on the spoon. With

12:17:19 1 the method of putting it on a pacifier, it is

12:17:23 2 self-limiting.

12:17:24 3 Q. Why is it self-limiting?

12:17:27 4 A. Because these small objects only hold one

12:17:31 5 drop. The spoon holds more than a drop. And

12:17:36 6 regardless as to whether a person is counting them,

12:17:40 7 they'll miscount.

12:18:15 8 Q. Well, she says:

12:18:16 9 "Under no circumstances should it be put

12:18:18 10 directly into the baby's mouth."

12:18:20 11 Do you agree that that's good advice?

12:18:22 12 A. What's the "it" that she's referring to?

12:18:26 13 Q. One drop of Vigantol Oil.

12:18:27 14 MR. ANDERSON: Object to the form of the

12:18:27 15 question.

12:18:30 16 THE WITNESS: I regard the sentence as

12:18:31 17 plain ambiguous. I can't answer an ambiguous

12:18:35 18 question.

12:18:36 19 BY MR. CONRAD::

12:18:39 20 Q. So just the sentence:

12:18:40 21 "Under no circumstances should one drop of

12:18:43 22 Vigantol Oil be put directly into the baby's mouth."

12:18:47 23 If I phrase it that way, would you agree

12:18:49 24 with that sentence?

12:18:51 25 A. Alternatively, it's -- you could say under

12:18:53 1 no circumstances put the spoon into a baby's mouth.

12:18:59 2 Q. Is that how you interpret it?

12:19:03 3 MR. ANDERSON: Object to the form of the
12:19:03 4 question.

12:19:09 5 THE WITNESS: It is grossly ambiguous.

12:19:17 6 BY MR. CONRAD::

12:19:21 7 Q. Are you familiar with the National Library
12:19:24 8 of Medicine?

12:19:25 9 A. Yes.

12:19:26 10 Q. What is it?

12:19:30 11 A. What is it?

12:19:31 12 Q. Yes, what's your familiarity with it?

12:19:35 13 A. Mostly, if you look at PubMed to search
12:19:38 14 the medical literature it's -- it connects with the
12:19:41 15 National Library of Medicine in the United States.

12:19:44 16 Q. So, is PubMed something that the National
12:19:47 17 Library of Medicine administers or is associated
12:19:51 18 with?

12:19:54 19 MR. ANDERSON: Object to the form of the
12:19:54 20 question.

12:19:56 21 THE WITNESS: I'm not sure of the
12:19:56 22 technicality --

12:19:56 23 COURT REPORTER: Sorry --

12:19:56 24 MR. ANDERSON: Sir, you need to wait for
12:19:56 25 me to finish my objection.

12:19:56 1 THE WITNESS: Sorry about that.

12:19:56 2 MR. ANDERSON: Objection, no foundation,

12:20:01 3 calls for speculation.

12:20:02 4 COURT REPORTER: I didn't get an answer.

12:20:05 5 MR. ANDERSON: Now you can answer.

12:20:07 6 THE WITNESS: I don't know the legal

12:20:08 7 connections.

12:20:09 8 BY MR. CONRAD::

12:20:09 9 Q. But they are associated?

12:20:11 10 MR. ANDERSON: Same objection, no

12:20:11 11 foundation, calls for speculation.

12:20:15 12 THE WITNESS: I don't know the

12:20:17 13 association.

12:20:17 14 BY MR. CONRAD::

12:20:17 15 Q. Okay. When — PubMed does connect to the

12:20:24 16 National Library of Medicine, correct?

12:20:31 17 A. I don't know the connection.

12:20:32 18 Q. Okay, but you testified that it connects

12:20:35 19 with the National Library of Medicine so are you

12:20:37 20 referring to PubMed linking to the National Library

12:20:42 21 of Medicine?

12:20:44 22 MR. ANDERSON: Object to the form of the

12:20:44 23 question.

12:20:46 24 THE WITNESS: You are asking me for my

12:20:48 25 knowledge of the connection. If you look at a

12:20:49 1 web page for PubMed you will find the words
12:20:52 2 "National Library of Medicine" somewhere on
12:20:55 3 that web page.
12:20:56 4 BY MR. CONRAD::
12:21:00 5 Q. And can you explain what PubMed is?
12:21:05 6 A. It is a very commonly-used search tool.
12:21:12 7 Q. By who?
12:21:14 8 A. Well, it relates to biomedical articles.
12:21:19 9 Q. So you, for example, would use PubMed to
12:21:23 10 conduct research in your field, right?
12:21:26 11 A. Yes.
12:21:31 12 Q. Would you also consider the National
12:21:32 13 Library of Medicine as a place where you would
12:21:35 14 search for references in your field?
12:21:39 15 MR. ANDERSON: Object to the form of the
12:21:39 16 question.
12:21:42 17 THE WITNESS: I should just answer your
12:21:44 18 question?
12:21:44 19 BY MR. CONRAD::
12:21:45 20 Q. Yes.
12:21:45 21 A. I've never gone there in particular other
12:21:47 22 than via PubMed.
12:21:48 23 Q. But you have gone there via PubMed, right?
12:21:52 24 A. Maybe. I don't know what's behind the
12:21:54 25 website.

12:22:02 1 MR. CONRAD: Let's take a break.

12:22:06 2 --- Recess taken at 12:22 p.m.

12:22:07 3 --- Upon resuming at 12:34 p.m.

12:34:35 4 BY MR. CONRAD::

12:34:36 5 Q. Let's turn to Exhibit 1001, the '958

12:34:42 6 Patent.

12:34:54 7 Are you there?

12:34:55 8 A. Mm-hmm.

12:34:56 9 Q. Can you turn to claim 1. Step 2 of claim

12:35:10 10 1 says:

12:35:10 11 "having said human being suck or lick said

12:35:16 12 composition directly from said object. "

12:35:18 13 Do you see that?

12:35:19 14 A. Yes.

