

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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12 CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY
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16 The virtual deposition of PAUL HOROWITZ,
17 M.D., called by the Petitioner for examination,
18 pursuant to agreement and pursuant to the applicable
19 rules, taken stenographically by Sandra L. Rocca,
20 CSR, CRR, via Zoom, on the 19th of March, 2024, at
21 the hour of 9:00 a.m.
22
23
24

25 Certification No. 084-003435, 1245

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03:16:43 1 MS. KRANING: Casey Kraning from Fish &
09:01:39 2 Richardson appearing on behalf of MOM Enterprises,
09:01:42 3 the Petitioner in this case.
09:01:43 4 MS. FLORENCE: And I am L. Reagan Florence,
09:01:49 5 and I am representing Elaine and Reinhold W. Vieth,
09:01:55 6 Patent Owners in this action and I will be defending
09:01:57 7 the deposition of Dr. Paul Horowitz today. And I'm
09:02:05 8 with Alan Anderson Law Firm.
09:02:05 9 PAUL S. HOROWITZ, M.D.,
09:02:05 10 having been first duly sworn, was examined and
09:02:05 11 testified as follows:
09:02:21 12 CROSS EXAMINATION
09:02:21 13 BY MS. KRANING:
09:02:24 14 Q Good morning, Dr. Horowitz.
09:02:25 15 A Good morning. I have to say it's a little
09:02:28 16 hard to hear you. So I will do my best to ask you
09:02:33 17 to repeat if I don't understand if that's all right.
09:02:36 18 Q Sure. Absolutely. I'll try and speak
09:02:39 19 loudly so that I come through better for you.
09:02:43 20 A Thank you.
09:02:43 21 Q Could you state your full name for the
09:02:46 22 record, please?
09:02:47 23 A Dr. Paul Horowitz.
09:02:50 24 Q And have you been deposed before?
09:02:53 25 A One time when I was very early in practice

09:03:00 1 about a medical case from when I was in training.

09:03:03 2 Q Okay. Was that a medical liability type
09:03:08 3 case?

09:03:09 4 A Yes.

09:03:09 5 Q Okay. So you've never been deposed in
09:03:13 6 connection with your testimony offered as an expert
09:03:17 7 witness?

09:03:17 8 A That's correct.

09:03:18 9 Q So I'm going to go over just a couple of
09:03:29 10 ground rules before we get started. So in the first
09:03:33 11 instance, obviously this is a remote deposition over
09:03:36 12 Zoom so there is inherently, you know, issues with
09:03:40 13 audio quality and transmission. So through all
09:03:43 14 this, our court reporter is going to write down
09:03:46 15 everything that you and I say, so let's do our best
09:03:50 16 to not talk over one another and give us space after
09:03:56 17 — before you answer a question. And so if you can
09:04:03 18 speak clearly and slowly and wait until my
09:04:06 19 question's finished, I'll try and do the same on my
09:04:09 20 end. Okay?

09:04:09 21 A Yes.

09:04:10 22 Q And if you need to take a break at any time,
09:04:13 23 just let me know. I will try to take a break about
09:04:16 24 once an hour, but if you need to take a break before
09:04:20 25 that, just let me know and we'll go off the record.

09:04:23 1 Okay?

09:04:23 2 A Thank you. Yes.

09:04:25 3 Q And you'll need to give verbal answers to my

09:04:31 4 questions. So head shaking or nodding won't be good

09:04:35 5 enough for the record, so give me a "yes" or "no,"

09:04:39 6 for example. Okay?

09:04:39 7 A Yes.

09:04:40 8 Q Now, your attorney may make objections, but

09:04:46 9 do you understand that unless she instructs you not

09:04:50 10 to answer and you choose not to answer, you're

09:04:53 11 otherwise obligated to answer to the extent you can?

09:04:56 12 A Yes, I understand that.

09:04:58 13 Q And you may ask me to clarify a question.

09:05:04 14 But if you answer it, I will take that as an

09:05:07 15 indication that you've understood my question. Is

09:05:11 16 that okay?

09:05:11 17 A Yes.

09:05:12 18 Q And you understand that you're under oath

09:05:17 19 today just as if you were in a courtroom in front of

09:05:21 20 a judge and a jury, right?

09:05:22 21 A I do understand that.

09:05:25 22 Q Is there any reason that you cannot give

09:05:29 23 accurate or complete testimony today?

09:05:32 24 A No.

09:05:34 25 Q Dr. Horowitz, when were you first retained

09:05:43 1 for this matter?

09:05:45 2 A I'm not sure of the exact date. I know that
09:05:50 3 my first communication about it was last -- was last
09:05:56 4 April, April of 2023 when I was first contacted.

09:06:03 5 Q And who contacted you?

09:06:08 6 A I first heard about the potential for an
09:06:15 7 opportunity to serve as an expert witness by Chris
09:06:23 8 Temovsky.

09:06:24 9 Q And did you know Chris Temovsky before he
09:06:32 10 reached out to you?

09:06:33 11 A I had met him I think one time -- one time
09:06:40 12 prior to that many years before.

09:06:43 13 Q Do you have -- did you have any -- let me
09:06:51 14 ask a better question.

09:06:52 15 Do you know why Mr. Temovsky reached out to
09:06:57 16 you as opposed to another pediatrician?

09:07:00 17 MS. FLORENCE: Objection, speculation.
09:07:03 18 Please answer.

09:07:04 19 THE WITNESS: No, I don't know why.

09:07:05 20 BY MS. KRANING:

09:07:09 21 Q You're aware that there's also a parallel
09:07:11 22 district court litigation?

09:07:14 23 A Yes, I have heard that.

09:07:17 24 Q Have you been retained in connection with
09:07:19 25 that litigation as well?

09:07:23 1 A I believe, yes, I have.

09:07:25 2 Q Okay. So just to get started, I want to get

09:07:35 3 a little sense of your background. So let's start

09:07:37 4 with college. Where did you attend college?

09:07:40 5 A I went to college at UC Berkeley.

09:07:46 6 Q And after college, you went to medical

09:07:53 7 school?

09:07:53 8 A I did.

09:07:53 9 Q And where was that?

09:07:56 10 A In Israel.

09:08:03 11 Q And what was the name of the university?

09:08:04 12 A The Tel Aviv University, Sackler School of

09:08:11 13 Medicine.

09:08:11 14 Q Did you always want to be a pediatrician?

09:08:20 15 A No. I did not.

09:08:24 16 Q When did you decide you wanted to become a

09:08:28 17 pediatrician?

09:08:30 18 A In medical school, through some of my

09:08:36 19 training years.

09:08:41 20 Q I see your dog in the background running

09:08:44 21 around. I love dogs so that make me very happy.

09:08:48 22 Okay.

09:08:48 23 So after medical school, what did you do

09:08:50 24 next?

09:08:51 25 A I did my internship, residency and then

09:08:58 1 chief resident year at Children's Hospital
09:09:01 2 Los Angeles.
09:09:02 3 Q Was that all in pediatric medicine?
09:09:11 4 A Yes.
09:09:12 5 Q And where did you go after leaving the
09:09:20 6 Children's Hospital in Los Angeles?
09:09:22 7 A My first job was as an employed physician at
09:09:32 8 the Facey -- that's f-a-c-e-y -- Medical Group.
09:09:42 9 Q Was that in Los Angeles as well?
09:09:45 10 A It's in Los Angeles County.
09:09:48 11 Q And how long were you with the Facey Medical
09:09:58 12 Group?
09:09:59 13 A Somewhere around nine years.
09:10:02 14 Q And where did you work after the Facey
09:10:11 15 Medical Group?
09:10:11 16 A I was recruited to work in Portland, Oregon.
09:10:22 17 Q And where specifically in Portland, Oregon?
09:10:26 18 A My office was in northeast Portland, and my
09:10:33 19 employer was Legacy Emanuel Children's Hospital
09:10:37 20 where I was the head of the pediatric clinics and I
09:10:46 21 was there for about three years.
09:10:48 22 Q Do you recall when that was specifically,
09:10:56 23 what three years?
09:10:57 24 A From around 2005 to around 2008.
09:11:07 25 Q And so in your role at the Emanuel

09:11:15 1 Children's Hospital, were you seeing patients on a
09:11:19 2 daily basis?

09:11:20 3 A Not every single day as I recall, but most
09:11:27 4 days, yes; or at least some of the days.

09:11:30 5 Q What were your other sort of
09:11:34 6 responsibilities other than seeing patients there?

09:11:36 7 A I had an administrative role.

09:11:39 8 Q And what did that entail?

09:11:44 9 A Management of the pediatric clinics, reviews
09:11:50 10 of physicians and extenders, process improvement and
09:12:03 11 participating in various meetings at the hospital
09:12:05 12 level.

09:12:06 13 Q If you had to estimate, about what percent
09:12:11 14 of your time when you were at Emanuel Children's
09:12:15 15 Hospital were you seeing patients compared to doing
09:12:19 16 the rest?

09:12:19 17 A I really don't remember. I can -- I can say
09:12:24 18 it was more than 10 percent and less than
09:12:28 19 100 percent. I just really -- I can't remember.

09:12:35 20 Q That's fair. It was 15 years ago.

09:12:39 21 So where did you go after leaving Emanuel
09:12:42 22 Children's Hospital?

09:12:43 23 A My wife and I moved our family back to Los
09:12:52 24 Angeles and we opened a private practice.

09:12:58 25 Q Was that just you and your wife in the

09:13:07 1 practice or were there other doctors that you

09:13:09 2 recruited in?

09:13:11 3 A For the first couple of years, it was just

09:13:15 4 my wife and me and then we hired a pediatrician.

09:13:25 5 Q And was it -- was it just the three of you

09:13:29 6 then practicing?

09:13:30 7 A Until that associate moved out of state and

09:13:33 8 then was replaced by another associate who is still

09:13:39 9 with us now.

09:13:40 10 Q So I take it now in your role you see

09:13:48 11 patients most days, is that fair?

09:13:50 12 A Most days, yes.

09:13:51 13 Q If you had to estimate, how many of your

09:14:05 14 patients are, you know, say under two years old that

09:14:10 15 you see?

09:14:10 16 A I really can't accurately give you a

09:14:21 17 percentage. I can say many of our patients are

09:14:24 18 under two years old.

09:14:27 19 Q I guess I'll ask a broader question. Just

09:14:32 20 trying to get a sense of your practice and whether

09:14:34 21 you specialize in kids who are under a certain age

09:14:36 22 or, you know, whether you see patients across the

09:14:39 23 spectrum. Can you just tell me a little bit about

09:14:43 24 your practice?

09:14:43 25 A We see newborns all the way up through their

09:14:47 1 21st birthday. I have -- on a given day, I can go
09:14:54 2 from a room where I see a 2-day old to a room where
09:14:59 3 I see a 19-year old. That's not unheard of. And so
09:15:07 4 we definitely see a broad range of ages. Just
09:15:18 5 yesterday I saw a child under two weeks old.

09:15:24 6 Q I want to get some of the terminology worked
09:15:33 7 out. So if we use the words infant and baby, do we
09:15:38 8 understand those to basically mean the same thing?

09:15:43 9 A No, I would not say that. Infant is
09:15:49 10 typically referred to as up to a year of age. A
09:15:54 11 baby could mean anything. These are not specific
09:16:01 12 terms.

09:16:03 13 Q Yeah. That's fair. That's why I kind of
09:16:06 14 wanted to make sure we're on the same page with the
09:16:10 15 language. So infant up to a year.

09:16:12 16 What about if we use the word newborn? What
09:16:16 17 would you consider a newborn?

09:16:19 18 A I think everybody has a different meaning
09:16:24 19 when they say newborn or baby. I prefer to speak in
09:16:36 20 specifics.

09:16:36 21 Q Okay. So all right. So if we say -- I'll
09:16:41 22 try and be specific in my questions. I guess is
09:16:46 23 there another sort of -- is there other terminology
09:16:51 24 that we can use to kind of separate out the stages
09:16:53 25 of an infant when they're under a year old or are

09:16:57 1 there different like developmental periods that
09:17:01 2 would be helpful to sort of think about?
09:17:03 3 MS. FLORENCE: Objection, compound. You can
09:17:10 4 answer to the extent that you can answer.
09:17:13 5 THE WITNESS: I just feel that we should
09:17:16 6 stick to being as specific as we can when we're
09:17:20 7 talking about any of these issues.
09:17:26 8 BY MS. KRANING:
09:17:26 9 Q Okay. I want to talk a little bit about how
09:17:40 10 you would give medicine to kind of these different
09:17:44 11 stages of infant. So let's start with say a newborn
09:17:48 12 who is under a month old. What methods would you
09:17:52 13 use to give an under one-month-old baby medicine?
09:18:00 14 MS. FLORENCE: Objection, beyond the scope.
09:18:02 15 Please answer to the extent you can.
09:18:04 16 THE WITNESS: Depending on the kind of
09:18:10 17 medicine that's being administered, you might
09:18:16 18 administer it via injection. You might administer
09:18:22 19 it orally. You might administer it via any manner
09:18:31 20 of instrumentation depending on the setting.
09:18:40 21 BY MS. KRANING:
09:18:46 22 Q Okay. So I heard you mention by injection,
09:18:49 23 orally, and through instrumentation. Are there any
09:18:55 24 other ways that you would administer medicine to a
09:18:59 25 baby who is under one month old?

09:19:01 1 A Yes, I think there are multiple other
09:19:04 2 methods of administration of medication or
09:19:11 3 therapeutic interventions.

09:19:17 4 Q And what are those?

09:19:18 5 A I cannot, sitting here, give you a
09:19:24 6 comprehensive list, but things like intrathecal
09:19:27 7 injections are one way. Intraoperatively
09:19:33 8 medications could be administered; intraocular, if
09:19:40 9 you are trying to treat something in the eyes, in
09:19:45 10 the ear, in the nose. So I cannot give you a
09:19:51 11 comprehensive listing.

09:19:55 12 Q That's helpful. Let's talk just about
09:20:07 13 administering a liquid form of medication. What are
09:20:12 14 the most common ways to administer a liquid
09:20:16 15 medication to a less than one-month-old baby?

09:20:21 16 A If you're talking about giving liquid
09:20:28 17 medication orally, there are some who would
09:20:37 18 administer it via an eye dropper. I have heard of,
09:20:49 19 or seen described anyway, people administering it
09:20:53 20 with a spoon. I have seen and personally had
09:21:00 21 experience administering it on a pacifier and on a
09:21:09 22 gloved fingertip. And there are probably other ways
09:21:21 23 that I cannot think of sitting here at the moment.

09:21:24 24 Q Now, what if we're -- instead of talking
09:21:32 25 about a less than one-month-old baby, what if we're

09:21:36 1 now talking about a one- to four-month old baby,
09:21:42 2 would the method you would use to administer a
09:21:45 3 liquid medication be any different for a one- to
09:21:49 4 four-month old baby?
09:21:50 5 MS. FLORENCE: Objection, speculative.
09:21:53 6 Please answer to the extent you can.
09:21:55 7 THE WITNESS: I think the best method is
09:22:09 8 going to be the method that works to effectively and
09:22:14 9 consistently administer the medication and that
09:22:22 10 might be different from child to child.
09:22:27 11 BY MS. KRANING:
09:22:35 12 Q Now, you mentioned a few different ways
09:22:37 13 earlier to administer liquids. I heard you say use
09:22:41 14 an eye dropper, a pacifier, gloved fingertip. Could
09:22:50 15 all of those be used to consistently and effectively
09:22:57 16 administer liquid medication?
09:23:00 17 MS. FLORENCE: Objection, argumentative.
09:23:02 18 Excuse me. Go ahead and answer.
09:23:03 19 THE WITNESS: Not in my -- no, not in my
09:23:08 20 opinion.
09:23:08 21 BY MS. KRANING:
09:23:08 22 Q And why do you say that? Why is that?
09:23:12 23 A I have a lot of experience working with
09:23:16 24 babies and children and parents and caregivers. And
09:23:26 25 no, they are not interchangeable and they are not

09:23:33 1 equally effective.

09:23:38 2 Q They all could be used to deliver a liquid
09:23:46 3 medicine to a child who is one to four months old?

09:23:49 4 MS. FLORENCE: Objection, speculative. Go
09:23:52 5 ahead and answer to the extent you can.

09:23:54 6 THE WITNESS: As I said, they cannot be used
09:24:01 7 to effectively and consistently administer a
09:24:05 8 medication to a child.

09:24:11 9 BY MS. KRANING:

09:24:12 10 Q So my question was a little bit different.
09:24:14 11 My question was could an eye dropper, spoon,
09:24:18 12 pacifier, and gloved fingertip be used to deliver a
09:24:23 13 liquid to a child who is one to four months old?

09:24:27 14 MS. FLORENCE: Objection, compound.

09:24:29 15 THE WITNESS: Could you just ask a simpler
09:24:33 16 question, please?

09:24:35 17 BY MS. KRANING:

09:24:35 18 Q Sure. Let's break it down. So could an eye
09:24:39 19 dropper be used to deliver liquid to a child who is
09:24:43 20 one to four months old?

09:24:48 21 A I don't believe it could be used to
09:24:51 22 effectively administer it to such a young child on a
09:24:56 23 regular basis, no.

09:24:58 24 Q So you're adding words in there that weren't
09:25:02 25 in my question. What I asked is if I used an eye

09:25:06 1 dropper, you would deliver some amount of a liquid
09:25:09 2 medicine to a child who was one to four months old,
09:25:12 3 right?

09:25:12 4 A Would you say that again, please? One of
09:25:17 5 the words got cut out.

09:25:19 6 Q Sure. I asked if I use an eye dropper to
09:25:23 7 deliver some -- let me start that and ask again.

09:25:29 8 You could use an eye dropper to deliver some
09:25:31 9 amount of a liquid medication to a child who is one
09:25:34 10 to four months old?

09:25:41 11 A Is that a question?

09:25:46 12 Q Yeah. Could an eye dropper be used to
09:25:50 13 deliver some amount of a liquid medication to a
09:25:53 14 child who is one to four months old?

09:25:57 15 A It might be done, but it would not be
09:26:05 16 effective in my opinion.

09:26:10 17 Q Is it your testimony that no liquid would be
09:26:16 18 administered using an eye dropper with a one- to
09:26:20 19 four-month old baby?

09:26:21 20 MS. FLORENCE: Objection, mischaracterizes
09:26:24 21 the testimony. Go ahead and answer.

09:26:30 22 THE WITNESS: There are some situations
09:26:32 23 where an eye dropper is used to administer
09:26:36 24 medication to young infants because that's the only
09:26:41 25 way the medication is provided, for example. But in

09:26:49 1 my experience, there are problems with it much of
09:26:55 2 the time.

09:26:57 3 BY MS. KRANING:

09:27:07 4 Q But again to ask my question, it is not your
09:27:11 5 testimony that no liquid would be administered if
09:27:13 6 you used an eye dropper with a one- to four-month
09:27:16 7 old baby?

09:27:17 8 A I'm sorry. But there are too many negatives
09:27:20 9 in that. I didn't -- maybe you can ask it again.
09:27:25 10 I'm sorry for that.

09:27:26 11 Q No, it's okay. So what I'm trying to get at
09:27:30 12 is some amount of liquid would be administered if
09:27:34 13 you used an eye dropper with a liquid medication in
09:27:37 14 a child one to four months old?