12:35:20 15 Q. That doesn't state a certain amount of

12:35:22 16 time to suck or a certain number of licks; correct?

12:35:25 17 A. Correct.

12:35:29 18 Q. So claim 1 doesn't require that the human

12:35:32 19 being suck or lick for a certain amount of time or a

12:35:38 20 certain number of licks, right?

12:35:41 21 MR. ANDERSON: Object to the form of the

12:35:41 22 question, calls for a legal conclusion, no

12:35:45 23 foundation.

12:35:46 24 THE WITNESS: I don't -- I don't quite get

12:35:50 25 the point

12:35:51 1 BY MR. CONRAD::

12:35:51 2 Q. Well, you see that the first step is

12:35:53 3 applying one drop of a composition, right?

12:35:56 4 A. Yes.

12:35:57 5 Q. And then the second step is having said

12:36:02 6 human beings suck or lick said composition directly

12:36:06 7 from said object, right?

12:36:08 8 A. Yes.

12:36:09 9 Q. And that doesn't further require that that

12:36:13 10 human perform that action for a certain number of

12:36:15 11 times, certain amount of time or a certain number of

12:36:20 12 times, right?

12:36:21 13 MR. ANDERSON: Object to the form of the

12:36:21 14 question, calls for a legal conclusion in the

12:36:24 15 form of claim construction. No foundation.

12:36:30 16 THE WITNESS: Can you ask that again

12:36:32 17 because I could lose it.

12:36:33 18 BY MR. CONRAD::

12:36:34 19 Q. Yeah. Claim 1 doesn't require a human

12:36:36 20 being performing an action for a certain amount of

12:36:39 21 time or a certain number of times?

12:36:43 22 MR. ANDERSON: Objection, no foundation.

12:36:46 23 Calls for a legal conclusion in that it calls

12:36:47 24 for claim construction.

12:36:56 25 THE WITNESS: I can't answer that. I

12:36:56 1 don't know.

12:36:57 2 BY MR. CONRAD::

12:36:57 3 Q. You don't know?

12:36:58 4 A. I don't quite know what I'm -- where this

12:37:01 5 is. What it states is what it states.

12:37:10 6 Q. Let's go back to the testimony we had

12:37:16 7 earlier where your wife had the idea of putting a

12:37:22 8 drop on a nipple for breast feeding?

12:37:26 9 A. Yes.

12:37:29 10 Q. Before you did your test to confirm

12:37:31 11 anything, did she attempt to try that with any

12:37:36 12 composition?

12:37:37 13 MR. ANDERSON: Object to the form of the

12:37:37 14 question. No foundation.

12:37:43 15 THE WITNESS: I don't know.

12:37:46 16 BY MR. CONRAD::

12:37:49 17 Q. You personally had gotten some of the oil

12:37:50 18 on your hands or fingers during your testing.

12:37:55 19 Did I understand you correctly?

12:37:58 20 MR. ANDERSON: Object to the form of the

12:37:58 21 question.

12:38:01 22 THE WITNESS: This is early on when I was

12:38:03 23 preparing oil vitamin D preparations, that's

12:38:06 24 where I made an observation it was different,

12:38:08 25 yeah.

12:38:10 1 BY MR. CONRAD::

12:38:11 2 Q. Mm-hmm.

12:38:11 3 A. You know, compared to other oils.

12:38:14 4 Q. Before you did test to confirm that

12:38:19 5 putting a drop on a surface could be an effective

12:38:24 6 way of actually delivering the complete dose, did

12:38:31 7 you or your wife ever test putting one drop on a

12:38:40 8 surface at all?

12:38:41 9 MR. ANDERSON: Object to the form of the

12:38:41 10 question.

12:38:43 11 THE WITNESS: Can you say that again?

12:38:45 12 BY MR. CONRAD::

12:38:45 13 Q. Sure. I mean, look at it --

12:38:48 14 A. Okay.

12:38:48 15 Q. Look at it this way: What I see in your

12:38:53 16 lab notebook is a lot of tests to confirm that

12:38:57 17 putting a drop on a surface actually can deliver

12:39:00 18 an effective dose, right?

12:39:05 19 A. A certain type of drop on a certain type

12:39:07 20 of surface through a certain method, a variety of

12:39:11 21 things, yes.

12:39:12 22 Q. Before you conducted those tests, did you

12:39:14 23 simply test putting a drop on a surface and seeing

12:39:22 24 if it sticks?

12:39:24 25 MR. ANDERSON: Object to the form of the

12:39:24 1 question.

12:39:24 2 THE WITNESS: I still -- I don't know what

12:39:26 3 you're getting at because like --

12:39:30 4 MR. ANDERSON: Well, if you don't

12:39:30 5 understand the question you can ask him to

12:39:33 6 rephrase it.

12:39:33 7 THE WITNESS: All right.

12:39:34 8 MR. ANDERSON: If you do understand the

12:39:35 9 question, please answer it.

12:39:37 10 THE WITNESS: No, the -- I don't know what

12:39:38 11 your question is.

12:39:40 12 BY MR. CONRAD::

12:39:40 13 Q. That's fair. I'm --

12:39:41 14 A. Because before -- I don't know when --

12:39:44 15 MR. ANDERSON: Well, just --

12:39:45 16 THE WITNESS: Okay, sorry.

12:39:46 17 BY MR. CONRAD::

12:39:47 18 Q. That's fair.

12:39:51 19 Let's take Harder for example. She

12:39:54 20 says put a drop on the tip of a spoon. Let's say

12:40:00 21 that was the idea. I would think about going about

12:40:05 22 this as one, test whether -- what putting a drop on

12:40:11 23 a spoon does and then two, testing whether that

12:40:14 24 method actually delivers the vitamin D.

12:40:19 25 I see tests for part two in your lab

12:40:23 1 notebook about putting a drop on a surface. Did you
12:40:27 2 or your wife simply test -- simply put a drop on a
12:40:32 3 surface to see what it does --

12:40:35 4 MR. ANDERSON: Object to the form --

12:40:35 5 BY MR. CONRAD:

12:40:35 6 Q. -- what it did?