09:27:48 15 A Some of the medication used in an eye
09:27:51 16 dropper to administer to an infant is expected to go
09:27:57 17 into the baby's mouth and get ingested. But I have
09:28:02 18 seen many times where it becomes a source of a
09:28:11 19 challenge for the medication to be administered when
09:28:16 20 done via an eye dropper like that.

09:28:19 21 Q So now, Dr. Horowitz, if the baby was
09:28:37 22 older -- so let's move away from the one- to
09:28:40 23 four-month old baby and let's move into say a four-
09:28:43 24 to six-month-old baby, would it be easier for an
09:28:50 25 older baby to use an eye dropper?

09:28:52 1 MS. FLORENCE: Objection, speculative.
09:28:55 2 Please answer to the extent you can.
09:28:58 3 THE WITNESS: It might be easier, but all
09:29:00 4 babies are different, so I think to expect me to
09:29:06 5 give an opinion about all children four to six
09:29:12 6 months old or in any specific age range is
09:29:18 7 unrealistic.
09:29:21 8 BY MS. KRANING:
09:29:23 9 Q Is it fair, as a general matter, the older a
09:29:27 10 baby gets, the easier it can be to administer liquid
09:29:30 11 medications?
09:29:37 12 A Arguably older children can begin to exert
09:29:44 13 their independence in different ways, so it can
09:29:49 14 become even more challenging for various reasons.
09:29:59 15 Q So in some circumstances it's easier to give
09:30:02 16 liquid medication to a less than -- a younger
09:30:06 17 infant?
09:30:09 18 A It might be.
09:30:10 19 MS. FLORENCE: Objection, mischaracterizes
09:30:11 20 the testimony.
09:30:14 21 BY MS. KRANING:
09:30:24 22 Q Let's talk a little bit about vitamin D
09:30:28 23 since that's sort of the product that we're here to
09:30:30 24 discuss.
09:30:32 25 Do you prescribe vitamin D in your practice?

09:30:40 1 A Vitamin D as an over-the-counter substance.

09:30:47 2 So it doesn't need to be prescribed in the strict

09:30:53 3 sense of the word, but I do recommend it, yes.

09:30:56 4 Q Okay, recommend it. That's the word that I

09:31:01 5 wanted. So let me ask that question again.

09:31:03 6 So do you recommend the use of vitamin D in

09:31:07 7 your current practice?

09:31:11 8 A In accordance with the recommendations by

09:31:15 9 the American Academy of Pediatrics and other

09:31:20 10 organizations, yes, I do recommend that families

09:31:26 11 give vitamin D to their children.

09:31:28 12 Q At what age ranges do you recommend your

09:31:46 13 patients to have vitamin D supplements?

09:31:52 14 A Beginning in the first several days of life

09:31:57 15 in accordance with the recommendations.

09:32:01 16 Q And what about ongoing throughout their, you

09:32:06 17 know, first couple of years, is there a point -- let

09:32:10 18 me ask a better question.

09:32:11 19 When do you generally recommend that parents

09:32:13 20 stop giving their child a vitamin D supplement?

09:32:19 21 MS. FLORENCE: Objection, argumentative.

09:32:22 22 THE WITNESS: In accordance with the

09:32:27 23 recommendations, when the needs of vitamin D are met

09:32:32 24 through other forms of nutrition, then a supplement

09:32:42 25 is no longer needed or recommended.

09:32:48 1 BY MS. KRANING:

09:32:49 2 Q When does that generally happen?

09:32:55 3 MS. FLORENCE: Objection, speculative.

09:32:56 4 THE WITNESS: It's different for all

09:33:01 5 children, but the American Academy of Pediatrics'

09:33:11 6 recommendation I think is that when a child is

09:33:16 7 drinking a liter of milk a day, but there are other

09:33:22 8 sources of vitamin D in a western diet due to

09:33:29 9 supplementation fortification, for example.

09:33:35 10 BY MS. KRANING:

09:33:38 11 Q What do you mean by that?

09:33:43 12 A Which part was not clear?

09:33:45 13 Q Yeah. So what are the other sources of

09:33:51 14 vitamin D in a western diet? What is that referring

09:33:55 15 to?

09:33:55 16 A The main -- well, fatty fish is a source of

09:34:10 17 vitamin D naturally, but many cereals and other

09:34:18 18 foodstuffs are fortified with vitamin D in order to

09:34:25 19 help meet the need.

09:34:27 20 Q Okay.

09:34:29 21 A So that's what I'm referring to.

09:34:31 22 Q Okay. That makes sense. You also mentioned

09:34:38 23 I think you said when a child is drinking a liter of

09:34:41 24 milk a day. When does that usually happen?

09:34:54 25 A Although that's written in the AAP's

09:35:02 1 recommendation, even at a year of age, we don't
09:35:09 2 recommend that infants are getting more than about
09:35:14 3 16 ounces of milk a day. So there are many children
09:35:20 4 who never get to a liter of milk in a given day.

09:35:26 5 Q Okay. So we wouldn't equate that to like a
09:35:32 6 two-year-old baby or something like that because at
09:35:34 7 that point, they would be given food from other
09:35:39 8 sources than just milk, is that fair?

09:35:41 9 MS. FLORENCE: Objection, calls for
09:35:43 10 speculation. Please answer to the extent you can.

09:35:45 11 THE WITNESS: They might be in my
09:35:49 12 experience, yes.

09:35:50 13 BY MS. KRANING:

09:36:00 14 Q In your experience, have you ever instructed
09:36:06 15 a patient -- or parents to stop giving their child a
09:36:13 16 vitamin D supplement?

09:36:20 17 A I have had patients ask me if they should
09:36:27 18 stop it and what I have instructed them to do is
09:36:30 19 calculate the amount of vitamin D that their child
09:36:34 20 gets based on what they're eating and the
09:36:38 21 fortification of those foods and the vitamin D
09:36:41 22 content in those foods to calculate whether or not
09:36:47 23 the child is getting enough based on the
09:36:51 24 recommendations.

09:36:53 25 Q So do you have -- do you have parents --

09:37:07 1 strike that.

09:37:07 2 Do you have patients who you see who aren't

09:37:12 3 taking vitamin D supplements after two years of age?

09:37:18 4 A I believe so.

09:37:19 5 Q Do you ever prescribe vitamin D to older

09:37:26 6 children or to adults?

09:37:30 7 A I have done so in the past for children who

09:37:44 8 are older and not getting their needs met via

09:37:50 9 nutrition.

09:37:52 10 Q Do you recall what age those patients were?

09:38:04 11 A No, I don't recall sitting here now. I can

09:38:10 12 say that sometimes even teenagers will get a

09:38:16 13 vitamin D and calcium supplement, but I cannot tell

09:38:25 14 you exactly a specific case or amount.

09:38:33 15 Q Now, in your practice when you recommend to

09:38:52 16 your patients -- let me strike that and use a more

09:38:58 17 specific term.

09:39:00 18 In your practice when you recommend to your

09:39:03 19 patients who are under a year of age to use

09:39:07 20 vitamin D, what form do you generally recommend that

09:39:11 21 they supplement with?

09:39:20 22 A A liquid vitamin D drop.

09:39:24 23 Q Anything else?

09:39:43 24 A No. I will tell them that there are other

09:39:50 25 forms on the market, but their choice is to give one

09:40:00 1 full milliliter of liquid versus giving a single
09:40:07 2 drop and in my experience, it's very easy to give a
09:40:16 3 single drop.

09:40:21 4 Q That's your practice today. I want to sort
09:40:42 5 of step back to the time of the invention, which is
09:40:45 6 in 2006, what we lawyers call the priority date of
09:40:51 7 the patent.

09:40:51 8 Now, I believe you said in 2006 you were
09:40:53 9 working at the Legacy Emanuel Hospital?

09:41:01 10 A Yes, that's right.

09:41:03 11 Q And while you were at the Legacy Emanuel
09:41:07 12 Hospital in 2006, were you recommending vitamin D
09:41:10 13 supplementation to your patients?

09:41:12 14 A I believe I was, but I cannot sit here and
09:41:20 15 definitively say that I recommended it.

09:41:24 16 Q Do you recall at all what form you would
09:41:28 17 have recommended the vitamin D supplementation in?

09:41:33 18 A Well, at the time as far as I know, there
09:41:35 19 were only the aqueous forms available to patients
09:41:42 20 which would be one full milliliter like the
09:41:47 21 D-Vi-Sol, for example.

09:41:53 22 Q Do you recall if there were any other forms
09:42:03 23 available at that time besides the 1 mL liquid
09:42:14 24 solution?

09:42:14 25 A Well, vitamin D could be given as an

09:42:23 1 injection and there may have been other forms
09:42:34 2 available elsewhere, but not that I was aware of at
09:42:39 3 the time as I recall sitting here now.

09:42:41 4 Q Are there vitamin D tablets?

09:42:58 5 A Tablets are generally for older children. I
09:43:01 6 thought we were talking about young children.

09:43:04 7 Q That's fair. That's fair. I sort of
09:43:07 8 switched my question a little bit.

09:43:09 9 So for young kids, tablets would not --
09:43:15 10 strike that.

09:43:16 11 For babies under one year, tablets are not a
09:43:19 12 good solution to the problem, right?

09:43:26 13 MS. FLORENCE: Objection, argumentative. Go
09:43:30 14 ahead and answer to the extent you can.

09:43:31 15 THE WITNESS: I don't think I would
09:43:37 16 recommend that a tablet be given orally to a very
09:43:46 17 young child.

09:43:49 18 BY MS. KRANING:

09:43:54 19 Q And a tablet could be given to an older --
09:43:56 20 an older child who could properly chew it?

09:44:04 21 MS. FLORENCE: Objection, speculative.

09:44:07 22 THE WITNESS: Tablets are given to older
09:44:10 23 children and adults.

09:44:14 24 BY MS. KRANING:

09:44:31 25 Q Going back to talking about children who are

09:44:34 1 under a year old, is it common in your experience
09:44:37 2 for a parent to give too much vitamin D to those
09:44:43 3 children?

09:44:46 4 A I don't know what you mean by common. I
09:44:55 5 have heard of case reports and I have seen a case
09:45:00 6 report of a situation where a full milliliter was
09:45:14 7 given when only a drop should have been given.

09:45:28 8 Q Apart from that one case, in your practice
09:45:34 9 have you had experience with patients or parents who
09:45:38 10 have given their child too much vitamin D?

09:45:46 11 A I can't think of a situation where that has
09:45:50 12 happened in my practice.

09:45:53 13 Q And would that have been true in 2006 when
09:45:59 14 you were at Emanuel Children's?

09:46:04 15 A I can't think of a situation at all in my
09:46:12 16 practice.

09:46:14 17 Q What about the opposite of that? In your
09:46:29 18 practice, how common is it that you've seen parents
09:46:32 19 who have given too little vitamin D to their
09:46:36 20 children under a year old?

09:46:39 21 A I think the only way to know if someone's
09:46:55 22 getting too little is to measure levels routinely,
09:47:00 23 which is not done in pediatrics, at least as a
09:47:07 24 matter of screening.

09:47:07 25 Q So it would be hard to tell if your routine

09:47:16 1 patients are not getting enough vitamin D?

09:47:19 2 MS. FLORENCE: Objection, mischaracterizes

09:47:20 3 the testimony. Answer to the extent you can.

09:47:22 4 THE WITNESS: Would you ask me again,

09:47:24 5 please?

09:47:25 6 BY MS. KRANING:

09:47:27 7 Q Sure. Is it fair to say that it would be

09:47:30 8 very difficult to tell if your patients were not

09:47:34 9 getting enough vitamin D?

09:47:37 10 A I can say I might not know if a patient is

09:47:55 11 not getting enough vitamin D.

09:48:01 12 Q I think you said that you would have to

09:48:03 13 screen the patient for that specifically, right?

09:48:11 14 A Well, you asked me if it's common for

09:48:14 15 children to not get enough vitamin D and I said that

09:48:19 16 the only way to know that is to screen, which is not

09:48:24 17 done as a matter of routine in general pediatrics.

09:48:29 18 Q So how can a parent know if they're giving

09:48:48 19 too much or too little vitamin D?

09:48:55 20 A I think a parent would not know for a fact

09:49:27 21 that their child is or is not getting enough

09:49:31 22 vitamin D without knowing what the levels are in

09:49:34 23 their blood. And we have recommendations that we

09:49:43 24 use to follow in order to assure that the children

09:49:54 25 are getting a recommended amount.

09:49:58 1 Q Am I right that severe vitamin D deficiency
09:50:16 2 leads to the development of rickets?
09:50:22 3 MS. FLORENCE: Objection, speculative.
09:50:23 4 Answer to the extent you can.
09:50:25 5 THE WITNESS: Vitamin D deficiency leads to
09:50:30 6 rickets in children.
09:50:32 7 BY MS. KRANING:
09:50:34 8 Q How common is rickets in children today?
09:50:38 9 A I think rickets is variable from place to
09:50:51 10 place and as it says in my testimony, depending on
09:51:01 11 what part of the world you're in and the seasonal
09:51:05 12 variation. But I can't give you prevalence data
09:51:10 13 because I don't know that off the top of my head.
09:51:14 14 Q Do you have any sense for how common rickets
09:51:19 15 is in children in the United States?
09:51:24 16 A What do you mean by rickets?
09:51:29 17 Q You used the term "rickets." What do you
09:51:37 18 mean by rickets?
09:51:38 19 A Rickets generally refers, in my world, to
09:51:48 20 changes in the appearance of the bones because of
09:51:51 21 the effect on the growth plates in growing children.
09:51:57 22 Q So using that understanding, do you have any
09:52:03 23 sense for how common rickets is in children in the
09:52:06 24 United States?
09:52:07 25 A No, I don't have numbers.

09:52:19 1 Q Have you yourself ever treated a patient for
09:52:22 2 rickets?

09:52:23 3 A I believe in my training there was a patient
09:52:30 4 with rickets, but not in practice that I can recall
09:52:36 5 sitting here right now.

09:52:37 6 Q Going back to 2006, I think you said earlier
09:53:05 7 that in 2006, the order of vitamin D supplementation
09:53:13 8 was generally the 1 mL dose, is that right?

09:53:17 9 A What I said was that that was the one that
09:53:24 10 was available that I can think of right here and
09:53:32 11 now, yeah. Like I said in my testimony, cod liver
09:53:51 12 oil had been recommended prior to that for
09:53:55 13 generations.

09:53:58 14 Q Fair. I think I read that for the cod liver
09:54:02 15 oil, that that was a recommended like 5 milliliter
09:54:07 16 dose?

09:54:09 17 A Well, I think in various places you would
09:54:11 18 see it as a teaspoon or a spoonful, but in our world
09:54:20 19 of medicine, we generally equate a teaspoon to
09:54:26 20 5 milliliters. So that's what I put in my
09:54:30 21 declaration.

09:54:31 22 Q Going back to 2006 and the 1 milliliter
09:54:41 23 dose, using that dose, how common was it for a
09:54:45 24 parent to give too much vitamin D?

09:54:51 25 A I don't know the answer to that.

09:54:52 1 MS. FLORENCE: Objection, speculative.

09:54:54 2 BY MS. KRANING:

09:55:00 3 Q Do you know how common it was in 2006 for a

09:55:04 4 parent using the 1 milliliter dose to give too

09:55:07 5 little vitamin D?

09:55:09 6 MS. FLORENCE: Same objection.

09:55:10 7 THE WITNESS: I don't know the answer to

09:55:14 8 that.

09:55:14 9 BY MS. KRANING:

09:55:38 10 Q In 2006, was a one drop vitamin D supplement

09:55:42 11 available in the United States?

09:55:45 12 A I don't know. I've seen prior art that

09:55:59 13 talks about a one drop substance, but I don't know

09:56:10 14 that it was available here.

09:56:12 15 Q And what prior art are you referring to?

09:56:23 16 A Harder.

09:56:24 17 Q And Wolf as well disclosed the one drop of

09:56:34 18 vitamin D, right?

09:56:36 19 A You would need to show me that.

09:56:42 20 Q We'll get to that in a bit, but we have been

09:56:46 21 going for about an hour so why don't we take a short

09:56:49 22 five-minute break.

09:56:51 23 (Short recess.)

10:03:15 24 BY MS. KRANING:

10:03:16 25 Q Welcome back, Dr. Horowitz. What in your

10:03:22 1 words is the problem that the invention of the '958
10:03:30 2 patent solved?

10:03:34 3 A The invention solves the problem of
10:03:40 4 administering a recommended amount of vitamin D to
10:03:45 5 very young children, and to actually all children,
10:03:56 6 because it delivers a specific amount in a specific
10:04:03 7 way with a specific method. And that was
10:04:12 8 unavailable previously and it was a long-standing
10:04:19 9 need.

10:04:23 10 Q You mention very young children in your
10:04:46 11 answer. And so I'm wondering, is it your opinion
10:04:49 12 that the problem that was solved related
10:04:52 13 specifically to just very young children?

10:04:59 14 A Generally speaking, it's more challenging to
10:05:11 15 give medication orally to younger children than to
10:05:20 16 older children.

10:05:22 17 Q And when you're using the phrase "very young
10:05:33 18 children," what is the actual age range that you are
10:05:37 19 attributing to that phrase?

10:05:41 20 A Well, in the spirit of this conversation,
10:05:44 21 since vitamin D is recommended to be given beginning
10:05:47 22 in the first few days of life, that's what I'm
10:05:51 23 referring to when I say that. But the invention
10:05:56 24 solves the problem for any age really.

10:06:02 25 Q And so your testimony is that the problem

10:06:12 1 applied to all ages of children?

10:06:18 2 MS. FLORENCE: Objection, mischaracterizes

10:06:19 3 the testimony. Please answer to the extent you can.

10:06:22 4 THE WITNESS: My testimony is that it can be

10:06:27 5 a challenge to administer vitamin D supplements to

10:06:35 6 people of any age.

10:06:43 7 BY MS. KRANING:

10:06:47 8 Q And that includes adults?

10:06:53 9 A I would say people of any age includes

10:06:57 10 adults, yes.

10:06:58 11 Q The invention here uses one drop of

10:07:20 12 vitamin D oil, right?

10:07:26 13 A The invention uses one drop.

10:07:32 14 Q And specifically just one drop, right?

10:07:38 15 A The recommended dosage of the invention is

10:07:43 16 one drop, as I understand it.

10:07:47 17 Q And that drop can be licked off of a clean

10:08:01 18 surface, right?

10:08:03 19 MS. FLORENCE: Objection, speculative.

10:08:06 20 Please answer to the extent you can.

10:08:08 21 THE WITNESS: The one drop is transferred

10:08:16 22 from a surface to the person.

10:08:25 23 BY MS. KRANING:

10:08:30 24 Q So the drop -- strike that.

10:08:35 25 The one drop of vitamin D oil can be licked

10:08:39 1 off a clean surface, right?

10:08:41 2 A I think you need to ask again. Your voice
10:08:45 3 dropped out.

10:08:46 4 Q Sure. The one drop of vitamin D oil can be
10:08:53 5 licked off of a clean surface, right?

10:08:56 6 A The inventor demonstrated that one drop
10:09:08 7 could be transferred from a surface the patient.
10:09:16 8 When you use the word "licked," it can mean
10:09:21 9 different things. I mean, how many licks, one lick?
10:09:25 10 I don't know. It hasn't -- I don't -- I don't see
10:09:28 11 that in any documentation or lab book. I see -- so
10:09:38 12 I'm trying my best to answer your question. But
10:09:45 13 infants don't lick -- as you see in my testimony,
10:09:47 14 infants don't routinely lick the way a dog or a cat
10:09:52 15 would do. So for the purposes of solving the unmet
10:09:56 16 need that the invention solves, licking is not a
10:10:06 17 word that I would use to characterize the benefit of
10:10:18 18 the invention.

10:10:19 19 Q The patent uses the word lick, right?

10:10:31 20 A Could you direct me to where you're looking?

10:10:34 21 Q Yes. Do you have a copy in front of you?

10:10:37 22 A I do.

10:10:38 23 MS. FLORENCE: Counsel, could you -- excuse
10:10:41 24 me, counsel. Could you put it in front for the
10:10:43 25 court reporter as well on the screen with the share

10:10:46 1 screen, please? Thank you.

10:10:50 2 MS. KRANING: Sure.

10:10:50 3 (Discussion off the record.)

10:10:50 4 (Document marked previously as

10:12:12 5 Exhibit 1001 was presented.)

10:12:12 6 BY MS. KRANING:

10:12:18 7 Q So Dr. Horowitz, for the record, we are

10:12:20 8 looking at MOM 1001. First, do you recognize this

10:12:27 9 document?

10:12:29 10 A I do.

10:12:30 11 Q And what is this document?

10:12:34 12 A United States Patent 9,066,958 B2.

10:12:48 13 Q And you understand this is the patent that's

10:12:53 14 being challenged in this proceeding, correct?

10:12:55 15 A Yes.

10:12:56 16 Q I would like to direct your attention to the

10:13:03 17 last page in column 9 and taking a look at claim 1

10:13:09 18 that starts around line 34.

10:13:17 19 A I see it.

10:13:17 20 Q And claim 1, Section (ii), the claim says,

10:13:24 21 "having said human being suck or lick said

10:13:28 22 composition directly from said object."

10:13:31 23 Do you see that?

10:13:33 24 A Yes, I see that it says suck or lick.

10:13:36 25 Q What is your understanding of what lick

10:13:40 1 means in this claim?

10:13:44 2 A That it's an alternative to suck in that
10:13:50 3 phrasing, that if you are talking about transferring
10:13:59 4 a substance from the surface to the human being,
10:14:08 5 that lick is one of the ways that you could
10:14:14 6 potentially do that.

10:14:15 7 Q Let me go back to my question that we were
10:14:27 8 talking about earlier, that one drop of vitamin D
10:14:29 9 oil can be licked off a clean surface, right?

10:14:32 10 MS. FLORENCE: Objection, mischaracterizes
10:14:33 11 the testimony. Please answer to the extent you can.

10:14:38 12 THE WITNESS: In the case of an adult who is
10:14:44 13 directed to lick a substance from a clean surface to
10:14:50 14 get it into their mouth, and to the extent that they
10:14:55 15 can follow that instruction and wish to do so,
10:15:00 16 licking is a viable — I would think is a viable way
10:15:04 17 to do that.

10:15:08 18 BY MS. KRANING:

10:15:15 19 Q And fair to say that one drop of vitamin D
10:15:17 20 oil can be licked off a clean surface by an adult,
10:15:20 21 right?

10:15:23 22 MS. FLORENCE: Objection, calls for
10:15:25 23 speculation. Please answer to the extent you can.

10:15:27 24 THE WITNESS: I don't know that that has
10:15:31 25 been tested. And without having evidence that that

10:15:38 1 happens with a particular drop, I don't think I can
10:15:45 2 answer that.

10:15:48 3 BY MS. KRANING:

10:15:49 4 Q So are you saying that one drop of vitamin D
10:15:51 5 oil cannot be licked off a clean surface by an
10:15:53 6 adult?

10:15:56 7 MS. FLORENCE: Objection, mischaracterizes
10:15:58 8 the testimony. Calls for speculation. Please
10:16:01 9 answer to the extent you can.

10:16:03 10 THE WITNESS: I cannot say that.

10:16:06 11 BY MS. KRANING:

10:16:19 12 Q So one drop of vitamin D oil could be licked
10:16:22 13 off a clean surface by an adult?

10:16:25 14 MS. FLORENCE: Same objections.

10:16:26 15 THE WITNESS: It might be. If I could
10:16:34 16 direct your attention to the patent, the first page
10:16:40 17 under the abstract it says specifically the
10:16:47 18 compositions are applied to an object such as skin,
10:16:51 19 or in the case of an infant, to a woman's nipple or
10:16:55 20 pacifier from which the infant sucks off the
10:16:59 21 composition.

10:17:02 22 BY MS. KRANING:

10:17:05 23 Q So are you -- Dr. Horowitz, is it your
10:17:08 24 testimony that the patent does not support licking
10:17:13 25 as a method of administering the vitamin D oil?

10:17:17 1 MS. FLORENCE: Objection, argumentative,
10:17:20 2 calls for speculation.
10:17:22 3 THE WITNESS: No, I'm not saying that.
10:17:24 4 BY MS. KRANING:
10:17:49 5 Q So if you instructed an adult to lick one
10:17:54 6 drop of the vitamin D oil from a surface, they would
10:17:59 7 be able to do so, right?
10:18:03 8 MS. FLORENCE: Objection, speculation.
10:18:05 9 Answer to the extent you can.
10:18:08 10 THE WITNESS: My area of expertise is in
10:18:10 11 children, not in adults.
10:18:14 12 BY MS. KRANING:
10:18:17 13 Q You can't say whether an adult could lick a
10:18:19 14 drop of oil off of a surface?
10:18:22 15 MS. FLORENCE: Objection, relevance.
10:18:23 16 THE WITNESS: There are physical properties
10:18:33 17 such as adhesion that determine whether anything can
10:18:37 18 be transferred from one surface to another.
10:18:44 19 BY MS. KRANING:
10:18:45 20 Q That wasn't my question. My question was
10:18:47 21 you can't say whether an adult could lick a drop of
10:18:51 22 oil off of a surface?
10:18:53 23 MS. FLORENCE: Objection, argumentative.
10:18:56 24 THE WITNESS: I can say that that's beyond
10:19:02 25 the scope of my area of expertise.

10:19:07 1 BY MS. KRANING:

10:19:28 2 Q And, Dr. Horowitz, do you have a copy of
10:19:30 3 your declaration?

10:19:37 4 A I do.

10:19:40 5 MS. FLORENCE: Counsel, could you drop that
10:19:41 6 in the chat as well? Sorry. Thank you.

10:19:44 7 MS. KRANING: Yep.

10:19:44 8 (Document marked previously as
10:19:49 9 Exhibit 2069 was presented.)

10:19:49 10 BY MS. KRANING:

10:19:50 11 Q Dr. Horowitz, do you have a clean copy or do
10:19:52 12 you have a copy with your markings on it?

10:19:55 13 A I mean, I have a few markings on it. Would
10:20:00 14 you like me to look at something in particular? If
10:20:04 15 so, please put it up on the screen.

10:20:06 16 Q Yes. And counsel, after this deposition I
10:20:14 17 would like to get a copy of the declaration that
10:20:17 18 he's looking at with those markings.

10:20:18 19 MS. FLORENCE: And just so counsel is aware
10:20:22 20 too, that just might be from his own markings right
10:20:25 21 now but not from previous notes, so no problem.
10:20:28 22 Thank you.

10:20:29 23 BY MS. KRANING:

10:20:29 24 Q So for the record, we are looking at what
10:20:33 25 has been previously marked as Exhibit 2029 [sic] in

10:20:38 1 this matter. And Dr. Horowitz, do you recognize
10:20:42 2 this document?
10:20:45 3 MS. FLORENCE: Sorry. Can you put it up for
10:20:48 4 -- our witness has asked if you would put it up for
10:20:51 5 him, please.
10:20:54 6 MS. KRANING: I thought I asked if he needed
10:20:55 7 me to. I'm fine with him using his paper copy.
10:20:59 8 MS. FLORENCE: Oh.
10:21:00 9 BY MS. KRANING:
10:21:00 10 Q Dr. Horowitz, do you have a preference?
10:21:02 11 MS. FLORENCE: Could you put it up for both
10:21:04 12 of us and just for the record, thank you.
10:21:49 13 BY MS. KRANING:
10:21:49 14 Q So Dr. Horowitz, do you recognize this
10:21:52 15 document?
10:21:52 16 A I do.
10:21:53 17 Q And you agree this is a copy of the
10:21:56 18 declaration that you submitted in this case?
10:22:00 19 A It looks like the front page of it, yes.
10:22:02 20 Q I'm going to go to page 18 of Exhibit 2029.
10:22:16 21 I think that this document has been mislabeled. I
10:22:20 22 think this is document is actually Exhibit 2069, but
10:22:23 23 as I see it, the Bates stamp says 2029. Let me just
10:22:29 24 double-check that for the record. Yeah, counsel,
10:22:36 25 does that seem right to you, that this is

10:22:38 1 Exhibit 2069 rather than 2029?

10:22:42 2 MS. FLORENCE: It might be. Let me

10:22:44 3 double-check that. That might be an error. Let me

10:22:47 4 look into that if that's okay, but let's just

10:22:51 5 identify it by date and signature because we're not

10:22:53 6 100 percent sure. But I'll double-check that.

10:22:56 7 Thank you.

10:22:57 8 MS. KRANING: Okay, thank you.

10:23:00 9 BY MS. KRANING:

10:23:01 10 Q So Dr. Horowitz, I'm on page 18 of this

10:23:05 11 declaration. Is that your signature there?

10:23:07 12 A Yes.

10:23:08 13 Q And you signed this declaration on

10:23:12 14 February 5th, 2024?

10:23:14 15 A Yes.

10:23:15 16 Q And how much time did you spend preparing

10:23:20 17 this declaration?

10:23:21 18 A I don't know how many -- exactly how much

10:23:30 19 time. I worked on it over the course of several

10:23:35 20 months.

10:23:37 21 Q And you testified earlier that you were

10:23:50 22 contacted about this case in April of 2023, is that

10:23:55 23 correct?

10:23:55 24 A Yes.

10:23:55 25 Q Do you recall when you began working on the

10:24:01 1 declaration?

10:24:02 2 A No.

10:24:03 3 Q If you had to ballpark the number of hours

10:24:12 4 that you spent working on this declaration, would it

10:24:16 5 be more or less than 50 hours?

10:24:20 6 A I really can't estimate. I would say --

10:24:39 7 Q Could it --

10:24:40 8 A Yeah, I really -- I don't know.

10:24:45 9 Q I didn't mean to cut you off there. I

10:24:48 10 apologize.

10:24:53 11 Could it have been more than 100 hours of

10:24:56 12 work on preparing this declaration?

10:24:59 13 A I don't think so, no.

10:25:03 14 Q How was this declaration prepared?

10:25:20 15 MS. FLORENCE: Objection, vague.

10:25:22 16 A I wrote it -- I wrote it on my computer.

10:25:31 17 BY MS. KRANING:

10:25:31 18 Q So you prepared the first draft of this

10:25:34 19 declaration?

10:25:34 20 A Yes.

10:25:35 21 Q Did anyone else provide input or revisions

10:25:39 22 to that draft?

10:25:42 23 MS. FLORENCE: Objection. To the extent it

10:25:44 24 calls for attorney-client privilege, please don't

10:25:46 25 answer. But to the extent you can answer any

10:25:49 1 non-privileged information, please do.

10:25:51 2 THE WITNESS: I sought assistance from
10:25:57 3 counsel regarding formatting and form, but not
10:26:08 4 content.

10:26:09 5 BY MS. KRANING:

10:26:19 6 Q So your testimony is that no one made any
10:26:22 7 substantive changes to this declaration besides
10:26:24 8 yourself?

10:26:25 9 A That's right.

10:26:26 10 Q Did you meet — I'm just looking for a
10:26:38 11 yes-or-no answer here. Please do not divulge any
10:26:43 12 privileged conversations.

10:26:47 13 Did you meet with counsel while you were
10:26:50 14 working on preparing this declaration?

10:26:54 15 A Yes.

10:26:54 16 Q And again just a yes-or-no question, did you
10:27:01 17 meet with counsel multiple times while you were
10:27:04 18 preparing this declaration?

10:27:08 19 A Yes.

10:27:09 20 Q Approximately how many times did you meet
10:27:13 21 with counsel while you were preparing this
10:27:16 22 declaration?

10:27:20 23 A Probably between 5 and 25 times. I can't
10:27:35 24 give you a more specific range than that.

10:27:38 25 Q Between 5 and 25 times?

10:27:48 1 A Between 5 and 25 times.

10:27:50 2 Q Other than counsel, did you talk to anyone

10:28:02 3 else in connection with this declaration while you

10:28:07 4 were preparing it?

10:28:08 5 A Yes.

10:28:10 6 Q And who did you speak with?

10:28:14 7 A During one of the meetings, I had asked to

10:28:22 8 meet with the patent holder, Reinhold Vieth, and he

10:28:29 9 participated in one of the meetings.

10:28:37 10 Q Anyone other than Reinhold Vieth?

10:28:45 11 A No.

10:28:45 12 Q And why did you ask to meet with the patent

10:28:52 13 owner, Mr. Vieth?

10:28:54 14 A I had a question about something that was in

10:29:00 15 the lab notebook copies.

10:29:03 16 Q Do you recall specifically what your

10:29:13 17 question was?

10:29:14 18 MS. FLORENCE: Objection. To the extent

10:29:15 19 anything is attorney-client, it's confidential,

10:29:19 20 please do not divulge that, but answer to the extent

10:29:21 21 you can.

10:29:22 22 THE WITNESS: Yes, I vaguely remember.

10:29:31 23 BY MS. KRANING:

10:29:35 24 Q And what was your question?

10:29:43 25 A There was a set of data that I didn't know

10:29:53 1 what the numbers were referring to and it was
10:29:59 2 explained to me what those numbers represented.

10:30:04 3 Q Was that the only question you had for
10:30:17 4 Reinhold Vieth?

10:30:20 5 A I think there were others.

10:30:30 6 Q And what were those questions?

10:30:35 7 A I think I asked him how he got the idea for
10:30:47 8 the invention. And I think there was one other bit
10:30:54 9 of data that I didn't know what the units were
10:30:57 10 referring to, so I asked him about that. But that's
10:31:07 11 all I can remember about that.

10:31:09 12 Q Anything else that you recall?

10:31:10 13 A No.

10:31:11 14 Q Sorry. One of my problems when you're very,
10:31:14 15 very small on the screen is I have a hard time
10:31:15 16 seeing whether it looks like you're still answering.
10:31:19 17 I apologize for that. Okay. So other than your
10:31:32 18 meeting -- well, strike that.

10:31:36 19 Did you only meet with Mr. Vieth one time?

10:31:42 20 A Yes.

10:31:42 21 Q And other than speaking with him, was there
10:31:51 22 anyone else that you spoke with in connection with
10:31:53 23 your declaration, apart from counsel?

10:31:55 24 A No.

10:31:56 25 Q Earlier you mentioned that you had met Chris

10:32:05 1 Temovsky once before. Do you recall that testimony?

10:32:09 2 A Yes.

10:32:11 3 Q Do you recall when you met him?

10:32:19 4 A I don't. It may have been at an American
10:32:27 5 Academy of Pediatrics meeting, but I really am not
10:32:31 6 100 percent sure on that.

10:32:32 7 Q Do you have a ballpark of what year that
10:32:44 8 could have been?

10:32:46 9 A I don't. I mean, it would probably have
10:33:01 10 been -- I really don't remember -- in between
10:33:06 11 probably 2002 and -- I really don't -- I don't
10:33:13 12 remember. I'm sorry. I just remember hearing about
10:33:18 13 these -- this drop to give vitamin D to young
10:33:25 14 children, to infants, and it being something that
10:33:35 15 would really make it a lot easier to administer
10:33:39 16 vitamin D. And I thought it was great. I mean,
10:33:48 17 it's as simple as that.

10:33:52 18 Q Let me ask this, did Mr. Temovsky, when he
10:34:01 19 reached out to you, recall that you had previously
10:34:04 20 met?

10:34:07 21 MS. FLORENCE: Objection, mischaracterizes
10:34:08 22 the testimony. Please answer to the extent you can.

10:34:10 23 THE WITNESS: Would you ask me again,
10:34:20 24 please?

10:34:20 25 ///

10:34:20 1 BY MS. KRANING:

10:34:22 2 Q Yeah. Basically what I'm trying to get at
10:34:25 3 is whether, you know, he reached out to you because
10:34:27 4 he had previously met you or after the fact did you
10:34:31 5 realize, oh, we met at this meeting ten years ago?

10:34:34 6 So my question was did Mr. Temovsky, when he
10:34:39 7 reached out to you, did he remember that you had
10:34:43 8 previously met?

10:34:43 9 A He did because I have been selling vitamin D
10:34:51 10 drops in my office and so we've -- I've had that
10:34:57 11 kind of -- I've had a sort of relationship with the
10:35:03 12 company over a number of years before he then
10:35:08 13 reached out to me and said that there was something
10:35:14 14 happening in the legal space and would it be
10:35:20 15 something that I might be interested in as a
10:35:23 16 pediatrician.

10:35:28 17 Q When did you start selling the vitamin D
10:35:33 18 product in your office?

10:35:37 19 A I don't remember exactly when. We opened
10:35:45 20 our office in 2008. And I saw a recent -- when I
10:35:55 21 looked in my file in anticipation of that question,
10:36:00 22 that there was an order made in 2014 I think it is.
10:36:06 23 So I suppose sometime in between there.

10:36:11 24 Q Do you sell other products out of your
10:36:23 25 office?

10:36:25 1 A We do.

10:36:25 2 Q Approximately how many products do you sell?

10:36:32 3 A Probably four -- you're talking about

10:36:45 4 totally different products. For example, we sell

10:36:50 5 earrings, but they're different colors so different

10:36:54 6 SKUs. We sell hats, different styles. We sell very

10:36:59 7 few albeit breast pads. So probably between three

10:37:10 8 or four and -- I mean, if you're counting all

10:37:13 9 different colors as different items, so you get --

10:37:18 10 you get the idea.

10:37:20 11 Q Okay. Setting aside the different colors

10:37:23 12 and the variants, are these vitamin D drops the only

10:37:28 13 nutritional supplement that you sell out of the

10:37:33 14 office?

10:37:33 15 A I think so.

10:37:33 16 Q How did that start?

10:37:40 17 A When I found that these existed and were

10:37:49 18 going to be such a -- they were a unique at the

10:37:57 19 time, I thought these are terrific, I want to make

10:38:00 20 it convenient for my patients to get it and have it.

10:38:05 21 And so we began -- I had to get a seller's permit

10:38:08 22 and then we began to sell it.

10:38:15 23 Q So was it you who reached out to Ddrops or

10:38:25 24 did Ddrops reach out to you to set that up?

10:38:30 25 A As far as I remember, I reached out to them.