12:40:35 7 MR. ANDERSON: Object to the form of the
12:40:35 8 question.

12:40:36 9 BY MR. CONRAD::

12:40:36 10 Q. Prior to beginning your test to confirm
12:40:38 11 that it's an effective method of delivery?

12:40:41 12 MR. ANDERSON: Object to the form of the
12:40:41 13 question.

12:40:42 14 THE WITNESS: Tried different surfaces,
12:40:45 15 yes.

12:40:46 16 BY MR. CONRAD::

12:40:46 17 Q. Okay. What substance were you using to
12:40:48 18 try?

12:40:50 19 A. Well, it's not in my notebook. Finger, a
12:40:58 20 couple of different types of pacifiers, baby bottle
12:41:03 21 nipples.

12:41:04 22 Q. Why a finger?

12:41:08 23 A. Because it's skin.

12:41:13 24 Q. Why would that matter?

12:41:16 25 A. Nipples are skin.

12:41:19 1 Q. So it was a way to test putting it on skin
12:41:22 2 without putting it on a nipple?

12:41:24 3 A. Yes.

12:41:24 4 Q. Did anybody test putting it on a nipple?

12:41:29 5 A. Yes, but I wasn't there.

12:41:36 6 Q. And who tested that?

12:41:41 7 A. I don't have a clear recollection of who
12:41:43 8 it was.

12:41:46 9 Q. Was it your wife?

12:41:47 10 A. Probably, one of.

12:41:54 11 Q. You are saying she -- there were multiple
12:41:58 12 people that tested putting a drop on a nipple. Your
12:42:01 13 wife probably was one of them. Who else could it
12:42:05 14 have been?

12:42:07 15 MR. ANDERSON: Objection, calls for
12:42:07 16 speculation.

12:42:09 17 THE WITNESS: I don't have a good
12:42:10 18 recollection.

12:42:13 19 BY MR. CONRAD::

12:42:13 20 Q. Were -- were these formal tests or were
12:42:16 21 these just informal tests?

12:42:24 22 A. Formal? What do you mean by formal?

12:42:27 23 Q. Well, for example, in your lab notebook
12:42:30 24 you have what I would describe as formal tests,
12:42:33 25 scientific approaches to testing.

12:42:36 1 The tests to put a drop on a nipple,
12:42:38 2 were those done in a scientific approach or were
12:42:42 3 they simply a woman just putting a drop on a nipple
12:42:47 4 to see what it does?

12:42:52 5 A. I would say it's not something that was
12:42:54 6 written down in the notebook and, therefore,
12:43:00 7 probably informal.

12:43:02 8 Q. About how many women would have been
12:43:05 9 involved in this?

12:43:06 10 A. Three, maybe four.

12:43:07 11 Q. Was it something your wife organized?

12:43:18 12 A. I can't comment on that.

12:43:19 13 Q. What do you mean?

12:43:20 14 A. I can't. I don't ...

12:43:22 15 Q. What do you mean you can't comment on it?

12:43:30 16 A. Do you want to know names?

12:43:33 17 Q. Mm-hmm.

12:43:34 18 A. I have three daughters.

12:43:36 19 Q. So your daughters were involved?

12:43:39 20 A. Mm-hmm.

12:43:39 21 Q. And your wife?

12:43:41 22 A. Well, okay, yes.

12:43:43 23 Q. In the 2005, 2006 timeframe, how old were
12:43:47 24 your daughters?

12:43:48 25 A. Goodness. I'm a father. How do I know

12:43:52 1 their ages?

12:43:54 2 Q. You told me birth years of 1980 to 1988,

12:43:59 3 so we can work backwards.

12:44:04 4 A. They were all post puberty.

12:44:07 5 Q. Post what?

12:44:08 6 A. Post puberty. In other words, they had

12:44:11 7 breasts.

12:44:14 8 Q. So they would have been in their 20s,

12:44:17 9 right, most of them?

12:44:20 10 A. You are trying to do math, have me do math

12:44:23 11 here. If you want me to think about it, I'll take

12:44:26 12 longer.

12:44:27 13 Q. I'll walk you through it.

12:44:27 14 Let's say your oldest, she was born

12:44:30 15 in 1980; is that right?

12:44:32 16 A. '83.

12:44:34 17 Q. '83.

12:44:35 18 So in 2006 she would be -- she would

12:44:37 19 have been 23 years old, right?

12:44:41 20 A. Okay. I'm not -- like, I'm not in a state

12:44:45 21 of mind to do math.

12:44:47 22 Q. Okay, fair enough. Do you have any

12:44:51 23 grandchildren?

12:44:54 24 A. Presently?

12:44:55 25 Q. Yes.

12:44:55 1 A. Yes.

12:44:56 2 Q. In 2005 and 2006 did you have any

12:44:58 3 grandchildren?

12:45:01 4 A. No.

12:45:12 5 Q. What other roles did your daughters play

12:45:15 6 in any effort to develop this invention?

12:45:23 7 MR. ANDERSON: Object to the form of the

12:45:23 8 question and assumes facts not in evidence.

12:45:27 9 THE WITNESS: Took part in the study of

12:45:28 10 sucking on the nipple -- pacifier.

12:45:35 11 BY MR. CONRAD::

12:45:36 12 Q. Okay. So the subjects of your test that

12:45:38 13 are described in the patent are your family members?

12:45:42 14 A. Correct.

12:45:44 15 Q. Were there any test subjects that were not

12:45:47 16 members of your family?

12:45:56 17 A. I'm trying to think at what point.

12:45:58 18 Not prior to the submission of the

12:45:59 19 application, no, just family.

12:46:06 20 Q. Let's turn to the formation of the Ddrops

12:46:15 21 Company.

12:46:16 22 First off, what financial

12:46:21 23 relationship do you have with the Ddrops Company

12:46:25 24 presently?