10:38:36 1 I don't think that they were looking to distribute
10:38:41 2 vitamin D drops in doctors' offices and that they
10:38:46 3 actively pursued me.

10:38:54 4 Q Do you know if they sell -- strike that.

10:39:05 5 Do you know if other doctors have a similar
10:39:09 6 arrangement with Ddrops to sell their product in
10:39:13 7 their offices?

10:39:14 8 MS. FLORENCE: Objection, calls for
10:39:15 9 speculation. Answer to the extent you can.

10:39:17 10 THE WITNESS: I don't know.

10:39:17 11 BY MS. KRANING:

10:39:28 12 Q So do you purchase the vitamin D drops from
10:39:33 13 Ddrops first?

10:39:37 14 A I do. Our office does, I should say.

10:39:40 15 Q Is there any sort of agreement that you have
10:39:45 16 set up with Ddrops?

10:39:53 17 A No, not that I'm aware of. We order it. We
10:39:59 18 pay for it. They deliver it. We sell it.

10:40:06 19 Q So you order it just like any customer
10:40:11 20 would?

10:40:13 21 A I don't know about how others do it.

10:40:22 22 Q Well, let me ask it this way. Do you order
10:40:25 23 it in say wholesale, like in bulk?

10:40:30 24 A We order it a case at a time.

10:40:36 25 Q Is it just one of their products or do you

10:40:44 1 offer multiple of their products to your patients?

10:40:47 2 A There's a 600 units per drop concentration
10:40:51 3 that we also order for the older children.

10:40:54 4 Q And what is the other product, the name of
10:41:03 5 it, that you sell?

10:41:04 6 A Pardon me?

10:41:05 7 Q What is the -- so the product, the main
10:41:11 8 product that you sell from Ddrops?

10:41:14 9 A The Baby Ddrops I think is what it's called.

10:41:25 10 Q Do you know approximately how many units
10:41:34 11 you've sold of these products since you started
10:41:39 12 offering them to patients?

10:41:42 13 A No. I can say that we maybe sell a couple a
10:41:48 14 week; a couple of bottles per week, you know. It's
10:41:56 15 not a big source of income to our business.

10:42:05 16 Q And do you resell them at the same price
10:42:13 17 that you purchase them for or do you resell them at
10:42:15 18 a higher markup?

10:42:18 19 MS. FLORENCE: Objection, compound. Please
10:42:21 20 answer to the extent you can.

10:42:22 21 THE WITNESS: We sell the product for more
10:42:27 22 than what it costs us to buy it and then add sales
10:42:33 23 tax to that.

10:42:36 24 BY MS. KRANING:

10:42:38 25 Q And what is the markup that you add to the

10:42:43 1 product?

10:42:44 2 A I don't know the number off the top of my
10:42:54 3 head, but probably somewhere between 30 and
10:43:05 4 70 percent. I know that we sell the 90-day supply
10:43:23 5 for \$20.01 I think it turns out to be with tax.

10:43:34 6 Q I think that you mentioned earlier that you
10:43:48 7 had somewhat of a relationship with the Ddrops
10:43:51 8 company. Did I get that right?

10:43:57 9 A I think I mentioned a professional
10:44:00 10 relationship that only extends to the extent that we
10:44:06 11 buy product. I know the name of Chris Temovsky and
10:44:10 12 I think someone else in the company named Sandy
10:44:14 13 Philp, p-h-i-l-p, who took my orders in the early
10:44:19 14 days when I was the one who actually called to place
10:44:25 15 the orders. But I don't do that anymore usually.

10:44:31 16 Q Is it someone else in your office who makes
10:44:34 17 those phone calls?

10:44:36 18 A Yeah, and I'm not even sure that she does
10:44:39 19 make the phone call or if she faxes in an order or
10:44:43 20 how that works. It's only a couple times a year
10:44:46 21 maybe.

10:44:47 22 Q Did you have to call to place an order that
10:45:04 23 large for a case?

10:45:09 24 A A case is 24 units, I think, or maybe it's
10:45:14 25 even 12. So I don't know if there are other ways

10:45:19 1 that orders can be placed. I'm not even sure how we
10:45:24 2 place them most recently to be honest.

10:45:28 3 Q Do you know or can you approximate how much
10:45:44 4 money you've made from selling the Ddrops products
10:45:48 5 over the past -- since you've been selling them?

10:45:53 6 A No.

10:45:54 7 Q Ballpark?

10:46:32 8 A No, but I would be shocked if it was more
10:46:35 9 than a couple thousand dollars a year.

10:46:38 10 Q Okay. Going back to your declaration, I
10:47:23 11 want to go to -- I want to go to page 6. And I'm
10:47:29 12 going to be looking at paragraph A. And
10:47:34 13 Dr. Horowitz, at any time if you want me to scroll
10:47:37 14 up or down or if you want to review in hard copy,
10:47:40 15 you're absolutely free to do that. Okay.

10:47:57 16 So looking at the last sentence in
10:48:01 17 paragraph 6a, you say, "As will be shown below, the
10:48:08 18 solution provided by the inventors and the '958
10:48:11 19 patent holders solved a problem that was hitherto
10:48:16 20 unmet and existed for a long time."

10:48:18 21 Did I read that right?

10:48:19 22 A Yes.

10:48:20 23 Q The problem that you're referring to in this
10:48:35 24 sentence, was that a problem in the United States?

10:48:51 25 A The problem was -- the problem of

10:48:58 1 administering an effective and efficacious amount of
10:49:05 2 vitamin D is or was a problem that wasn't just
10:49:20 3 unique to young children in the United States as far
10:49:26 4 as I could estimate.

10:49:33 5 Q Do you know from your experience whether
10:49:36 6 this problem existed outside the United States?

10:49:45 7 A I have no experience practicing outside the
10:49:48 8 United States.

10:49:54 9 Q So is the answer no?

10:49:57 10 A Would you ask the question again?

10:49:59 11 Q Sure. Do you know from your experience
10:50:03 12 whether this problem existed outside the United
10:50:06 13 States?

10:50:06 14 A No, I do not know.

10:50:10 15 Q Okay. I'm going to turn in your declaration
10:50:37 16 to page 8 and paragraph F. This is paragraph 6f.
10:50:47 17 Six is on a previous page. You state in
10:50:54 18 paragraph 6f in the first sentence, "It is my
10:50:58 19 understanding that Harder is a midwife who
10:51:02 20 co-authored parts of a book in Germany in 2003 about
10:51:06 21 postpartum care with the intended audience of other
10:51:09 22 midwives."

10:51:10 23 Did I read that right?

10:51:12 24 A Yes.

10:51:13 25 Q In your analysis of obviousness, what was

10:51:31 1 the importance of an intended audience of a
10:51:37 2 document?

10:51:49 3 A Well, one of the points I'm making here is
10:51:53 4 that a person of ordinary skill in the art would --
10:52:04 5 and by that I'm referring to a person of ordinary
10:52:10 6 skill in the art would not necessarily look to a
10:52:15 7 resource by a midwife for midwives. As I state
10:52:31 8 further down, as a pediatrician skilled in the art,
10:52:35 9 I have conferred directly with midwives, but I've
10:52:38 10 never relied on information from a book by a midwife
10:52:42 11 as if it were an academic medical reference.

10:52:45 12 Q Are you assuming that for a document to be
10:52:55 13 considered in an obviousness analysis that it has to
10:53:01 14 have the inventor as its intended audience?

10:53:04 15 MS. FLORENCE: Objection, mischaracterizes
10:53:06 16 the testimony and argumentative.

10:53:11 17 THE WITNESS: Would you ask a simpler
10:53:19 18 question, please?

10:53:20 19 BY MS. KRANING:

10:53:33 20 Q What was confusing about my question?

10:53:36 21 A Well, I'm trying to understand exactly what
10:53:43 22 you want to know. And if you ask it, I will try my
10:53:47 23 hardest to answer it.

10:53:48 24 Q Okay. What I'm trying to understand is if
10:53:53 25 you made an assumption in your declaration that for

10:53:58 1 a reference to be relevant to an obviousness

10:54:02 2 analysis that it has to have the inventor as the

10:54:08 3 intended audience for the reference?

10:54:10 4 MS. FLORENCE: Objection, vague. Counsel,

10:54:18 5 I'm not sure that the witness understands the

10:54:20 6 question. If there's another way to ask it.

10:54:40 7 BY MS. KRANING:

10:54:40 8 Q I mean for an obviousness analysis, does the

10:54:45 9 intended audience need to be a person of ordinary

10:54:48 10 skill in the art?

10:54:50 11 MS. FLORENCE: Objection, outside the scope.

10:54:52 12 Answer to the extent you can.

10:55:06 13 THE WITNESS: I can say that I'm not an

10:55:10 14 expert in obviousness in terms of every aspect

10:55:22 15 around it. But my understanding about obviousness

10:55:29 16 extends to the point that a person skilled in the

10:55:32 17 art would need to have studied or been exposed to

10:55:50 18 material that is intended for use by a person

10:55:59 19 skilled in the art. And in this case, I would not

10:56:08 20 look to a resource by a midwife for midwives as a

10:56:21 21 resource in trying to determine whether something

10:56:27 22 was obvious or not.

10:56:33 23 BY MS. KRANING:

10:56:40 24 Q And do you consider yourself to be a person

10:56:42 25 of ordinary skill in the art?

10:56:51 1 A I'm an expert on children and their health

10:56:58 2 and I know a lot about my area of expertise.

10:57:06 3 Q Do you consider yourself a person of

10:57:08 4 ordinary skill in the art?

10:57:12 5 A Yes.

10:57:13 6 Q So is it fair to say that you as a person

10:57:57 7 skilled in the art would have referred -- would have

10:58:00 8 referred to the academic medical references rather

10:58:05 9 than a reference like Harder?

10:58:07 10 MS. FLORENCE: Objection, calls for

10:58:09 11 speculation, argumentative.

10:58:12 12 THE WITNESS: As a person skilled in the

10:58:22 13 art, I would not look to a resource like a book from

10:58:37 14 a midwife for midwives.

10:58:48 15 BY MS. KRANING:

10:58:48 16 Q What would you have looked to instead?

10:58:57 17 MS. FLORENCE: Objection, calls for

10:58:58 18 speculation. Please answer to the extent you can.

10:59:01 19 THE WITNESS: When making decisions or

10:59:13 20 choices or recommendations for my patients, I look

10:59:25 21 to resources that I consider more authoritative and

10:59:42 22 rigorously evaluated for the most part. There are

10:59:54 23 -- there may be exceptions to that, but I can't

10:59:57 24 think of any right now. I would generally look to

11:00:07 25 materials from people at the highest academic

11:00:13 1 levels, expert consensus statements from groups like
11:00:24 2 the American Academy of Pediatrics or the Institute
11:00:44 3 of Medicine as examples.

11:00:44 4 BY MS. KRANING:

11:00:46 5 Q I think you mentioned the references are
11:00:51 6 rigorously evaluated. Are you referring to peer
11:00:54 7 review when you say that?

11:00:55 8 A When possible, I would look to peer reviewed
11:01:01 9 materials, yes.

11:01:02 10 Q Okay. We've been going about another hour.
11:01:13 11 Would this be a good time for a break?

11:01:16 12 A Sure. Thank you.

11:01:18 13 (Short recess.)

11:11:12 14 BY MS. KRANING:

11:13:43 15 Q So Dr. Horowitz, you agree that Vigantol oil
11:13:50 16 was available by prescription in Germany at the time
11:13:55 17 that Harder was published, right?

11:13:58 18 MS. FLORENCE: Objection, speculation.

11:13:59 19 Answer to the extent you can.

11:14:01 20 THE WITNESS: I have seen the translation of
11:14:07 21 Harder that says that, but I was not in Germany. I
11:14:14 22 do not speak German to read the original version and
11:14:18 23 so I can't speak from firsthand experience that it
11:14:21 24 was available.

11:14:22 25 ///

11:14:22 1 BY MS. KRANING:

11:14:24 2 Q Do you have any reason to think that it was
11:14:27 3 not available in Germany at the time Harder was
11:14:30 4 published?

11:14:32 5 A I have no reason to think that it was other
11:14:36 6 than what's written there and that it wasn't would
11:14:40 7 be the same. I have no reason to think either way.
11:14:46 8 I'm just going by what it says in the translated
11:14:49 9 Harder reference.

11:14:51 10 Q Let's go ahead and I'll mark what was
11:15:03 11 previously provided as Exhibit MOM 1009 and I'll
11:15:10 12 drop that in the chat. I'll share my screen.

11:15:10 13 (Document marked previously as
11:15:26 14 Exhibit 1009 was presented.)

11:15:26 15 BY MS. KRANING:

11:15:26 16 Q Dr. Horowitz, do you recognize Exhibit 1009
11:15:32 17 that is being shown on the screen. I can scroll
11:15:59 18 down?

11:15:59 19 A I mean I can see the cover page, but I don't
11:16:03 20 recognize the name Simon Chun Hsieh Liu.

11:16:09 21 Q Okay. Do you recognize if we go to page 6
11:16:16 22 of Exhibit 1009, does this look familiar to you?

11:16:21 23 A I have seen the name Wolf in some prior art,
11:16:25 24 yes.

11:16:25 25 Q This is the Wolf prior art reference that

11:16:32 1 was presented in a petition in this case?

11:16:38 2 MS. FLORENCE: Objection, speculation as to
11:16:41 3 authenticity.

11:17:29 4 BY MS. KRANING:

11:17:30 5 Q Did you review a reference called Wolf in
11:17:32 6 connection with this case?

11:17:34 7 A I reviewed a lot of material and some of it
11:17:38 8 more than others. I think I did see something by
11:17:43 9 Wolf.

11:17:45 10 Q Okay. This is one of the references -- I'll
11:17:50 11 represent to you that is one of the references being
11:17:53 12 used in connection with Harder in the petition
11:17:56 13 challenging the '958 patent. Okay?

11:18:01 14 A I understand what you're saying.

11:18:03 15 Q And so if we look at the top left -- I can
11:18:09 16 blow this up -- Wolf was published in July 1970. Do
11:18:15 17 you see that there?

11:18:15 18 A I do.

11:18:16 19 Q I'm going to scroll to page 8 of
11:18:26 20 Exhibit 1009 and looking at Table 1, do you see that
11:18:30 21 the title of Table 1 is "Prophylaxis of rickets in
11:18:34 22 babies and small children with pure vitamin D3
11:18:39 23 preparations"?

11:18:40 24 A I see that.

11:18:41 25 Q Okay. And do you see in this table it lists

11:18:55 1 as one of the preparations Vigantol?

11:19:02 2 A I see that.

11:19:03 3 Q And do you see it says it's manufactured by
11:19:14 4 Bayer/Merck?

11:19:17 5 A I see that.

11:19:17 6 Q And if you look on the right-hand column
11:19:20 7 under daily dose, it says one drop?

11:19:24 8 A I see that it says that.

11:19:27 9 Q So would you agree that based on the
11:19:32 10 information in this table that as of 1970,
11:19:36 11 Bayer/Merck was manufacturing Vigantol oil?

11:19:41 12 MS. FLORENCE: Objection, calls for
11:19:44 13 speculation. Objection, relevance and outside the
11:19:47 14 scope of this testament knowledge.

11:19:54 15 THE WITNESS: I see what it says on the
11:20:16 16 table that under the column "daily dose" it says one
11:20:20 17 drop, but it does not spell out exactly how big a
11:20:25 18 drop. It does not spell out anything more than what
11:20:35 19 you've described.

11:20:39 20 BY MS. KRANING:

11:20:39 21 Q Well, if we look to the third column here,
11:20:42 22 do you see where it says 1 mL equals 0.5 milligrams
11:20:47 23 equals 30 drops equals 20,000 IU of D3?

11:20:53 24 A I see that.

11:20:54 25 Q And wouldn't that tell you how big of a drop

11:20:59 1 to administer?

11:21:02 2 A It looks like it would be 1/30th of one
11:21:06 3 milliliter.

11:21:09 4 Q So as of 1970, there was a liquid vitamin D
11:21:20 5 solution manufactured by Bayer/Merck where the daily
11:21:26 6 dose was one drop, correct?

11:21:30 7 MS. FLORENCE: Objection, mischaracterizes
11:21:31 8 the testimony. Please answer to the extent you can.

11:21:35 9 THE WITNESS: According to the translation
11:21:41 10 of this document, there was a preparation called
11:21:50 11 Vigantol manufactured by Bayer/Merck, just reading
11:21:57 12 along the columns, that 1/30th of 1 milliliter
11:22:02 13 contained 20,000 IUs of D3 and a daily dose was one
11:22:07 14 drop.

11:22:09 15 BY MS. KRANING:

11:22:18 16 Q Just to make sure we have this clean, the
11:22:21 17 dose that it describes, that 20,000 IU, that's in
11:22:28 18 30 drops, right?

11:22:33 19 A That is what it says in column 3.

11:22:39 20 Q So one drop would be 20,000 IU divided by
11:22:46 21 30. Is that fair?

11:22:49 22 MS. FLORENCE: Objection, speculation.

11:22:50 23 THE WITNESS: No. That's not -- that's not
11:22:52 24 right. Say it again, please, or you could read it
11:22:56 25 back.

11:22:56 1 BY MS. KRANING:

11:22:56 2 Q Sure. Yeah. So my understanding of this
11:23:01 3 table is that the 20,000 IU is in 30 drops. Do you
11:23:11 4 agree with that?

11:23:12 5 A That's what it looks like.

11:23:15 6 Q So to get the IU of one drop, you would take
11:23:20 7 20,000 and divide it by 30?

11:23:25 8 A That's correct.

11:23:26 9 Q Fair to say that in 1970, there was a
11:24:05 10 vitamin D oil, Vigantol oil, that was taught it
11:24:11 11 could be administered in one drop?

11:24:15 12 MS. FLORENCE: Objection, mischaracterizes
11:24:16 13 the testimony, calls for speculation. Answer to the
11:24:20 14 extent you can.

11:24:20 15 THE WITNESS: No, ma'am. That's not what
11:24:27 16 this says. This translated version says that in
11:24:32 17 1970, the preparation was Vigantol, not Vigantol oil
11:24:40 18 as you stated a moment ago, at a daily dose of one
11:24:47 19 drop.

11:24:54 20 BY MS. KRANING:

11:24:58 21 Q Thank you for clarifying that question. Let
11:25:00 22 me reask it.

11:25:02 23 Is it fair to say that in 1970, there was a
11:25:05 24 vitamin D oil, Vigantol, that was taught could be
11:25:09 25 administered in a daily dose of one drop?

11:25:15 1 MS. FLORENCE: Objection, speculation.

11:25:17 2 Please answer to the extent you can.

11:25:19 3 THE WITNESS: No. I'm sorry. This doesn't
11:25:23 4 say anything about oil.

11:25:33 5 BY MS. KRANING:

11:25:41 6 Q You're familiar with the word Vigantol from
11:25:44 7 its use in the Harder reference, right?

11:25:48 8 A I am.

11:25:49 9 Q And in the Harder reference, it's referred
11:25:54 10 to as Vigantol oil?

11:25:57 11 A In the translated version of Harder that
11:25:59 12 I've seen, they refer to Vigantol oil. But if we're
11:26:03 13 going to talk about the Harder reference, I would
11:26:06 14 ask that we put it up so we can all be speaking from
11:26:09 15 the same page.

11:26:12 16 Q Sure. I can share that.

11:26:12 17 (Document marked previously as
11:26:16 18 Exhibit 1007 was presented.)

11:26:16 19 BY MS. KRANING:

11:26:17 20 Q I think I previously dropped this in the
11:26:20 21 chat. Harder is MOM 1007. And this is the Harder
11:26:27 22 reference that you're referring to, Dr. Horowitz?

11:26:30 23 A Which translation is this?

11:26:34 24 Q This is the original -- the Harder -- the
11:26:40 25 Sherman translation.

11:26:42 1 A I think it said it was the Tinworth
11:26:47 2 translation.

11:26:48 3 Q Yeah. So it's Sherman's declaration based
11:26:52 4 on Ms. Tinworth's translation, yes.

11:26:55 5 A Yes. I am familiar with this art.

11:27:01 6 Q Okay. And if we go to page -- page 6 at the
11:27:26 7 bottom, page 4 of the reference of Harder, do you
11:27:30 8 recall reviewing this section of Harder for your
11:27:35 9 analysis?

11:27:35 10 A I do.

11:27:36 11 Q And do you recall looking at this Option 3
11:27:43 12 that's described here?

11:27:44 13 A I recall seeing this in the context of a
11:27:56 14 total of four options, Option 3 being one of the
11:28:00 15 less reliable ways to prevent rickets.

11:28:13 16 Q So Option 3 here refers to Vigantol oil,
11:28:18 17 correct?

11:28:18 18 A It does.

11:28:20 19 Q And Vigantol here has a trademark symbol
11:28:26 20 next to it? Do you see that?

11:28:28 21 A I see that.

11:28:30 22 Q Do you have any reason to believe that this
11:28:36 23 Vigantol oil is a different product than the
11:28:42 24 Vigantol that is described in Exhibit 1009, the Wolf
11:28:49 25 reference?

11:28:50 1 MS. FLORENCE: Objection, calls for
11:28:51 2 speculation and outside the scope and relevance.
11:28:52 3 Answer to the extent you can.
11:28:54 4 THE WITNESS: I have seen somewhere in the
11:29:06 5 materials that I've reviewed that Vigantol was a
11:29:11 6 tablet. So without it saying Vigantol oil, it may
11:29:21 7 or may not have been oil.
11:29:26 8 BY MS. KRANING:
11:29:27 9 Q Are tablets administered in drops?
11:29:32 10 A Well, that's a great question. And if we go
11:29:36 11 back to the Harder reference, Options 1 and 2 talk
11:29:41 12 about taking tablets and dissolving them in water.
11:29:47 13 So she describes --
11:29:50 14 Q And in this disclosure it says one drop is a
11:29:54 15 daily dose of Vigantol, correct?
11:29:57 16 A In column 1 it says Vigantol. In column 4
11:30:03 17 it says drop, yes.
11:30:06 18 Q And in column 4, for two of the other
11:30:12 19 preparations in this table, the daily dose is
11:30:15 20 described as half a tablet. Do you see that?
11:30:19 21 MS. FLORENCE: Objection, mischaracterizes
11:30:21 22 the testimony.
11:30:25 23 THE WITNESS: I see that it says half a
11:30:34 24 tablet under daily dose for two of the items in
11:30:37 25 Table 1 on the translated reference.

11:30:43 1 BY MS. KRANING:

11:30:44 2 Q But for Vigantol it says one drop, right?

11:30:55 3 A For Vigantol, reading straight across it
11:30:59 4 says one drop.

11:31:02 5 Q Would that tell you that the Vigantol that's
11:31:10 6 being described here is not a tablet?

11:31:13 7 A I think I need you to clarify your question.

11:31:27 8 Q Well, my initial question was do you have
11:31:32 9 any reason to believe that the Vigantol oil
11:31:38 10 described in Harder is different than the Vigantol
11:31:42 11 that is described in Wolf? And I believe you said
11:31:48 12 that you see Vigantol described as a tablet. But
11:31:53 13 what we've just established is that the Vigantol in
11:31:55 14 Wolf is administered in a drop and not a tablet. Is
11:32:00 15 that right?

11:32:00 16 A According to this table, the Vigantol in the
11:32:11 17 Wolf reference is a drop, but it is not clear to me
11:32:18 18 that it is an oil because it doesn't say oil. And
11:32:24 19 since it exists in another form, if in fact it also
11:32:29 20 exists as a tablet, it could be referring to that,
11:32:37 21 dissolved in water or some other liquid.

11:32:41 22 Q Going back to the Harder reference, which is
11:34:13 23 Exhibit 1007, do you see that Harder states that
11:34:27 24 Vigantol oil has proved to be successful over many
11:34:33 25 years and contains only one excipient as a vehicle

11:34:35 1 for the fat-soluble vitamin D, namely medium-chain
11:34:42 2 triglycerides (vegetable oil)?

11:34:44 3 MS. FLORENCE: Objection, counsel. Can you
11:34:45 4 show us where you're -- you mentioned Harder. Can
11:34:49 5 you tell us exactly where -- excuse me, what -- if
11:34:52 6 you could Zoom out. I can't see what page. I
11:34:55 7 apologize.

11:34:56 8 MS. KRANING: No problem. Sorry.

11:34:57 9 MS. FLORENCE: I'm looking at a copy as
11:35:00 10 well. Sorry, page 6.

11:35:02 11 MS. KRANING: No worries. We're on page 6.
11:35:04 12 So we're looking under the Option 3.

11:35:06 13 MS. FLORENCE: Thank you.

11:35:13 14 THE WITNESS: I can see that the Harder
11:35:15 15 reference translation Option 3 says the oil has
11:35:22 16 proved to be successful over many years and contains
11:35:25 17 only one excipients as a vehicle for the fat-soluble
11:35:28 18 vitamin D, namely medium chain triglycerides
11:35:34 19 (vegetable oil). Yes, I see that.

11:35:37 20 BY MS. KRANING:

11:35:38 21 Q And you agree that vitamin D is fat soluble?

11:35:45 22 A Yes.

11:35:45 23 Q And do you agree that a vitamin that is fat
11:35:52 24 soluble will not be soluble in aqueous solution?

11:36:00 25 MS. FLORENCE: Objection, relevance.

11:36:02 1 THE WITNESS: I'm not a chemist, so I can
11:36:07 2 tell you that fat-soluble vitamins store and get
11:36:12 3 built up in the body as opposed to water-soluble
11:36:16 4 vitamins.

11:36:20 5 BY MS. KRANING:

11:36:34 6 Q You agree that Vigantol oil was available
11:36:37 7 via prescription at the time Harder was published,
11:36:40 8 right?

11:36:41 9 A I agree that it says under Option 3 of the
11:36:53 10 Harder reference that Vigantol oil is a
11:36:56 11 prescription-only medicine as it says in the next
11:37:00 12 paragraph.

11:37:01 13 Q Let me go back to your declaration. I want
11:37:08 14 to turn to paragraph 6h of your declaration. And
11:37:16 15 here you say, "Vigantol oil is a prescription-only
11:37:20 16 product available in limited countries."

11:37:23 17 Do you see that?

11:37:24 18 A I see it. It goes on to say that I did a
11:37:32 19 search personally with our suppliers to see if it
11:37:38 20 was something that could be ordered and there was no
11:37:45 21 record found.

11:37:59 22 Q How does the fact that Vigantol oil appears
11:38:10 23 to not be available in the United States affect your
11:38:12 24 analysis?

11:38:26 25 A My analysis of what?

11:38:31 1 Q How does the fact that Vigantol oil appears
11:38:35 2 to not be available in the United States affect your
11:38:38 3 obviousness analysis?

11:38:53 4 MS. FLORENCE: Objection, vague. Please
11:38:54 5 answer to the extent you can.

11:38:56 6 THE WITNESS: Stating that it's a
11:39:40 7 prescription-only product and it's not available in
11:39:42 8 the United States speaks to the unfamiliarity of a
11:39:49 9 product that a person of ordinary skill in the art
11:39:53 10 would have when determining if you could make the
11:40:08 11 connection between something that you didn't know
11:40:11 12 existed to something new and different. So that's
11:40:22 13 how.

11:40:32 14 BY MS. KRANING:

11:40:33 15 Q So are you saying that because Vigantol oil
11:40:36 16 was not available in the United States, a person of
11:40:41 17 skill in the art would not have been aware of it?

11:40:49 18 A They probably would not be aware of it.

11:40:52 19 Q By your understanding, does a product have
11:41:13 20 to be available in the United States to be relied on
11:41:19 21 in an obviousness analysis?

11:41:21 22 MS. FLORENCE: Objection, calls for
11:41:23 23 speculation and outside the scope. Please answer to
11:41:25 24 the extent you can.

11:41:26 25 THE WITNESS: Well, I'm not an expert in

11:41:32 1 obviousness, but I don't think so.

11:41:37 2 BY MS. KRANING:

11:41:44 3 Q You offer opinions in your declaration about
11:41:45 4 a long-felt, unmet need. Is that fair?

11:41:50 5 A Yes.

11:41:50 6 Q Would a product that was only offered for
11:42:16 7 sale outside the United States be able to fill a
11:42:24 8 long-felt, unmet need?

11:42:26 9 MS. FLORENCE: Objection, calls for
11:42:27 10 speculation. Please answer to the extent you can.

11:42:31 11 THE WITNESS: Would you just ask one more
11:42:42 12 time, please? I'm sorry.

11:42:44 13 BY MS. KRANING:

11:42:45 14 Q Sure. Would a product that was only offered
11:42:48 15 for sale outside the United States be able to fill a
11:42:53 16 long-felt, unmet need?

11:42:57 17 MS. FLORENCE: Objection again. And I
11:43:03 18 believe that calls for a legal conclusion.

11:43:07 19 THE WITNESS: I think it might be.

11:43:09 20 BY MS. KRANING:

11:43:23 21 Q So a product outside the U.S. could have met
11:43:28 22 that long-felt, unmet need in the United States?

11:43:33 23 MS. FLORENCE: Objection, speculation.

11:43:35 24 THE WITNESS: In this situation we're
11:43:53 25 talking about the unmet need of being able to

11:43:56 1 administer a vitamin D supplement to young children
11:44:04 2 in particular efficaciously and consistently. And
11:44:14 3 so no, I'm not hearing about something that solves
11:44:23 4 that unmet need.

11:44:32 5 BY MS. KRANING:

11:44:38 6 Q And that's in Germany and not in the United
11:44:44 7 States, right?

11:44:45 8 MS. FLORENCE: Objection, mischaracterizes
11:44:46 9 the testimony.

11:44:48 10 THE WITNESS: Absolutely not. Let's look at
11:44:52 11 the Harder reference a little more comprehensively
11:45:00 12 and we'll see that Option 1, which is the most
11:45:03 13 reliable way to prevent rickets, was to dissolve a
11:45:09 14 tablet and give it year round. Option 2 was to give
11:45:13 15 it during only certain months in that same way. And
11:45:16 16 Option 3 was to give something called Vigantol oil,
11:45:23 17 which is of unclear specifications in terms of
11:45:28 18 things like its adhesion and its viscosity, to
11:45:37 19 prevent rickets in rare circumstances where one of
11:45:42 20 the first two options led to bloating or there's a
11:45:46 21 child that's predisposed to allergy.

11:45:51 22 So it's not just that it's in another
11:45:54 23 country. It's that in my experience and my opinion,
11:46:04 24 a Vigantol oil doesn't solve the need — solve the
11:46:08 25 unmet need.

11:46:10 1 BY MS. KRANING:

11:46:15 2 Q Have you ever used Vigantol oil?

11:46:19 3 A No.

11:46:20 4 Q So you don't know whether its properties --
11:46:34 5 -- strike that.

11:46:35 6 So you can't say whether its adhesion and
11:46:39 7 the viscosity properties would have met a long-felt,
11:46:43 8 unmet need, right?

11:46:46 9 A I have never used Vigantol oil. The Harder
11:46:57 10 reference goes on to say that it should be
11:46:59 11 administered on the tip of a spoon. And I have put
11:47:05 12 a drop of oil on the tip of a spoon. That oil rolls
11:47:12 13 down into the bowl of the spoon. And just that fact
11:47:17 14 in the Harder reference shows me that she doesn't
11:47:23 15 necessarily understand how infants feed. It's
11:47:32 16 essentially impossible for the newborn to get the
11:47:38 17 oil out of the bottom of a spoon if you're using a
11:47:43 18 spoon the way we use it as an adult, as people
11:47:56 19 ordinarily use a spoon.

11:47:58 20 Q So you can't say whether Vigantol oil has
11:48:02 21 the adhesion and viscosity properties to have met a
11:48:06 22 long-felt, unmet need that the invention met, right?

11:48:12 23 MS. FLORENCE: Objection, calls for a legal
11:48:14 24 conclusion. Please answer to the extent you can.

11:48:15 25 THE WITNESS: I can't say that Vigantol oil

11:48:32 1 does that. I can say that the invention does solve
11:48:38 2 that unmet need because it has been demonstrated in
11:48:46 3 experiments, among other reasons.

11:48:51 4 BY MS. KRANING:

11:49:06 5 Q You agree that Harder says to use one drop
11:49:08 6 of Vigantol oil, correct? I'm on page 6 of
11:49:22 7 Exhibit 1007?

11:49:23 8 A Could you scroll down because I think it
11:49:26 9 says use of --

11:49:27 10 Q Sorry.

11:49:29 11 A It says, "Use of the oil is simple. One
11:49:34 12 drop of Vigantol oil is given to the baby to be
11:49:37 13 licked off from the tip of a spoon once a day before
11:49:42 14 a breastfeed or a meal." That's what it says in the
11:49:48 15 translated -- the translated Harder reference.

11:49:53 16 Q So the translated Harder reference says to
11:49:57 17 use one drop of Vigantol oil?

11:50:05 18 A It says that use of the oil is simple, one
11:50:09 19 drop is given, yes. It goes on to give a very clear
11:50:16 20 caution, but it does say to use one drop.

11:50:20 21 Q Right. It says definitely don't use two
11:50:24 22 drops, right?

11:50:29 23 A It says, "Under no circumstances should it
11:50:35 24 be put directly in the baby's mouth" with an
11:50:38 25 exclamation point. And "Should two drops fall onto

11:50:43 1 the spoon, the spoon should be washed and the
11:50:45 2 process started again" which speaks to the danger of
11:50:52 3 giving too much.

11:50:57 4 Q Right. And you talk about that in your
11:51:01 5 declaration, right, that too much can be dangerous
11:51:03 6 for the baby?

11:51:08 7 A I refer to it as a toxic amount, yes.

11:51:12 8 Q So you and Harder both agree that two drops
11:51:18 9 is potentially dangerous?

11:51:20 10 MS. FLORENCE: Objection, mischaracterizes
11:51:21 11 the testimony.

11:51:23 12 THE WITNESS: We agree that giving a
11:51:39 13 recommended amount is a good idea.

11:51:46 14 BY MS. KRANING:

11:51:54 15 Q And two drops exceeds the recommended
11:51:56 16 amount, right?

11:52:04 17 A She says the recommended amount is one drop
11:52:06 18 of Vigantol oil. The recommended amount of
11:52:14 19 vitamin D is 400 international units. Furthermore,
11:52:21 20 if you go back up to the opening of that where it
11:52:26 21 says one drop contains 500 IUs, I would submit that
11:52:34 22 that's not exactly consistent with the Wolf
11:52:38 23 reference if you do the arithmetic.

11:52:48 24 Q But regardless, two drops would exceed the
11:52:52 25 recommended amount?

11:52:53 1 A If the recommended amount is one drop and

11:52:55 2 you give two drops, yes, two is more than one.

11:53:01 3 Q Harder goes on to say, "In my experience,

11:53:22 4 skeptical parents are more likely to be accepting of

11:53:24 5 administering drops on a daily basis than a daily

11:53:27 6 dose of tablets."

11:53:28 7 Do you see that?

11:53:30 8 A I see that.

11:53:31 9 Q Do you agree with that statement?

11:53:35 10 MS. FLORENCE: Objection, calls for

11:53:37 11 speculation. Answer to the extent you can.

11:53:39 12 THE WITNESS: I don't know. I think you

11:53:53 13 would need to survey skeptical parents, whatever

11:53:56 14 that means.

11:53:58 15 BY MS. KRANING:

11:54:02 16 Q I mean, in your practice, would you agree

11:54:05 17 that parents are more likely to accept administering

11:54:08 18 drops on a daily basis than a daily dose of tablets?

11:54:20 19 A In my experience, it is much more realistic

11:54:32 20 to get drops into a baby than a tablet, if that

11:54:42 21 helps answer your question.

11:54:45 22 Q Drops are easier to administer to a baby

11:54:58 23 than a tablet, fair?

11:55:06 24 A Drops are easier to administer to a baby via

11:55:11 25 the mouth than tablets, I would say, yes.

11:55:16 1 Q Going back to your declaration, now looking
11:55:35 2 on -- this is page 10 in paragraph 6h, and I'm
11:55:45 3 looking at the sentence that starts, "Furthermore,
11:55:48 4 Harder's advice to administer from the tip of a
11:55:51 5 spoon is ineffective."

11:55:55 6 Do you see that?

11:55:57 7 A I see that.

11:55:58 8 Q So it is your opinion that a spoon would be
11:56:05 9 an ineffective method of delivery to an infant?

11:56:13 10 MS. FLORENCE: Objection, mischaracterizes
11:56:14 11 the testimony. Please answer to the extent you can.

11:56:16 12 THE WITNESS: What I say there is that the
11:56:22 13 advice is ineffective. It reflects a lack of
11:56:27 14 understanding that the tongue is on the floor of the
11:56:31 15 mouth and when you insert a spoon, it goes on top of
11:56:37 16 the tongue, so there's no way for the child to, in
11:56:45 17 the most recent version of the translation, lick the
11:56:50 18 drop off.

11:56:52 19 BY MS. KRANING:

11:56:59 20 Q You specifically say it's an ineffective
11:57:01 21 method, right? That's what you say in the next part
11:57:04 22 of the sentence?

11:57:05 23 A What I say is that administering medication
11:57:08 24 to school-aged children is routinely given by a
11:57:12 25 spoon, but giving a liquid to an infant, newborn via

11:57:21 1 the tip of a spoon is going to be ineffective.

11:57:30 2 Q What about giving a liquid to a two-year-old
11:57:37 3 child via the tip of a spoon, would that be
11:57:41 4 effective?

11:57:41 5 MS. FLORENCE: Objection, calls for
11:57:44 6 someplace. Answer to the extent you can.

11:57:52 7 THE WITNESS: I believe I've seen
11:57:53 8 two-year-olds who accept a liquid via spoon and I've
11:58:03 9 seen two-year-olds who refuse to take liquid by the
11:58:08 10 tip of a spoon.

11:58:23 11 BY MS. KRANING:

11:58:23 12 Q So your opinion here that using a spoon was
11:58:26 13 an ineffective method of delivery to infants, you're
11:58:31 14 assuming that the baby -- is it true that you're
11:58:35 15 assuming that the baby cannot receive an effective
11:58:39 16 amount of dose if placed on a spoon?