12:46:30 25 A. Umm... I don't pay attention to that part

12:46:33 1 frankly, financial connection. Basically my wife
12:46:40 2 and the other partner are 50-50 owners, or whatever,
12:46:48 3 partners of it.

12:46:49 4 Q. So my understanding of this is that the
12:46:53 5 Ddrops Company has two 50-50 owners that are legal
12:47:01 6 entities. One of those entities is your wife's and
12:47:07 7 the other is Chris Temovsky's; is that accurate?

12:47:16 8 MR. ANDERSON: Objection, no foundation.

12:47:25 9 THE WITNESS: I would tend to agree with
12:47:27 10 you.

12:47:27 11 BY MR. CONRAD::

12:47:27 12 Q. And then the entity that is your wife's is
12:47:29 13 called The Fifth Child?

12:47:31 14 A. That's correct.

12:47:33 15 Q. I'm going to take a guess. Is The Fifth
12:47:36 16 Child named The Fifth Child because you have four
12:47:40 17 children and the company is your fifth child?

12:47:43 18 MR. ANDERSON: Objection, calls for
12:47:44 19 speculation.

12:47:49 20 THE WITNESS: You are correct.

12:47:50 21 BY MR. CONRAD::

12:47:50 22 Q. I can adduce with logic. I can do that.

12:47:53 23 Who -- are you -- do you own any part
12:48:01 24 of The Fifth Child?

12:48:03 25 A. Mm-hmm, good question. Honestly, I don't

12:48:04 1 know. We share it, kind of, like --

12:48:09 2 (Simultaneous speakers - unclear)

12:48:10 3 MR. ANDERSON: Just answer the question.

12:48:11 4 THE WITNESS: I have no idea. I have no

12:48:12 5 idea.

12:48:15 6 BY MR. CONRAD::

12:48:16 7 Q. So she owns it for sure and you don't know

12:48:18 8 if you have a direct interest, other than just an

12:48:22 9 interest through family?

12:48:23 10 A. Correct.

12:48:36 11 Q. I'm curious, if it wasn't clearly

12:48:37 12 something that you and your wife, say, co-owned

12:48:39 13 50-50, why would that be the case? Why would your

12:48:42 14 -- why is it that your wife would be the owner and

12:48:45 15 you didn't take any ownership interest in it?

12:48:48 16 A. Is this a curiosity question?

12:48:51 17 Q. It's a curiosity question, yes.

12:48:54 18 A. You know, I was working for the university

12:48:56 19 and the hospital and I didn't want to have any kind

12:49:03 20 of connection between the two.

12:49:04 21 Furthermore, it's kind of annoying

12:49:08 22 but, like, I had, for example, when the vitamin D

12:49:15 23 guidelines came out around 2010 or when the

12:49:19 24 Endocrine Society was setting up a committee to come

12:49:24 25 up with its recommendations, I had to decline

12:49:26 1 because of conflicts so, frankly, I didn't want to
12:49:31 2 have any university, hospital or any kind of mess
12:49:34 3 up, but because my wife had a financial interest in
12:49:41 4 a company related to vitamin D, there were
12:49:42 5 opportunities that I lost. That was it.

12:49:51 6 Q. I see. It would have complicated things?

12:49:53 7 A. It was just uncomfortable.

12:50:00 8 Q. I understand that Simon Vieth is your son,
12:50:02 9 right?

12:50:03 10 A. That's right.

12:50:03 11 Q. And he's involved in the Ddrops Company
12:50:06 12 today, right?

12:50:07 13 A. He was hired eventually, yeah.

12:50:09 14 Q. Are any of your daughters participating in
12:50:11 15 the company?

12:50:12 16 A. No.

12:50:21 17 Q. Does your wife -- does Mrs. Vieth have
12:50:24 18 any -- beyond a financial interest as a part owner,
12:50:28 19 does she have any other managerial responsibilities
12:50:31 20 in the company?

12:50:35 21 A. No.

12:50:42 22 Q. Are you today personally receiving
12:50:43 23 royalties from Ddrops for the '958 Patent?

12:50:52 24 A. Yes.

12:50:59 25 Q. If the '958 Patent were to be found

12:51:02 1 invalid, would you stop receiving royalties from
12:51:06 2 Ddrops?
12:51:06 3 MR. ANDERSON: Objection, lacks
12:51:08 4 foundation, calls for speculation and a legal
12:51:09 5 conclusion.
12:51:14 6 THE WITNESS: Answer: I don't know.
12:51:26 7 BY MR. CONRAD::
12:51:27 8 Q. How did the Ddrops Company come to be
12:51:31 9 formed? What do you remember about that?
12:51:34 10 MR. ANDERSON: Objection, no foundation.
12:51:38 11 THE WITNESS: The Ddrops Company is some
12:51:40 12 sort of a legal word and I don't know the
12:51:45 13 sequence of things. I recognize -- I stayed
12:51:49 14 out of it as much as I could.
12:51:51 15 BY MR. CONRAD::
12:51:52 16 Q. Yeah, it was a bad question. My
12:51:53 17 apologies. I'll ask it a different way.
12:51:57 18 How did you go about commercializing
12:52:00 19 your patent application?
12:52:04 20 MR. ANDERSON: Object to the form of the
12:52:04 21 question.
12:52:14 22 THE WITNESS: Is this something that is
12:52:15 23 relevant?
12:52:15 24 MR. ANDERSON: It's not -- the question is
12:52:16 25 for you to answer.

12:52:17 1 THE WITNESS: All right. Well, after the
12:52:21 2 patent was filed Elaine sourced components of
12:52:28 3 products, we kind of evaluated them, whether
12:52:31 4 they would work. And then we got it branded.

12:52:37 5 We found eventually, through various
12:52:40 6 traumas, custom manufacturers for the product.
12:52:43 7 So we had product manufactured, hired a
12:52:48 8 distributor and got it put into stores.