11:58:44 17 A I'm saying that that's an ineffective method
11:58:47 18 of delivery to get them to take an efficient dose of
11:58:53 19 medication on a consistent basis. That just
11:59:01 20 completely goes against the normal way infants feed
11:59:07 21 and is not going to be tolerated to meet the need
11:59:17 22 which is to give a consistent dose efficaciously.

11:59:24 23 Q So your opinion assumes that the invention
11:59:30 24 requires a consistent -- the ability to consistently
11:59:35 25 and effectively administer the vitamin D?

11:59:45 1 A Yes.

11:59:47 2 Q And is it fair to say that your opinion
11:59:55 3 assumes that the baby cannot lick in order to remove
12:00:00 4 all the material from the spoon, that's why it's
12:00:02 5 ineffective?

12:00:04 6 MS. FLORENCE: Objection, mischaracterizes
12:00:05 7 testimony. Please answer to the extent you can.

12:00:08 8 THE WITNESS: I state very clearly that
12:00:15 9 although infants might lick as part of rooting to
12:00:22 10 find mother's nipple, that is not a consistent
12:00:30 11 behavior that you can rely on when trying to get
12:00:34 12 them to take a dose of vitamin D on a daily basis as
12:00:38 13 is recommended. Not to mention that you don't know
12:00:46 14 how many licks it will take to transfer. You don't
12:00:50 15 know -- there's too much that you don't know without
12:00:54 16 doing appropriate testing. But licking is not a
12:01:00 17 natural way that infants feed.

12:01:04 18 BY MS. KRANING:

12:01:09 19 Q Did the '958 patent test how many licks was
12:01:12 20 needed to get a drop of oil off of a surface?

12:01:18 21 A We can look at it together, but as far as I
12:01:20 22 know, it talks about the amount of time needed to
12:01:27 23 suck, but I don't believe that it says anything
12:01:32 24 about the number of licks it takes. Not to mention
12:01:40 25 that all licks are not the same.

12:01:48 1 Q So is it your opinion that a person of skill
12:02:03 2 in the art would not know how many licks it would
12:02:06 3 take to administer one drop of vitamin D oil on an
12:02:14 4 object?

12:02:17 5 MS. FLORENCE: Objection to form. Answer to
12:02:21 6 the extent you can.

12:02:23 7 THE WITNESS: Yes, I don't think a person
12:02:29 8 skilled in the art would know how many licks it
12:02:31 9 takes to transfer a certain amount of oil from a
12:02:37 10 surface to ingest.

12:02:42 11 BY MS. KRANING:

12:02:55 12 Q Going back to the baby with the spoon,
12:03:04 13 you're not suggesting that it's impossible for the
12:03:07 14 baby to remove any of the drop of vitamin D oil from
12:03:11 15 the spoon with its tongue, are you?

12:03:16 16 A I'm saying that I've never seen a baby whose
12:03:21 17 tongue is on the roof of his mouth by, you know,
12:03:27 18 just -- I guess strike that. Ask me the question
12:03:34 19 again. I'm not quite following what you're asking
12:03:37 20 me.

12:03:37 21 Q Yeah. So what I'm asking is you're not
12:03:42 22 suggesting that it's impossible for the baby to
12:03:46 23 remove any of the drop of the vitamin D oil from the
12:03:48 24 spoon with its tongue?

12:04:00 25 A I am saying it's impossible to rely on a

12:04:21 1 baby to lick from a spoon to get a consistent dose
12:04:30 2 on the daily basis.

12:04:31 3 Q Setting aside whether the dose is
12:04:42 4 consistent, you would agree that the baby will get
12:04:44 5 some amount of the oil onto his tongue versus the
12:04:53 6 spoon?

12:04:53 7 MS. FLORENCE: Objection, speculation.
12:04:54 8 Answer to the extent you can.

12:04:56 9 THE WITNESS: The baby might get some amount
12:05:04 10 of whatever you put in its mouth.

12:05:17 11 BY MS. KRANING:

12:05:18 12 Q Is it fair to say that if you put a spoon up
12:05:21 13 to an infant's mouth, they're going to stick their
12:05:24 14 tongue out?

12:05:25 15 MS. FLORENCE: Objection, speculation.

12:05:26 16 THE WITNESS: No, not always.

12:05:30 17 BY MS. KRANING:

12:05:33 18 Q In your declaration, turning now to page 11,
12:05:38 19 you say at the top of the page here, the first full
12:05:42 20 sentence, "Infants naturally thrust their tongue
12:05:45 21 when hard objects like the tip of a spoon or other
12:05:49 22 feeding utensils are inserted into their mouth until
12:05:53 23 four to six months of age when this protective
12:05:57 24 reflex typically fades"?

12:05:57 25 A Yes, and your question was if you put it up

12:06:00 1 to their mouth. This says if you put it in their
12:06:04 2 mouth. And I'm referring to the gag reflex where
12:06:07 3 infants will try to protect their airway if you try
12:06:12 4 to feed them solids, for instance, in the first few
12:06:19 5 months in particular.

12:06:25 6 Q So if you put the tip of a spoon into an
12:06:28 7 infant's mouth, they're going to stick their tongue
12:06:32 8 out, right?

12:06:35 9 A They're going to thrust their tongue to try
12:06:39 10 to protect their airway. They're not going to stick
12:06:42 11 their tongue out, as you said, in order to try to
12:06:46 12 take in what you're putting in there.

12:06:54 13 Q But some of what's on the spoon will make
12:06:57 14 contact with the infant's tongue?

12:07:00 15 MS. FLORENCE: Objection, speculation.

12:07:02 16 THE WITNESS: The underside of the spoon
12:07:12 17 would make contact with the infant's tongue.

12:07:20 18 BY MS. KRANING:

12:07:20 19 Q And there's no circumstance in which the
12:07:22 20 baby's tongue will come into contact with the top
12:07:25 21 side of the spoon?

12:07:29 22 MS. FLORENCE: Same objection.

12:07:30 23 THE WITNESS: Could you define the top side
12:07:32 24 of the spoon?

12:07:33 25 ///

12:07:33 1 BY MS. KRANING:

12:07:33 2 Q Let me reask the question.

12:07:35 3 You're saying there's no circumstance in
12:07:37 4 which the baby's tongue will come into contact with
12:07:40 5 the bowl side of the spoon?

12:07:48 6 A No, that is not impossible for some of the
12:07:55 7 contents in the bowl of the spoon to come in contact
12:07:58 8 with the tongue, if the adult turns the spoon over,
12:08:04 9 for example.

12:08:13 10 Q And are you saying in your declaration on
12:08:14 11 this page that at four to six months, that
12:08:17 12 protective reflex typically fades, right?

12:08:24 13 A Yes.

12:08:25 14 Q So after four to six months, an infant may
12:08:34 15 allow the tip of a spoon into its mouth without this
12:08:38 16 protective reflex?

12:08:40 17 MS. FLORENCE: Objection, calls for
12:08:42 18 speculation.

12:08:42 19 THE WITNESS: That may happen. It's the
12:08:51 20 reason that we -- it's one of the reasons that we
12:08:54 21 wait until four to six months to begin introducing
12:08:58 22 solids.

12:09:06 23 BY MS. KRANING:

12:09:10 24 Q How are solids generally introduced to
12:09:14 25 infants that are four to six months old?

12:09:25 1 A Well, a child who has good head and neck
12:09:28 2 control and shows an interest in feeding might be
12:09:35 3 ready to start solids, in which case I would counsel
12:09:39 4 them on the introduction of an iron-fortified
12:09:46 5 cereal, then fruits and vegetables and other solids
12:09:52 6 in a step-wise approach.

12:10:00 7 Q And what about baby food?

12:10:07 8 A By baby food, do you mean food for babies?
12:10:11 9 That is what I was just describing.

12:10:14 10 Q I want to clarify. By baby food, I mean
12:10:18 11 when you go to the grocery store and buy
12:10:21 12 off-the-shelf that says Gerber's -- some sort of
12:10:25 13 mashed product, that kind of baby food.

12:10:31 14 A You're referring to a puree?

12:10:37 15 Q Yeah. They still give that to babies these
12:10:41 16 days, don't they?

12:10:42 17 A Yes.

12:10:44 18 Q And how does a baby generally -- how would
12:10:51 19 you administer that pureed baby food product to a
12:10:56 20 baby who is four to six months old?

12:11:00 21 A If they are ready for it, then we will
12:11:02 22 recommend the use of a spoon. And the way I
12:11:10 23 describe it is that at first, the child's tongue
12:11:14 24 will probably thrust. And if they do, you can try
12:11:20 25 to stick the baby food up to the roof of their mouth

12:11:26 1 so hopefully their tongue will begin to work it back
12:11:29 2 and then they'll tolerate the solids. And I always
12:11:35 3 go on to say that if the child spits it out and
12:11:41 4 cries and doesn't like it, to wait a few days and
12:11:45 5 try again.

12:11:47 6 Q Is it fair to say that generally between six
12:11:57 7 months and a year, infants will get used to eating
12:12:02 8 food off of a spoon?

12:12:05 9 MS. FLORENCE: Objection, speculation.

12:12:06 10 THE WITNESS: That is our goal, to try and
12:12:16 11 get children to do that in that second half of the
12:12:21 12 first year of life.

12:12:23 13 BY MS. KRANING:

12:12:31 14 Q Are you assuming for the purposes of your
12:12:33 15 analysis here that for the invention, the vitamin D
12:12:38 16 has to be able to be administered in the first few
12:12:41 17 days of life?

12:12:45 18 A In accordance with the recommendations, the
12:12:53 19 invention solves the need to do that. But the
12:12:57 20 invention also provides for usefulness well beyond
12:13:05 21 the first days, weeks and months of a child's life.

12:13:10 22 Q I understand that. My question is are you
12:13:19 23 assuming that in order to meet the requirements of
12:13:26 24 the invention, the vitamin D has to be able to be
12:13:29 25 administered in the first few days of life?

12:13:36 1 A Yes.

12:13:42 2 MS. KRANING: Okay. I think this is a good

12:13:43 3 time to do a break. We can break for lunch. Let's

12:13:48 4 go off the record.

12:13:48 5 (Whereupon, the deposition in the

12:13:48 6 above-entitled cause was recessed

12:13:48 7 to 12:47 p.m. this date.)

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12:13:48 1 A F T E R N O O N S E S S I O N

12:46:15 2 CROSS EXAMINATION (Resumed)

12:46:15 3 BY MS. KRANING:

12:47:55 4 Q Dr. Horowitz, welcome back. I want to go

12:47:59 5 back to a topic we were discussing before the break.

12:48:05 6 And I think you testified that if you're trying to

12:48:11 7 administer one drop of oil on a spoon to an infant,

12:48:16 8 that if you flipped over the spoon, that some amount

12:48:21 9 of the oil would make contact with the infant's

12:48:24 10 tongue. Is that right?

12:48:28 11 A I think I said it might.

12:48:34 12 Q What about if you tried to administer the

12:48:42 13 one drop on a spoon, but instead of flipping it

12:48:44 14 over, you just held it upright and kind of pressed

12:48:48 15 the bottom of the -- the tip of the spoon into the

12:48:50 16 baby's mouth? If that thrusting happened, that

12:48:56 17 thrusting tongue would make contact with the

12:48:59 18 interior bowl of the bottom of the spoon?

12:49:02 19 MS. FLORENCE: Objection, speculation. Go

12:49:03 20 ahead and answer.

12:49:05 21 BY MS. KRANING:

12:49:05 22 Q Right?

12:49:07 23 A I don't think I've ever seen an infant's

12:49:09 24 tongue go out and down the way a dog does to lick

12:49:14 25 out of a bowl. I mean, this is literally licking

12:49:18 1 out of a bowl. You're asking me if it would happen.
12:49:20 2 But tongue thrusts to protect the airway, the tongue
12:49:23 3 goes forward. It doesn't necessarily go down into a
12:49:27 4 bowl like the bowl of a spoon, for instance.

12:49:30 5 Q Right. I guess what I have in mind is if
12:49:34 6 you are holding the spoon upright, then the oil
12:49:37 7 would run down to the tip of the spoon, so the baby
12:49:41 8 wouldn't have to get their tongue into the bottom of
12:49:44 9 the bowl, they would just have to make contact with
12:49:47 10 the tip of the spoon, right?

12:49:49 11 A No, they would gag and it would drip down
12:49:52 12 and they would potentially aspirate. And as you
12:49:56 13 might know, aspirating an oily substance is
12:50:01 14 extremely dangerous because if it gets into the
12:50:05 15 lungs, it can lead to a lipoid pneumonia. It's
12:50:09 16 different from an aqueous solution. So we're very
12:50:12 17 careful with regard to oils and dripping and
12:50:17 18 potential for gagging in that way.

12:50:22 19 Q And so even if it was just that one drop, it
12:50:26 20 was residue on the spoon, you would have a concern
12:50:29 21 that the baby could aspirate that?

12:50:35 22 A If it's being dropped in their mouth, yes.

12:50:39 23 Q That's not what I am suggesting here. What
12:50:43 24 I am suggesting is that the oil would stay on the
12:50:47 25 tip of the spoon like this, and then when the baby's

12:50:52 1 tongue was thrust out, it would make contact with
12:50:54 2 the bottom of the spoon.

12:50:58 3 A I think in any event, you would need to
12:51:02 4 demonstrate that you can effectively do that on a
12:51:08 5 regular basis for it to be relevant to meet the need
12:51:14 6 that we're talking about here.

12:51:18 7 Q Okay. And that's because consistency is
12:51:28 8 important to the invention?

12:51:34 9 A Consistency and efficaciousness, yes, those
12:51:41 10 are both important because we're not talking about
12:51:44 11 just a product, we're talking about the method of
12:51:47 12 administration.

12:51:50 13 Q Okay. I'm going to go back to your
12:52:16 14 declaration. I'm going on page 11 in paragraph 6i.
12:52:34 15 Show you the screen over here. Okay. So here in
12:52:42 16 paragraph 6i, you state that there are physical
12:52:45 17 properties of the substance that Harder suggests
12:52:49 18 using that are unknown such as the viscosity and
12:52:52 19 adhesion. See that?

12:52:58 20 A Yes, I see that.

12:52:59 21 Q Now, you're not suggesting that no one knew
12:53:04 22 the viscosity and adhesion of Vigantol oil, right?

12:53:09 23 A I have not seen anything in the prior art
12:53:14 24 that describes viscosity and adhesion or has
12:53:19 25 demonstrated that the adhesion meets the needs that

12:53:24 1 the invention solves.

12:53:28 2 Q Viscosity is a property that's inherent to a
12:53:36 3 liquid, right?

12:53:38 4 A Viscosity refers to the internal friction of
12:53:41 5 that liquid; the thickness, if you will.

12:53:45 6 Q So Vigantol oil is going to have a
12:53:49 7 viscosity, right?

12:53:52 8 A Yes.

12:53:55 9 Q The question is whether it has the viscosity
12:53:59 10 that you say is required by the invention?

12:54:05 11 A What I'm saying is that the viscosity is an
12:54:08 12 important property to understand because, for
12:54:14 13 example, it dictates or it's one of the determinants
12:54:18 14 of the size of a drop, just like density, just like
12:54:23 15 gravitational field. I'm not a physicist, but
12:54:28 16 unless you have a clear understanding of the
12:54:32 17 viscosity, you can't necessarily meet the need. And
12:54:43 18 I've seen in some of the other testimony that they
12:54:46 19 mix up viscosity and adhesion where they're not
12:54:50 20 being clear about these two different properties.
12:54:55 21 But I try to spell it out in my declaration.

12:54:59 22 Q So you don't know the viscosity of the
12:55:10 23 Vigantol oil, right?

12:55:13 24 A I do not know the viscosity of Vigantol oil,
12:55:18 25 that's true.

12:55:19 1 Q But a person who was administering a drop of
12:55:26 2 Vigantol oil, they would have a sense for the
12:55:29 3 viscosity of the oil, fair?

12:55:33 4 MS. FLORENCE: Objection, speculation.

12:55:34 5 THE WITNESS: I don't know what they would
12:55:39 6 know or what they wouldn't know.

12:55:41 7 BY MS. KRANING:

12:55:50 8 Q Well, take the Ddrops product that you sell
12:55:54 9 in your office. So you can take that product and
12:55:57 10 put a drop of it on a spoon or another object and
12:56:02 11 you can get a sense for how viscous the solution is,
12:56:05 12 right?

12:56:10 13 A It would be completely wrong of me to put it
12:56:13 14 on the tip of a spoon since it's off-label. It's
12:56:17 15 intended to be put on a nipple or a knuckle or a
12:56:22 16 fingertip or a pacifier. So I wouldn't put it on
12:56:29 17 the tip of a spoon.

12:56:30 18 Q Okay. So let's talk about that. So say you
12:56:33 19 took a drop of the Ddrops oil and you put that on a
12:56:37 20 pacifier, you would be able to tell by the
12:56:41 21 properties of how it rolled down or didn't on the
12:56:44 22 pacifier whether it had sufficient viscosity and
12:56:49 23 adhesion to stay on the pacifier, right?

12:56:52 24 A Well, now those are two different
12:56:54 25 properties.

12:56:54 1 MS. FLORENCE: Objection, form.

12:56:56 2 BY MS. KRANING:

12:56:56 3 Q Okay. That's fair. Let me ask a better
12:56:58 4 question.

12:56:59 5 So say you took a drop of the Ddrops oil and
12:57:05 6 you put that on a pacifier. Would you believe able
12:57:07 7 to tell by the -- would you be able to tell by the
12:57:12 8 way it rolled down or didn't roll down the pacifier
12:57:15 9 whether it had sufficient viscosity to stay on the
12:57:18 10 pacifier?

12:57:19 11 A When I put a drop of Ddrops onto a pacifier,
12:57:33 12 I can see how it spreads on the pacifier which would
12:57:40 13 be an indication of its viscosity.

12:57:47 14 Q So similarly, if someone took a drop of
12:57:50 15 Vigantol oil and dropped that onto a pacifier tip,
12:57:55 16 they could tell by its properties of how it rolled
12:57:58 17 down or didn't on the pacifier whether it had
12:58:02 18 sufficient viscosity, is that fair?

12:58:03 19 MS. FLORENCE: Objection, foundation and
12:58:04 20 speculation. Go ahead and answer to the extent you
12:58:08 21 can.

12:58:08 22 THE WITNESS: They might be able to tell.
12:58:21 23 Viscosity is a measurable property also. And for
12:58:26 24 the purposes of the invention, the viscosity was
12:58:34 25 found to be appropriate to meet the unmet need,

12:58:42 1 meaning that they were able to consistently and
12:58:45 2 efficaciously transfer by putting a drop onto a
12:58:50 3 pacifier, get that sucked off into the patient.

12:59:03 4 BY MS. KRANING:

12:59:10 5 Q Is it your opinion that you would have to
12:59:12 6 quantify the viscosity to know whether it worked for
12:59:16 7 the invention?

12:59:22 8 A No. I'm just saying that the viscosity is
12:59:34 9 an important factor because it's one of the
12:59:47 10 determinants of drop size. For example, honey is
12:59:51 11 very viscous. Have you ever tried to drop a single
12:59:55 12 drop of honey? It stretches out and becomes very
13:00:02 13 large. I don't know anything about Vigantol oil
13:00:08 14 other than what I've seen in the prior art since
13:00:10 15 I've never used it.

13:00:12 16 Q But fair to say that a person of ordinary
13:00:16 17 skill in the art at the time of the invention, if
13:00:19 18 they had access to Vigantol oil, they could do that
13:00:23 19 test, right, of putting one drop of Vigantol oil
13:00:26 20 onto a pacifier?

13:00:29 21 A Under experimental conditions, they might be
13:00:36 22 able to do that.

13:00:39 23 Q Why do you say under experimental
13:00:43 24 conditions?

13:00:49 25 A Because I think they need to be paying close

13:00:58 1 attention to what they're doing.

13:01:15 2 Q Do you think a person of ordinary skill in
13:01:19 3 the art would have to quantify the viscosity of the
13:01:22 4 Vigantol oil to determine if it met the claims of
13:01:30 5 the invention?

13:01:35 6 A No, I think you asked me that. I don't
13:01:40 7 think they need to have a measured viscosity.

13:01:53 8 Q They would need to do it under experimental
13:01:57 9 conditions, but they would not have to measure
13:01:58 10 viscosity?

13:02:00 11 MS. FLORENCE: Objection, compound.

13:02:01 12 THE WITNESS: I'm saying they need to be
13:02:07 13 paying attention to the complete picture of trying
13:02:15 14 to administer a predictable amount of vitamin D to
13:02:23 15 the patient by way of putting a drop on the pacifier
13:02:29 16 in this example.

13:02:31 17 BY MS. KRANING:

13:02:36 18 Q And it's possible that a person of skill in
13:02:40 19 the art could have done that with Vigantol oil?

13:02:44 20 MS. FLORENCE: Objection, calls for
13:02:46 21 speculation. Go ahead and answer.

13:02:48 22 THE WITNESS: I don't know.

13:02:51 23 BY MS. KRANING:

13:02:54 24 Q Is it impossible that a person of skill in
13:02:57 25 the art could have done that test with Vigantol oil?

13:03:02 1 A No, I don't think it's impossible.

13:03:05 2 Q So it's possible a person of skill in the
13:03:17 3 art could have performed that test with Vigantol
13:03:19 4 oil?

13:03:25 5 MS. FLORENCE: Objection, calls for
13:03:26 6 speculation. Go ahead and answer.

13:03:28 7 THE WITNESS: If a person skilled in the art
13:03:36 8 had done that, I think it would be available in
13:03:41 9 prior art.

13:03:47 10 BY MS. KRANING:

13:03:47 11 Q And why do you say that?

13:03:55 12 A I think if a study were done to determine
13:04:08 13 whether Vigantol oil consistently and efficaciously
13:04:13 14 delivered 400 units of vitamin D to an infant, it
13:04:25 15 would have been known by a person of ordinary skill
13:04:32 16 in the art.

13:04:32 17 Q Going back to your declaration, in the same
13:04:53 18 paragraph at the bottom you say, Without a firm
13:04:56 19 understanding of a supplement's viscosity and
13:04:59 20 adhesion to the spoon, and appropriate testing to
13:05:04 21 demonstrate that an adequate but not toxic amount of
13:05:07 22 vitamin D will be consistently and efficaciously
13:05:11 23 taken by an infant, Harder's instructions introduced
13:05:17 24 the unacceptable risk that well-meaning caregivers
13:05:20 25 will administer too little or toxic amounts of

13:05:23 1 vitamin D.

13:05:26 2 Those are the sentences that you wrote?

13:05:28 3 A I see that, yes. I wrote that. That is one
13:05:34 4 sentence, to be clear.

13:05:38 5 Q Would a pediatrician, if he was prescribing
13:05:44 6 Vigantol oil, know the viscosity and adhesion
13:05:47 7 properties it had?

13:05:49 8 MS. FLORENCE: Objection, speculation.

13:05:50 9 THE WITNESS: A pediatrician prescribing a
13:06:09 10 vitamin D supplement would do well to make sure that
13:06:23 11 giving an appropriate amount of the vitamin D had
13:06:30 12 been demonstrated in this case by the inventor.

13:06:42 13 BY MS. KRANING:

13:06:50 14 Q So are you saying that a pediatrician would
13:06:53 15 need to test the viscosity properties of a vitamin D
13:06:58 16 supplement before prescribing it?

13:07:05 17 A No. I'm saying that I as a pediatrician,
13:07:18 18 before I recommend that a parent or caregiver give a
13:07:25 19 vitamin D substance -- supplement to their newborn
13:07:31 20 child, I am confident that the right dose is
13:07:44 21 effectively being given on a consistent basis. So
13:07:50 22 it's not the actual measurement -- measured number
13:07:57 23 of viscosity or let's say the frictional adhesive
13:08:09 24 properties to the surface from which the vitamin D
13:08:16 25 is transferred. That's not what is important.

13:08:21 1 What's important to me as the pediatrician is that
13:08:24 2 the patient get the right amount and that it get
13:08:30 3 transferred to them consistently and efficaciously.

13:08:42 4 Q How do you as a pediatrician determine if
13:08:45 5 the right dose is effectively being given on a
13:08:49 6 consistent basis?

13:08:54 7 A It depends on what we're talking about. If
13:09:01 8 we are discussing vitamin D, I feel confident based
13:09:11 9 on my knowledge about what the product is and how it
13:09:20 10 works and how the method of administration has been
13:09:32 11 substantiated by scientific study.

13:09:44 12 Q So let's take the Ddrops product that you
13:09:50 13 recommend to your patients. How do you determine if
13:09:54 14 the right dose of the Ddrops product is effectively
13:10:01 15 being given on a consistent basis?

13:10:03 16 A I don't measure vitamin D levels as a part
13:10:15 17 of routine screening of patients which would be the
13:10:23 18 only way to definitively say what those levels are,
13:10:32 19 no matter how they got there.

13:10:46 20 Q So looking at your testimony from a moment
13:10:48 21 ago and what I have here is you say, I'm saying that
13:10:53 22 as a pediatrician -- let's start over. "I'm saying
13:10:56 23 that I as a pediatrician, before I recommend to the
13:11:00 24 parent or caregiver to give a vitamin D supplement
13:11:04 25 to a newborn child, I'm confident the right dose is

13:11:07 1 effectively being given on a consistent basis. "

13:11:13 2 So how do you satisfy yourself for that
13:11:17 3 requirement for the Ddrops product?

13:11:18 4 A I think you left off at the end of the quote
13:11:21 5 where I said by scientific study because there is
13:11:29 6 documentation in Dr. Vieth's notebooks and in the
13:11:34 7 patent itself that support the fact that the right
13:11:42 8 amount of vitamin D is being administered and that
13:11:47 9 the patient is receiving it.

13:11:53 10 Q When did you first see the '958 patent
13:11:58 11 that's being challenged in this proceeding?

13:12:03 12 A Sometime between April and now.

13:12:12 13 Q And Dr. Vieth's notebook, you understand
13:12:17 14 that that's a confidential document, right?

13:12:20 15 A Okay.

13:12:24 16 Q So my question is when you started
13:12:29 17 recommending to your patients that they administer
13:12:34 18 the Ddrops product to their children, how did you
13:12:39 19 know that the right dose was being consistently and
13:12:44 20 effectively given?

13:12:47 21 A Well, since it wasn't measured, I did not
13:13:03 22 know for an absolute fact.

13:13:06 23 Q Okay. So let's talk about how you got an
13:13:59 24 amount. Now, I think that we established earlier
13:14:01 25 that if you followed Harder's instructions and just

13:14:04 1 put one drop of Vigantol oil on a spoon -- and here
13:14:09 2 I can get this back in front of us -- the Vigantol
13:14:12 3 oil that contains -- one drop contains 500 IU -- let
13:14:18 4 me set up my question again.

13:14:20 5 If you followed Harder's instruction of
13:14:23 6 administering one drop that contains 500 IU to a
13:14:29 7 baby, you would never get a toxic dose, right?

13:14:35 8 MS. FLORENCE: Objection, relevance and
13:14:37 9 scope. Go ahead and answer to the extent you can.

13:14:40 10 THE WITNESS: Well, first of all, the
13:14:52 11 concentration of Vigantol oil -- the concentration
13:14:57 12 of vitamin D conflicts here with what was in Wolf.
13:15:04 13 So that brings into question the actual
13:15:09 14 concentration of vitamin D in Vigantol oil. And the
13:15:16 15 size of a drop here is not quantified, so I don't
13:15:23 16 think you can say that it would never lead to a
13:15:29 17 toxic dose.

13:15:34 18 BY MS. KRANING:

13:15:37 19 Q But you agree that Harder discloses that one
13:15:39 20 drop contains 500 IU, correct?

13:15:45 21 A That is what this translation says.

13:15:52 22 Q Is 500 IU of vitamin D a toxic dose to a
13:15:56 23 baby?

13:15:58 24 MS. FLORENCE: Objection, calls for
13:15:59 25 speculation. Go ahead and answer to the extent you

13:16:02 1 can.

13:16:05 2 THE WITNESS: I don't think so, but all

13:16:07 3 babies are different.

13:16:08 4 BY MS. KRANING:

13:16:21 5 Q You testified earlier that Ddrops sells a
13:16:40 6 product that is 600 IU per drop?

13:16:43 7 A Yes.

13:16:44 8 Q I think we established that Vigantol oil at
13:17:15 9 the time of Harder was a prescription medicine,
13:17:18 10 right?

13:17:24 11 A We established that the translation of
13:17:26 12 Harder says that Vigantol oil is a prescription-only
13:17:30 13 medicine.

13:17:31 14 Q And do you have any reason to dispute that
13:17:38 15 Vigantol oil was a prescription-only medicine?

13:17:44 16 A No.

13:17:45 17 Q When a medicine is approved to be given to
13:18:01 18 patients, is it fair to say that means it's
13:18:05 19 undergone toxicity testing?

13:18:08 20 MS. FLORENCE: Objection, calls for
13:18:10 21 speculation and outside the scope and vague.

13:18:17 22 THE WITNESS: I believe this was in Germany
13:18:20 23 and I don't pretend to know what their process is.
13:18:30 24 And we are not looking at a package insert of a
13:18:34 25 prescription medication that at least in this

13:18:38 1 country would spell out some of what you're asking.

13:18:43 2 BY MS. KRANING:

13:18:46 3 Q So is it your opinion that at this time in
13:18:54 4 Germany, a nutritional supplement could have been on
13:18:57 5 the market that was toxic?

13:18:58 6 MS. FLORENCE: Objection. Same objections.
13:19:01 7 Calls for speculation.

13:19:04 8 THE WITNESS: I think that's possible.

13:19:09 9 BY MS. KRANING:

13:19:14 10 Q Do you think the 500 IU drop of Vigantol oil
13:19:17 11 was toxic?

13:19:19 12 MS. FLORENCE: Objection, calls for
13:19:21 13 speculation.

13:19:21 14 THE WITNESS: In most cases, no, I don't
13:19:31 15 think so.

13:19:49 16 BY MS. KRANING:

13:19:50 17 Q Is it fair to say that given the fact that
13:19:52 18 both Harder and Wolf tell you to use one drop of
13:19:57 19 Vigantol oil or Vigantol, that presumably if someone
13:20:03 20 wanted to arrive at one drop as the right dose, it
13:20:08 21 would be adequate and not toxic?

13:20:09 22 MS. FLORENCE: Objection, compound.
13:20:12 23 Objection, speculation.

13:20:15 24 THE WITNESS: I'm going to ask you to please
13:20:20 25 just ask in simpler questions if you don't mind.

13:20:25 1 BY MS. KRANING:

13:20:25 2 Q Sure. Do you think -- strike that.

13:20:39 3 Is it your opinion that the one drop that's
13:20:42 4 disclosed in Harder and Wolf is an arbitrary amount?

13:20:47 5 MS. FLORENCE: Same objections. Go ahead.

13:20:49 6 THE WITNESS: I can't be certain that the
13:21:00 7 two are referring to the exact same thing in terms
13:21:06 8 of the product. And I think Wolf doesn't get into
13:21:14 9 the detail about how the supplement is administered
13:21:20 10 from what you showed me earlier. So I don't think
13:21:26 11 you can lump them all together.

13:21:32 12 BY MS. KRANING:

13:21:33 13 Q In your opinion, is 500 IU an effective
13:21:37 14 amount of vitamin D?

13:21:38 15 A The recommended amount of vitamin D is
13:21:49 16 400 units per day for children under one, or most
13:21:56 17 children under one.

13:21:59 18 Q Right. I think we said a minute ago Ddrops
13:22:02 19 actually have a product that has 600 IU as a daily
13:22:06 20 dose, right?

13:22:10 21 MS. FLORENCE: Objection, mischaracterizes
13:22:12 22 the testimony.

13:22:16 23 THE WITNESS: You asked if they make a
13:22:18 24 product that has 600 units and I said yes.

13:22:22 25 ///

13:22:22 1 BY MS. KRANING:

13:22:27 2 Q A product that has 600 IU, is that
13:22:30 3 delivering 600 IU in a daily dose?

13:22:34 4 A Yes, 600 IU per drop.

13:22:38 5 Q So the 500 IU that's disclosed in Harder for
13:22:46 6 Vigantol oil falls in between the recommended amount
13:22:49 7 and the higher IU product that Ddrops sells?

13:22:54 8 MS. FLORENCE: Objection, mischaracterizes
13:22:55 9 the testimony. Go ahead and answer to the extent
13:22:58 10 you can.

13:22:59 11 THE WITNESS: Would you scroll up, please,
13:23:07 12 in the -- up some more. Keep going. There we go.
13:23:41 13 What is your question again?

13:23:42 14 BY MS. KRANING:

13:23:44 15 Q The 500 IU dose that's disclosed in Harder
13:23:48 16 for Vigantol oil in Option 3 falls in between the
13:23:52 17 recommended amount of 400 IU and the higher 600 IU
13:23:57 18 product that Ddrops sells?

13:24:01 19 MS. FLORENCE: Same objection.
13:24:03 20 Mischaracterizes evidence, testimony and calls for
13:24:07 21 speculation. Sorry, counsel, you're comparing
13:24:12 22 different products.

13:24:16 23 BY MS. KRANING:

13:24:16 24 Q Do you understand my question, Dr. Horowitz?

13:24:18 25 A I don't think there was a question in there.

13:24:20 1 I think you were just saying that 500 falls between
13:24:24 2 400 and 600. The 600 IUs per drop is for older
13:24:30 3 children where 600 international units per day is
13:24:33 4 what's recommended. And the 400 international units
13:24:37 5 per drop is for children under a year of age.

13:24:44 6 Q So in any event, the 500 IU dose is not
13:24:48 7 going to be toxic to infants?

13:24:52 8 MS. FLORENCE: Objection, speculation. Go
13:24:54 9 ahead and answer to the extent you can.

13:24:55 10 THE WITNESS: I don't know that you can say
13:25:01 11 that 500 units is not toxic for any child.

13:25:07 12 BY MS. KRANING:

13:25:11 13 Q So it's your opinion that for some children,
13:25:15 14 500 IU is a toxic amount of vitamin D?

13:25:19 15 MS. FLORENCE: Objection to form. Go ahead
13:25:22 16 and answer.

13:25:23 17 THE WITNESS: No, I'm saying it might be.

13:25:26 18 BY MS. KRANING:

13:25:29 19 Q Right. So your opinion is that for some
13:25:31 20 children, 500 IU is a toxic amount of vitamin D?

13:25:36 21 MS. FLORENCE: Objection, asked and
13:25:49 22 answered. You can go ahead and answer.

13:25:51 23 THE WITNESS: I said it might be.

13:25:53 24 BY MS. KRANING:

13:25:59 25 Q In your experience, in your 30 years as a

13:26:03 1 pediatrician, have you ever seen a 500 IU dose given
13:26:06 2 to a baby that was toxic?

13:26:16 3 A Have I ever seen that a 500 IU dose of
13:26:21 4 vitamin D was given to a baby and it was toxic? Is
13:26:26 5 that your question? No, I have never seen that.

13:26:30 6 Q Okay. I'm going to go back to your
13:26:35 7 declaration. And I'm going to go to page 12 and
13:26:41 8 paragraph 6j. And in this paragraph you say that
13:26:50 9 the supplement must stick to the surface of the
13:26:52 10 nipple, pacifier or knuckle (the object) to which it
13:26:56 11 is initially applied without running off, yet leave
13:27:00 12 less than or equal to 10 percent of the provided
13:27:03 13 supplement behind.

13:27:04 14 Did I get that right?

13:27:05 15 A Yes.

13:27:06 16 Q Where did you get the 10 percent from?

13:27:14 17 A When determining if an appropriate amount of
13:27:28 18 something is administered, 10 percent is the cutoff,
13:27:36 19 at least 90 percent of it must successfully
13:27:40 20 transfer.

13:27:49 21 Q And why is that?

13:27:51 22 A Well, for labeling purposes, one needs to
13:28:04 23 demonstrate that at least 90 percent of what you
13:28:09 24 intend to administer is being, in fact,
13:28:12 25 administered. And the inventor demonstrates that.

13:28:23 1 Q Why not 95 percent?

13:28:33 2 A It's my understanding that 90 percent is the
13:28:42 3 cutoff.

13:28:46 4 Q You're using the word "cutoff." Where is
13:28:50 5 that coming from?

13:28:59 6 A Well, I'm not sure if it's something I read
13:29:04 7 in some documentation from the FDA or some other
13:29:08 8 place, but 90 percent is that minimum amount that
13:29:17 9 needs to -- you need to be in that range of 90 to
13:29:24 10 100 percent.

13:29:26 11 Q Why not 80 percent?

13:29:26 12 CERTIFIED STENOGRAPHER: Counsel, you're
13:29:35 13 muted if you're trying to make an objection.

13:29:41 14 MS. FLORENCE: Thank you. Objection, calls
13:29:46 15 for speculation. Answer to the extent you can.
13:29:48 16 Thank you.

13:29:49 17 THE WITNESS: I don't know where the
13:29:53 18 90 percent number comes from.

13:30:00 19 BY MS. KRANING:

13:30:02 20 Q You don't cite anything for this sentence,
13:30:04 21 right? I'll just scroll down to the bottom of the
13:30:06 22 page. This is to a different -- this goes to this.
13:30:12 23 There's no citation at the end of this sentence
13:30:15 24 about leave less than or equal to the 10 percent of
13:30:18 25 the provided supplement behind, right?

13:30:20 1 A I don't see any reference there, no.

13:30:23 2 Q Okay. So in the next sentence you reference
13:30:35 3 the inventor's lab notebook. You say that the
13:30:42 4 invention, as tested by the inventor, was shown to
13:30:46 5 deliver the appropriate dose of vitamin D in an
13:30:50 6 efficacious way. I noticed for this particular
13:30:57 7 citation, you did not include this as an exhibit at
13:31:03 8 the end of your declaration. Does that sound right?

13:31:09 9 A Yes. If it's not there, it's not there.

13:31:20 10 Q Was there a reason that you didn't include
13:31:22 11 that as an exhibit to your declaration?

13:31:25 12 A Not that I can think of.