12:52:52 9 We were lucky it got listed but it didn't
12:52:57 10 do really well. We needed marketing help and
12:53:02 11 eventually Chris came along.

12:53:04 12 BY MR. CONRAD::

12:53:04 13 Q. So you had launched or attempted to launch
12:53:08 14 a commercial product for your vitamin D drops?

12:53:13 15 A. Yeah, well --

12:53:14 16 MR. ANDERSON: Wait for him to finish the
12:53:15 17 question.

12:53:16 18 BY MR. CONRAD::

12:53:16 19 Q. So you had launched or attempted to launch
12:53:18 20 a commercial product for your vitamin D drops, had
12:53:21 21 some trouble with marketing and you found the answer
12:53:24 22 to that problem with Chris Temovsky and that's where
12:53:29 23 the partnership began?

12:53:30 24 MR. ANDERSON: Object to the form of the
12:53:31 25 question. Mischaracterizes testimony, no

12:53:35 1 foundation.

12:53:35 2 THE WITNESS: At the time, you don't know
12:53:37 3 what an answer is. Entrepreneurship is like an
12:53:41 4 exploration and who knows what the path will
12:53:45 5 lead to, whether it was Chris or not. So it
12:53:48 6 was not something that I was hugely involved
12:53:50 7 with.

12:53:54 8 BY MR. CONRAD::

12:53:58 9 Q. Okay. About how long -- so the initial
12:54:04 10 launch was run by Mrs. Vieth. Before Chris Temovsky
12:54:13 11 came into the picture, who else was with her, if
12:54:16 12 anybody, helping her run that business?

12:54:19 13 MR. ANDERSON: Objection, no foundation.

12:54:21 14 THE WITNESS: There was one other
12:54:22 15 employee.

12:54:24 16 BY MR. CONRAD::

12:54:24 17 Q. Who was that?

12:54:26 18 A. You want to know the name?

12:54:28 19 Q. If you remember, yes.

12:54:29 20 A. The name was Shannon Fisher.

12:54:32 21 Q. Is she still with Ddrops today?

12:54:34 22 A. No.

12:54:36 23 Q. About how long was she trying to
12:54:40 24 commercialize the product independently before she
12:54:43 25 partnered with Chris Temovsky?

12:54:45 1 MR. ANDERSON: Object to the form of the
12:54:47 2 question, mischaracterizes testimony, no
12:54:51 3 foundation.

12:54:52 4 THE WITNESS: A bit over a year, I guess.

12:54:54 5 BY MR. CONRAD::

12:54:59 6 Q. How did -- did you know Mr. Temovsky
12:55:03 7 before you were introduced to him? That's a bad
12:55:07 8 question.

12:55:10 9 How did you get introduced to
12:55:13 10 Mr. Temovsky?

12:55:14 11 MR. ANDERSON: Objection, assumes facts
12:55:15 12 not in evidence.

12:55:19 13 THE WITNESS: How did we -- I first met
12:55:26 14 him at a meeting. He approached Elaine and we
12:55:31 15 met at his wife's office actually.

12:55:35 16 BY MR. CONRAD::

12:55:36 17 Q. What was the meeting you are referring to?

12:55:38 18 A. Pardon me?

12:55:39 19 Q. Which meeting?

12:55:43 20 A. Kind of a "Hi, I'm Chris Temovsky. I've
12:55:48 21 worked with some major pharmaceutical company in
12:55:54 22 marketing. I think I can help you. Let's be
12:55:57 23 partners."

12:55:57 24 Q. Okay. So he pitched to you and
12:56:01 25 Mrs. Vieth?

12:56:02 1 A. Correct.

12:56:03 2 Q. How did he learn about your product?

12:56:06 3 MR. ANDERSON: Objection, no foundation.

12:56:08 4 Calls for speculation.

12:56:11 5 THE WITNESS: A contract manufacturer that

12:56:12 6 we had had a person working there who

12:56:20 7 apparently told Chris "Hey, there's a good

12:56:24 8 product. They just need some marketing help."

12:56:28 9 And that's how Chris learned about Elaine.

12:56:36 10 BY MR. CONRAD::

12:57:47 11 Q. Do you -- prior to this legal action, do

12:57:53 12 you -- did you know Dr. Paul Horowitz, personally?

12:58:00 13 A. Never, no.

12:58:32 14 Q. Other than vitamin D, did you use

12:58:35 15 medium-chain triglycerides to make compositions with

12:58:39 16 other sorts of -- any other active substances?

12:58:43 17 A. At what time? What context?

12:58:45 18 Q. Let's talk about ever.

12:58:47 19 A. Ever? Ever?

12:58:49 20 Q. Yes.

12:58:51 21 A. Well, if you look, you will find that we

12:58:53 22 have a patent with medium-chain triglycerides and

12:58:57 23 menthol that arose around 2012, 2013.

12:59:05 24 Q. So since vitamin D there are other

12:59:08 25 substances -- substances that you are using

12:59:15 1 medium-chain triglyceride as the base of the

12:59:19 2 composition?

12:59:20 3 A. Yes.

12:59:20 4 Q. What about before -- before the '958

12:59:26 5 Patent; were there any other uses of MCT that you

12:59:30 6 had?

12:59:31 7 A. It was not on my radar.

12:59:54 8 Q. Earlier you mentioned some of the ways

12:59:56 9 you -- some of the surfaces you tested putting a

12:59:59 10 drop on. You mentioned a pacifier, a finger, others

01:00:07 11 tested a nipple. A bottle nipple, you tested,

01:00:16 12 right?

01:00:17 13 A. Mm-hmm.

01:00:18 14 Q. Was that a "yes"?

01:00:19 15 A. Yes.

01:00:21 16 Q. Why were those the surfaces that you came

01:00:25 17 up with to put a drop on?

01:00:32 18 A. Those were surfaces that were related to

01:00:35 19 the way infants feed.

01:00:40 20 Q. So they were surfaces that you knew babies

01:00:46 21 get -- that they put in their mouth to feed?

01:00:51 22 MR. ANDERSON: Object to the form of the

01:00:51 23 question.

01:00:52 24 MR. CONRAD: Well, it is a bad question.

01:00:56 25 MR. ANDERSON: I got one right.

01:00:57 1 MR. CONRAD: You did. Congratulations.

01:01:00 2 MR. ANDERSON: Thank you.

01:01:00 3 BY MR. CONRAD::

01:01:01 4 Q. The -- I guess it's natural to assume that

01:01:03 5 those surfaces are the type that a baby would accept

01:01:08 6 in its mouth because of its -- how it's naturally

01:01:13 7 fed, right?

01:01:14 8 MR. ANDERSON: Object to the form of the

01:01:14 9 question.

01:01:18 10 THE WITNESS: You know, they are all

01:01:22 11 surfaces that a baby would suck on.

01:01:24 12 BY MR. CONRAD::

01:01:25 13 Q. Are there any other surfaces like that

01:01:27 14 that you had thought of to test?

01:01:31 15 A. Not that I can think of right now, in

01:01:36 16 terms of trying to re-recall. Would pacifiers --

01:01:51 17 MR. ANDERSON: Wait for the question, sir.

01:02:14 18 MR. CONRAD: All right. I will pass the

01:02:15 19 witness.

01:02:18 20 RE-DIRECT EXAMINATION BY MR. ANDERSON

01:03:29 21 Q. Dr. Vieth, I get to ask you a few

01:03:31 22 questions.

01:03:32 23 A. Yes.

01:03:33 24 Q. Okay. So first off, earlier in your

01:03:35 25 testimony you described attempting to obtain or

01:03:38 1 going to a pharmacy in Germany to obtain Vigantol;
01:03:43 2 do you recall that testimony, sir?
01:03:45 3 A. Yes.
01:03:45 4 Q. And you weren't able to get it; is that
01:03:46 5 correct?
01:03:47 6 A. That's correct.
01:03:48 7 Q. And do you know if that was because you
01:03:51 8 did not have any prescription for it?
01:03:55 9 A. Yes.
01:03:57 10 Q. Do you know whether Vigantol was available
01:04:01 11 by prescription only for adults or for adults and
01:04:06 12 children or either one?
01:04:11 13 A. To my knowledge it was an adult product.
01:04:15 14 Q. So, to your knowledge, it was not a
01:04:18 15 prescription product for children?
01:04:19 16 A. I did not --
01:04:23 17 MR. CONRAD: Objection, foundation.
01:04:26 18 BY MR. ANDERSON::
01:04:26 19 Q. Do you know whether it is a prescription
01:04:28 20 product for children?
01:04:30 21 A. No.
01:04:31 22 Q. No, you don't know or no, it's not?
01:04:33 23 A. I don't know whether it's a -- I knew it
01:04:34 24 was an adult product. I do not know if it's a
01:04:37 25 children product.

01:04:38 1 Q. Okay. Do you know whether Vigantol is
01:04:42 2 available by prescription or otherwise in Canada?
01:04:47 3 A. It is not available.
01:04:49 4 Q. Do you know whether Vigantol is available
01:04:50 5 by prescription or otherwise in the United States?
01:04:55 6 A. It is not available there.
01:04:56 7 (Court reporter clarification)
01:04:56 8 THE WITNESS: It is not available in the
01:04:59 9 United States.
01:05:02 10 BY MR. ANDERSON:
01:05:04 11 Q. You were asked some questions, sir,
01:05:07 12 relating to -- and the context was paragraphs 47,
01:05:18 13 48, 49, 50 and 51 of your declaration, which is
01:05:25 14 Exhibit 2068.
01:05:27 15 You were asked some questions about
01:05:29 16 how you know how or what infants or babies do in
01:05:34 17 terms of lick; do you remember those questions, sir?
01:05:36 18 A. Yes.
01:05:41 19 Q. And you mentioned that you read research
01:05:43 20 in peer-reviewed articles; do you recall that, sir?
01:05:45 21 A. Yes.
01:05:46 22 Q. Were you -- are you aware of how infants
01:05:52 23 lick or feed based on your examination of
01:05:55 24 peer-reviewed articles as a researcher in your
01:05:58 25 field?

01:05:59 1 MR. CONRAD: Objection, foundation,
01:06:01 2 improper opinion testimony.
01:06:04 3 THE WITNESS: Can you repeat that
01:06:05 4 question.
01:06:05 5 MR. ANDERSON: Sure. Can you read the
01:06:06 6 question back, please, for me?
01:06:07 7 COURT REPORTER: "Question: Are you aware
01:06:07 8 of how infants lick or feed based on your
01:06:07 9 examination of peer-reviewed articles as a
01:06:07 10 researcher in your field?"
01:06:21 11 THE WITNESS: Yes.
01:06:21 12 BY MR. ANDERSON:
01:06:21 13 Q. And is that, you know, reading
01:06:25 14 peer-reviewed articles something that you normally
01:06:27 15 do as a researcher in your field?
01:06:31 16 A. Yes.
01:06:32 17 Q. Why do you do that?
01:06:40 18 A. It is my modus operandi, is the way I
01:06:44 19 work.
01:06:45 20 Q. What do you gain from reading
01:06:47 21 peer-reviewed articles in your field?
01:06:52 22 A. By reading peer-reviewed articles you get
01:06:55 23 what is, by objective measure, the most complete,
01:06:59 24 objective, real answer to a topic.
01:07:03 25 Q. And did that include peer-reviewed

01:07:06 1 articles, three of which are identified in your
01:07:09 2 declaration, relating to how infants feed or -- what
01:07:14 3 I'll call their licking function or licking
01:07:16 4 movement?

01:07:17 5 A. Yes.

01:07:30 6 Q. You were asked some questions with regard
01:07:31 7 to what's been referred to as the Harder reference;
01:07:34 8 do you recall that, sir?

01:07:35 9 A. Yes.

01:07:36 10 Q. And you had a number of, I'll call them
01:07:40 11 criticisms that you described of the Harder
01:07:42 12 reference; do you recall that, sir?

01:07:45 13 A. Yes.

01:07:48 14 Q. In your declaration, which is Exhibit
01:07:51 15 2068, do you have a number of criticisms or issues
01:07:59 16 with Harder, that you describe there?

01:08:04 17 A. Yes.

01:08:05 18 Q. And without going through them, would
01:08:07 19 you -- would it be fair to say that, as you sit here
01:08:09 20 today, you would refer to those -- those criticisms
01:08:13 21 or comments on Harder?

01:08:18 22 A. I'm sorry, I didn't understand what --

01:08:20 23 Q. Sure. Without taking the time to go
01:08:22 24 through every single one --

01:08:23 25 A. Yes.

01:08:23 1 Q. -- would it be fair to say that, as you
01:08:25 2 sit here today, you would refer to or rely on your
01:08:27 3 comments relating to Harder as set forth in your
01:08:30 4 declaration?

01:08:30 5 A. I would refer to those, yes.

01:08:32 6 Q. Okay. You were asked some questions with
01:08:38 7 regard to commercialization of the product after you
01:08:44 8 filed a patent application; do you recall those
01:08:46 9 questions, sir?

01:08:47 10 A. Yes.

01:08:47 11 Q. And you indicated, and correct me if I'm
01:08:52 12 wrong, that you were not really involved in
01:08:54 13 commercialization of the product; is that correct?

01:08:58 14 A. That's correct.

01:08:58 15 Q. So it would be fair to say that you don't
01:09:01 16 have any first-hand knowledge of how it was being
01:09:05 17 received in the market; is that true?

01:09:12 18 MR. CONRAD: Objection, misstates
01:09:13 19 testimony.

01:09:20 20 THE WITNESS: I didn't have knowledge of
01:09:21 21 how it was being received because I never
01:09:23 22 contacted -- yeah.

01:09:25 23 BY MR. ANDERSON::

01:09:26 24 Q. Okay. I'd like to refer you to paragraphs
01:09:30 25 54 and 55 of your declaration, Exhibit 2068, sir; do

01:09:36 1 you have those, sir?

01:09:37 2 A. Yes.

01:09:38 3 Q. In paragraph 54 you relate an incident at

01:09:43 4 a trade show in about 2008; do you see that, sir?

01:09:48 5 A. Yes.

01:09:49 6 Q. Do you have any -- do you recall, as you

01:09:51 7 say, indicate in that paragraph that "A

01:09:55 8 representative of Enfamil, which sells D-Vi-Sol,

01:09:59 9 told me 'You have a nice new technology here, it's

01:10:04 10 really good'."

01:10:06 11 A. Yes.

01:10:07 12 Q. Is there any question in your mind that

01:10:09 13 that was related to you by the representative of

01:10:12 14 Enfamil?

01:10:14 15 MR. CONRAD: Objection, hearsay.

01:10:16 16 THE WITNESS: No. No doubt.

01:10:17 17 BY MR. ANDERSON::

01:10:19 18 Q. You don't know whether, at least -- never

01:10:22 19 mind.

01:10:22 20 In paragraph 55 you relate to an

01:10:31 21 instance where a sales representative for Jamieson

01:10:36 22 told your wife that they wanted to figure out how to

01:10:38 23 do a product like Ddrops; do you see that, sir?

01:10:42 24 A. Yes.

01:10:42 25 Q. What is Jamieson?

01:10:44 1 A. Jamieson is Canada's biggest vitamin
01:10:48 2 company. Any drug store you walk into, you will see
01:10:51 3 shelves of it.
01:10:52 4 Q. Okay. And were you sitting across the
01:10:56 5 aisle, the airplane from your wife?
01:10:59 6 A. Yes.
01:11:00 7 Q. And did you overhear this conversation?
01:11:04 8 MR. CONRAD: Objection, hearsay.
01:11:05 9 THE WITNESS: Most of the conversation,
01:11:05 10 yes. They were talking.
01:11:06 11 BY MR. ANDERSON::
01:11:07 12 Q. Did you overhear the sales representative
01:11:09 13 for Jamieson telling your wife that they wanted to
01:11:12 14 figure out how to do a product like Ddrops?
01:11:15 15 MR. CONRAD: Objection, hearsay.
01:11:17 16 THE WITNESS: Well, that's what my wife
01:11:19 17 reported back.
01:11:20 18 I know the conversation went on, but on an
01:11:22 19 airplane how can I --
01:11:23 20 BY MR. ANDERSON:
01:11:25 21 Q. Okay.
01:11:25 22 A. You know, that's what my wife told me and
01:11:28 23 it was clear that Jamieson was interested.
01:11:31 24 Q. Now, you are not a -- you are not a
01:11:37 25 certified translator in any way of the German

01:11:39 1 language into English, correct, sir?

01:11:41 2 A. Correct.

01:11:42 3 Q. And you were asked some questions about

01:11:46 4 whether in your -- as you described it, household

01:11:50 5 German --

01:11:51 6 A. Mm-hmm.

01:11:51 7 Q. -- with your parents, whether you

01:11:54 8 recalled -- the two words are "zum Ablecken" being

01:11:59 9 used?

01:12:00 10 A. Yeah.

01:12:02 11 Q. As you sit here today, do you have a

01:12:04 12 recollection of those two words ever being used in

01:12:06 13 your household German --

01:12:08 14 A. Absolutely not. That's funny.

01:12:11 15 Q. Now, in your declaration you reference

01:12:18 16 that there are three different translations. This

01:12:21 17 is in paragraph 57, sir --

01:12:23 18 A. Yes.

01:12:23 19 Q. -- of the so-called Harder reference; do

01:12:25 20 you see that?

01:12:26 21 A. Yes.

01:12:27 22 Q. As a researcher, if you were confronted

01:12:30 23 with a foreign language publication, would you keep

01:12:36 24 getting translations until you got one that suited

01:12:38 25 you or would you take the first one?

01:12:41 1 A. The first one.

01:12:42 2 MR. CONRAD: Objection, leading.

01:12:43 3 Objection leading.

01:12:44 4 BY MR. ANDERSON::

01:12:45 5 Q. Why?

01:12:46 6 A. No, you take what the expert gives you.

01:12:55 7 Q. Why wouldn't you keep going back to get

01:12:57 8 different variations?

01:12:59 9 MR. CONRAD: Objection, leading.

01:13:00 10 THE WITNESS: I could not see any rational

01:13:02 11 reason why, if I had a translation that I would

01:13:05 12 want something different.

01:13:07 13 BY MR. ANDERSON::

01:13:15 14 Q. I'm going to hand you, sir, what has been

01:13:17 15 marked as Exhibit 2071. It is a copy of an article

01:13:30 16 that appeared in the publication "VMC Public Health"

01:13:35 17 entitled "Very high vitamin D supplementation rates

01:13:39 18 among infants aged two months in Vancouver and

01:13:44 19 Richmond, British Columbia, Canada."

01:13:47 20 And there are a number of authors,

01:13:49 21 the lead author is an individual named Barbara

01:13:53 22 Crocker.

23 (R. VIETH Exhibit 2071 was marked for

24 identification.)

25 BY R. ANDERSON:

01:13:55 1 Q. Do you see Exhibit 2071, sir?

01:13:57 2 A. Yes.

01:13:58 3 Q. Are you familiar with the journal "VMC

01:14:04 4 Public Health"?

01:14:05 5 A. Yes.

01:14:05 6 Q. Is it a -- how are you familiar with it?

01:14:09 7 A. It's a well-recognized peer-reviewed

01:14:13 8 journal. As a minor, point I have reviewed for that

01:14:17 9 journal as well.

01:14:18 10 Q. Is it a journal that you, as a person in

01:14:21 11 your field, would reference and rely on as an

01:14:23 12 authoritative source for information?

01:14:27 13 A. Yes.

01:14:35 14 Q. I'd like to direct your attention to page

01:14:36 15 6 of 8 of the journal article, the second column,

01:14:42 16 sir.

01:14:48 17 A. Mm-hmm.

01:14:48 18 Q. If you go down to the very bottom of the

01:14:50 19 second column there is a sentence that begins

01:14:52 20 "Interestingly". Do you see that, sir?

01:14:56 21 A. Six of 8.

01:14:58 22 Q. Second column at the bottom, the very last

01:15:00 23 sentence begins: "Interestingly, 80 per cent".

01:15:06 24 Do you see that, sir?

01:15:07 25 A. Mine says "multiple regressions" --

01:15:09 1 Q. The last sentence I'm referring to; not

01:15:11 2 the last paragraph.

01:15:17 3 A. Oh, "Interestingly." Got it.

01:15:19 4 Q. Okay. Could you please read into the

01:15:24 5 record the sentence that begins "Interestingly,

01:15:26 6 80 per cent," and continue to the end of that

01:15:28 7 paragraph, where there then is the reference number

01:15:32 8 25.

01:15:36 9 MR. CONRAD: Objection, hearsay.

01:15:37 10 BY MR. ANDERSON:

01:15:37 11 Q. You can go ahead.

01:15:37 12 A. "Interestingly, 80 per cent of caregivers

01:15:40 13 reported giving their infants Ddrops versus only

01:15:45 14 16 per cent who supplemented with D-Vi-Sol. The

01:15:53 15 reason for the popularity of Ddrops may be their

01:15:56 16 ease of administration, requiring only a single drop

01:16:00 17 that can be placed on a mother's breast prior to

01:16:03 18 nursing, versus the need to use a dropper to

01:16:08 19 administer D-Vi-Sol."

01:16:12 20 Q. What was the year of publication of this

01:16:13 21 article, sir?

01:16:19 22 A. 2011.

01:16:20 23 MR. ANDERSON: Thank you.

01:16:20 24 Pass the witness.

01:16:21 25 MR. CONRAD: No further questions.

01:16:22 1 MR. ANDERSON: We will read and sign. And
01:16:25 2 as I indicated, we will designate, at least for
01:16:27 3 the time being, the transcript as
01:16:29 4 "Confidential, Attorneys' Eyes Only Under the
01:16:32 5 Protective Order."

01:16:33 6 MR. CONRAD: Thank you for your time,
01:16:34 7 Dr. Vieth. You are done.

01:16:35 8 MR. ANDERSON: Now you're done.

01:16:37 9 THE WITNESS: Okay, thank you.

10 --- Whereupon the hearing concluded at 1:16 p.m.

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ERRATA SHEET

CASE NAME: MOM Enterprises LLC v Vieth

CASE NUMBER: IPR2023-00726

DATE: TUESDAY, APRIL 2, 2024

DEPONENT: REINHOLD VIETH, Ph.D.

CORRECTIONS

PG.	LN.	NOW READS	SHOULD READ	REASON
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SIGNATURE _____ DATE _____

1 CERTIFICATE OF SHORTHAND REPORTER

2 I, Lisa M. Barrett, the officer before
3 whom the foregoing deposition was taken, do
4 hereby certify that the foregoing transcript is
5 a true and correct record of the testimony
6 given; that said testimony was taken by me
7 stenographically and thereafter reduced to
8 typewriting under my direction; that reading
9 and signing was not requested; and that I am
10 neither counsel for, related to, nor employed
11 by any of the parties to this case and have no
12 interest, financial or otherwise, in its
13 outcome.

14 IN WITNESS WHEREOF, I have hereunto
15 set my hand this 3rd day of April, 2024

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18
19
20



21 Lisa M. Barrett, RPR, CRR, CRC, CSR
22 Certified Realtime Court Reporter
23 Commissioner of Oaths
24 for the Province of Ontario
25