13:31:27 13 Q Okay. I'm going to mark for the record
13:31:54 14 Exhibit 2068 which is the doctor -- is it Mr. or
13:32:02 15 Dr. Vieth? I apologize if I've been saying it
13:32:06 16 wrong -- Reinhold Vieth's declaration.

13:32:10 17 MS. FLORENCE: I've got it in the chat too,
13:32:12 18 right?

13:32:13 19 MS. KRANING: Yes, I think I just did it
13:32:17 20 right.

13:32:18 21 MS. FLORENCE: Thank you.

13:32:18 22 (Document marked previously as

13:32:26 23 Exhibit 2068 was presented.)

13:32:26 24 BY MS. KRANING:

13:32:26 25 Q So this is the place where I was able to

13:32:28 1 find in the record for where the lab notebook was.
13:32:32 2 That's why I'm putting this up.
13:32:33 3 Did you review Dr. Vieth's declaration?
13:32:41 4 A At some point I have seen it.
13:32:46 5 Q Okay. Today we're just going to go to
13:32:49 6 page 76. And so if you notice here at the bottom
13:32:56 7 and looking at what we call the Bates numbers
13:32:59 8 here -- I'll blow it up in just a second -- you had
13:33:01 9 cited to pages 394 to 414, and so here it says Vieth
13:33:11 10 394. So is this the lab notebook that you were
13:33:17 11 referring to in your declaration?
13:33:20 12 A It looks like it, yes.
13:33:22 13 Q Okay. Could you point me to where the
13:33:26 14 documentation is in this notebook that supports your
13:33:29 15 statement that the invention has less than
13:33:33 16 10 percent loss basically?
13:33:42 17 MS. FLORENCE: Objection, it
13:33:42 18 mischaracterizes the testimony, but go ahead and
13:33:44 19 answer to the extent you can.
13:33:45 20 THE WITNESS: I think -- no.
13:34:15 21 BY MS. KRANING:
13:34:17 22 Q I'll give you remote control if it will
13:34:20 23 help.
13:34:20 24 A Are there other pages that I can have access
13:34:22 25 to?

13:34:23 1 Q There's several. Let me know when you want
13:34:49 2 to go on to the next page. There's a few pages.
13:35:06 3 A Go on. I think there's a page that has a
13:35:08 4 table of pacifier weights or something on it. Let's
13:35:16 5 see.
13:35:17 6 Q Let's see. I'm scrolling a little bit
13:35:23 7 quickly to see if I can see a table. Is this --
13:35:27 8 this is a table.
13:35:52 9 A Go on. Keep going. Keep going. Go back.
13:36:42 10 Q Back here?
13:36:44 11 A Go back one page, please.
13:36:49 12 Q This one?
13:36:51 13 A No. Go back one more. Can I take control,
13:37:33 14 please?
13:37:34 15 Q Yes. Let me give you -- there we go.
13:38:08 16 A I don't know how to work this.
13:38:11 17 Q You can also -- Dr. Horowitz, you can
13:38:14 18 download this through the chat and then manipulate
13:38:16 19 it through your computer. That might be an easier
13:38:19 20 way rather than trying to do the remote.
13:38:23 21 A Thanks.
13:38:25 22 MS. FLORENCE: It's 2068, the last document
13:38:31 23 in there.
13:38:31 24 THE WITNESS: Got it.
13:43:56 25 MS. KRANING: While we're waiting, Sandra,

13:43:58 1 could you give me an estimate of how long I've been
13:44:00 2 on the record.

13:47:01 3 (Discussion off the record.)

13:47:01 4 THE WITNESS: Is this the only art with
13:49:53 5 pages from Dr. Vieth's notebooks?

13:49:58 6 BY MS. KRANING:

13:49:58 7 Q So this is the range that you cited to in
13:50:02 8 your declaration in that footnote 12. It is the
13:50:08 9 full range, I believe, 394 to 414.

13:51:05 10 A Well, I don't see it here. I was looking
13:51:08 11 for a table that had before and after sucking off
13:51:16 12 the pacifier with some measurements.

13:51:28 13 Q Okay. Do you think that's in a different
13:51:31 14 inventor notebook that you had seen?

13:51:34 15 A It might have been, yes, because I don't
13:51:37 16 even see the table I was looking for.

13:51:44 17 MS. KRANING: Counsel, is that something you
13:51:45 18 can follow up with after the deposition if there is
13:51:47 19 a different page or a different notebook? You're on
13:51:51 20 mute.

13:51:52 21 MS. FLORENCE: Yeah, we will. Sorry. Thank
13:51:55 22 you.

13:51:56 23 MS. KRANING: No worries.

13:51:58 24 BY MS. KRANING:

13:51:58 25 Q Okay. You can set that aside. I appreciate

13:52:01 1 you doing that exercise with me to look for that
13:52:03 2 information.

13:52:05 3 A I would say it was my pleasure.

13:52:07 4 Q At least it was a period of time where you
13:52:11 5 weren't having questions thrown at you. Okay.

13:52:17 6 Going back to your declaration, I'm going to
13:52:21 7 go back to page 12 and paragraph 6k. I'll share my
13:52:27 8 screen again. And actually I'm going to go down --
13:52:43 9 I was looking at the sentence where you talk about
13:52:45 10 the shortcomings of the then available options, such
13:52:50 11 as cod liver oil, Vigantol oil and injectable
13:52:56 12 vitamin D. Do you see that?

13:52:57 13 A I see it.

13:52:58 14 Q What were the shortcomings of Vigantol oil?

13:53:02 15 A The shortcomings include, but are not
13:53:09 16 limited to, what is known about drop size,
13:53:18 17 concentration, adhesion and the ability to
13:53:20 18 administer it consistently and efficaciously.

13:53:27 19 Q Is it fair to say that the shortcomings you
13:53:45 20 identified are just shortcomings because they
13:53:47 21 weren't expressly disclosed in the prior art?

13:54:08 22 MS. FLORENCE: Objection, calls for
13:54:10 23 speculation. Go ahead and answer to the extent you
13:54:12 24 can.

13:54:13 25 THE WITNESS: Well, I have not seen any

13:54:17 1 demonstration that Vigantol oil, and especially with
13:54:22 2 the way it was described for use in the Harder
13:54:25 3 reference, meets the need.

13:54:33 4 BY MS. KRANING:

13:54:47 5 Q Is it possible that it could meet the need?

13:54:51 6 MS. FLORENCE: Objection, speculation. Go
13:54:53 7 ahead and answer to the extent you can.

13:54:54 8 THE WITNESS: I don't know.

13:54:56 9 BY MS. KRANING:

13:55:17 10 Q Is it fair to say that your assumption is
13:55:19 11 that a person of skill in the art would have known
13:55:23 12 that Vigantol oil could not be reliably delivered
13:55:27 13 with a spoon?

13:55:29 14 MS. FLORENCE: Objection, argumentative,
13:55:30 15 speculation. Go ahead and answer to the extent you
13:55:34 16 can.

13:55:35 17 THE WITNESS: According to the Harder
13:55:39 18 reference, there's no way to use Vigantol oil via
13:55:47 19 the tip of a spoon as described to meet the need.

13:55:55 20 BY MS. KRANING:

13:55:56 21 Q So a person of skill in the art would have
13:55:57 22 understood that a spoon would not have worked. Is
13:56:01 23 that your opinion?

13:56:08 24 MS. FLORENCE: Objection, form. Go ahead
13:56:13 25 and answer to the extent you can.

13:56:14 1 THE WITNESS: I think a person skilled in
13:56:16 2 the art would not rely on spooning into the mouth of
13:56:25 3 an infant a supplement like what we're talking about
13:56:31 4 here.

13:56:31 5 BY MS. KRANING:

13:56:35 6 Q So is it fair to say that your opinion is
13:56:37 7 that a person of ordinary skill in the art would not
13:56:41 8 have selected a spoon to administer a vitamin D oil
13:56:46 9 to an infant?

13:56:48 10 MS. FLORENCE: Objection, speculation and
13:56:51 11 form. Go ahead and answer to the extent you can.

13:56:53 12 THE WITNESS: It might have been done that
13:56:58 13 way, but there's a better way now thanks to the
13:57:03 14 invention.

13:57:04 15 BY MS. KRANING:

13:57:07 16 Q Setting aside the invention though, your
13:57:11 17 opinion is that a person of ordinary skill in the
13:57:13 18 art would not have used a spoon to administer
13:57:20 19 vitamin D oil to an infant?

13:57:22 20 MS. FLORENCE: Same objections. Go ahead.

13:57:24 21 THE WITNESS: I expect that they would
13:57:37 22 explore other options to using a spoon because it's
13:57:43 23 such an unnatural way to feed a newborn.

13:57:51 24 BY MS. KRANING:

13:58:28 25 Q At the beginning of your deposition,

13:58:30 1 Dr. Horowitz, do you recall we talked through the
13:58:33 2 different options that a parent would have to
13:58:39 3 administer medicines or nutritional supplements to a
13:58:44 4 baby?

13:58:46 5 A Yes.

13:58:47 6 Q And do you recall that one of those options
13:58:52 7 was a pacifier?

13:58:56 8 A Yes.

13:58:57 9 Q And another was a gloved fingertip?

13:59:04 10 A Yes.

13:59:04 11 Q Were those methods of administering a
13:59:11 12 medicine or a nutritional supplement known back in
13:59:15 13 2006?

13:59:21 14 MS. FLORENCE: Objection, calls for
13:59:23 15 speculation. Go ahead and answer to the extent you
13:59:25 16 can.

13:59:25 17 THE WITNESS: I don't know that that was
13:59:27 18 done as a matter of a recommendation that was
13:59:35 19 followed or that people did or did not do that.
13:59:44 20 When I heard about the invention, it seemed like a
13:59:53 21 novel way to administer the vitamin D supplement.

14:00:03 22 BY MS. KRANING:

14:00:10 23 Q So you had not seen that method of
14:00:13 24 administration before?

14:00:17 25 A Of a nutritional supplement, no.

14:00:21 1 Q In 2006, would a person of skill in the art
14:00:42 2 have understood or believed that a pacifier would be
14:00:48 3 a more effective method of administration than a
14:00:53 4 spoon for an infant?

14:00:56 5 MS. FLORENCE: Objection, form. Go ahead
14:00:58 6 and answer to the extent you can.

14:01:00 7 THE WITNESS: I think a person of ordinary
14:01:06 8 skill in the art would know that a baby is more
14:01:10 9 likely to suck on a pacifier than off of a spoon.

14:01:14 10 BY MS. KRANING:

14:01:23 11 Q And similarly in 2006, when a person of
14:01:27 12 ordinary skill in the art believed that the tip of a
14:01:32 13 gloved finger would be a more effective method of
14:01:37 14 administering a nutritional supplement than a spoon?

14:01:40 15 MS. FLORENCE: Same objections. Go ahead
14:01:42 16 and answer to the extent you can.

14:01:43 17 THE WITNESS: I think a person of ordinary
14:01:46 18 skill in the art would intuit that because a gloved
14:01:53 19 fingertip is more similar in shape and texture to a
14:01:57 20 nipple, which is the gold standard form of nutrition
14:02:04 21 for an infant, that it would be closer and -- closer
14:02:12 22 to what the baby is likely to take than a spoon.

14:02:24 23 BY MS. KRANING:

14:02:35 24 Q Okay. Going back to your declaration, I'm
14:02:38 25 turning to page 13. And this is paragraph 61. And

14:02:43 1 here in this sentence or -- in the sentence at the
14:02:47 2 end of this paragraph you say, "Since advocating for
14:02:52 3 the use of a single drop to administer vitamin D, I
14:02:55 4 have not heard of any conflicts around its
14:02:59 5 administration from families with infants under my
14:03:02 6 care. "

14:03:03 7 Did I read that right?

14:03:04 8 A Yes.

14:03:05 9 Q In this sentence, are you talking about
14:03:11 10 delivering a single drop generally or on a surface?

14:03:19 11 A I don't know what you mean.

14:03:21 12 Q Yeah. Let me do the contrary. Are you
14:03:25 13 aware of another method of administering a vitamin D
14:03:32 14 supplement to be one drop in a bottle of formula?

14:03:40 15 MS. FLORENCE: Objection, form.

14:03:42 16 THE WITNESS: I think that some of the prior
14:03:52 17 art refers to putting it either in milk or mash, I
14:03:59 18 think they say. But that doesn't make a lot of
14:04:05 19 sense because essentially whatever you put into the
14:04:13 20 volume of milk or mash, they have to take all of it
14:04:18 21 for them to get the prescribed dose.

14:04:22 22 BY MS. KRANING:

14:04:25 23 Q So in your opinion, in this paragraph are
14:04:27 24 you really -- are you really saying since advocating
14:04:31 25 for the use of a single drop on an object or on a

14:04:35 1 surface?

14:04:39 2 MS. FLORENCE: Objection, form.

14:04:39 3 THE WITNESS: Yes. I'm speaking from my

14:04:52 4 personal experience with families.

14:04:58 5 BY MS. KRANING:

14:04:58 6 Q I'm going to go still your declaration to

14:05:02 7 page 15 and paragraph 6p. I'll Zoom out a little

14:05:17 8 bit so we can see more of this. Where I want to

14:05:22 9 focus is really the second part of this paragraph.

14:05:27 10 There's a sentence that starts "the spark that led."

14:05:29 11 If you can review that for me. I'm not going to

14:05:33 12 read into it the record?

14:05:34 13 A Yes, I see it.

14:05:35 14 Q Okay. I am going to read it into the

14:05:44 15 record. I lied. The sentence says, "The spark that

14:05:48 16 led to the innovation described by the '958 patent

14:05:52 17 is analogous to the spark that led to the

14:05:55 18 identification of vitamin C in 1928." And did you

14:06:02 19 write that sentence?

14:06:04 20 A I did.

14:06:04 21 Q What do you mean by that?

14:06:09 22 A I mean that even though there were -- it was

14:06:13 23 well-known that you could give lemons and limes and

14:06:15 24 other citrus to sailors to prevent and treat scurvy,

14:06:23 25 it wasn't until the discovery of vitamin C that it

14:06:27 1 became more of a standardized substance that could
14:06:52 2 be used in a more predictable way, meaning you
14:06:58 3 didn't know how many lemons or limes you would have
14:07:03 4 to eat in order to treat or prevent scurvy, and
14:07:12 5 discovering vitamin C made it possible that you
14:07:17 6 could make, for example, tablets that would prevent
14:07:20 7 and treat scurvy.

14:07:22 8 So it was the discovery of the actual
14:07:26 9 substance that was a real achievement. And that's
14:07:34 10 what I'm saying, as we compare it to the vitamin D
14:07:39 11 drops with the substance and the method of delivery
14:07:46 12 that makes it so much better than what came before
14:07:52 13 it because maybe you could give cod liver oil or you
14:08:00 14 could inject vitamin D or you could give some other
14:08:03 15 amount of a liquid or a solid to a young child, but
14:08:10 16 it wasn't until the invention that you could
14:08:16 17 demonstrate that you were reliably and consistently
14:08:22 18 and efficaciously giving a dose in a way that babies
14:08:28 19 will take it.

14:08:34 20 Q Let's unpack that a little bit. So you
14:08:41 21 would agree with me that the patentee here did not
14:08:44 22 invent vitamin D, right?

14:08:49 23 A Yes, I'm not saying that the inventor
14:08:56 24 discovered vitamin D. But I am saying that he
14:09:04 25 invented a -- he invented something that allows for

14:09:11 1 babies to get their dose of vitamin D consistently
14:09:16 2 and efficaciously and that is an achievement.

14:09:21 3 Q So let's walk through this step-wise. You
14:09:24 4 agree with me that the patentee did not discover
14:09:26 5 vitamin D, right?

14:09:29 6 A Yes.

14:09:29 7 Q And you would agree with me that the
14:09:35 8 patentee did not invent vitamin D in a medium-chain
14:09:44 9 triglyceride oil, right?

14:09:47 10 A I don't know that for a fact.

14:09:51 11 Q Well, we saw in the Harder reference -- we
14:09:56 12 can pop back to that in Exhibit 1007 going back down
14:10:01 13 to Option 3, Harder -- the translation of Harder
14:10:06 14 says that the Vigantol oil, which has vitamin D in
14:10:09 15 it, contains only one excipient as a vehicle for the
14:10:14 16 fat-soluble vitamin D, namely medium-chain
14:10:19 17 triglycerides. Do you see that?

14:10:20 18 A Yes, I do.

14:10:21 19 Q Okay. So the patentee did not invent
14:10:26 20 vitamin D in medium-chain triglyceride oil, right?

14:10:32 21 MS. FLORENCE: Objection, misstates the
14:10:35 22 evidence. Go ahead.

14:10:36 23 THE WITNESS: If Vigantol oil is vitamin D
14:10:43 24 in medium-chain triglycerides and that existed
14:10:48 25 before Dr. Vieth's invention, then yes.

14:10:51 1 BY MS. KRANING:

14:10:57 2 Q And it's fair to say -- it's fair to say
14:11:00 3 that Dr. Vieth did not invent this dosage of
14:11:05 4 vitamin D, right? That was set by guidelines?

14:11:11 5 MS. FLORENCE: Objection, compound question.

14:11:13 6 THE WITNESS: I'll take it one at a time.

14:11:20 7 The recommendation is 400 IUs of vitamin D per day
14:11:26 8 for babies. And did you have another question?

14:11:35 9 BY MS. KRANING:

14:11:36 10 Q Yeah. Maybe the better way to do this is to
14:11:39 11 look at the patent. So now I'm turning to
14:11:44 12 Exhibit 1001, which is the '958 patent and just
14:11:49 13 looking at claim 1, claim 1 includes an amount 9 to
14:11:56 14 9,000 micrograms per mL of vitamin D. Do you see
14:12:01 15 that?

14:12:01 16 A I do.

14:12:02 17 Q That's not a novel amount of vitamin D, is
14:12:10 18 it?

14:12:10 19 MS. FLORENCE: Objection, calls for
14:12:11 20 testimony outside the scope. Go ahead and testify
14:12:14 21 to the extent you can.

14:12:15 22 THE WITNESS: Well, 500 is between 9 and
14:12:20 23 9,000. But actually this is talking about
14:12:28 24 micrograms per milliliter, and we were talking about
14:12:31 25 international units. So I'd need to do the

14:12:38 1 calculation to determine -- you know, we're talking
14:12:45 2 about amounts versus concentrations. That's all.

14:12:48 3 BY MS. KRANING:

14:12:48 4 Q Sure. Let me put it like this, Dr. Vieth
14:13:00 5 did not come up with the recommendation for a daily
14:13:06 6 dose of vitamin D for infants, right?

14:13:13 7 A I don't believe that Dr. Vieth participated
14:13:16 8 in the determination of what the appropriate amount
14:13:18 9 of vitamin D is for infants to get on a daily basis,
14:13:24 10 if that's your question.

14:13:25 11 Q Yeah. Who sets that guideline?

14:13:31 12 A The one that I referenced is the American
14:13:37 13 Academy of Pediatrics from 2008 I think it was. But
14:13:40 14 there were other resources also listed in my
14:13:44 15 declaration.

14:13:53 16 Q Fair to say to say that the desirable dosage
14:13:56 17 was set by guidelines for pediatricians, fair?

14:13:59 18 A Yes.

14:14:00 19 Q And then the patentee did not invent
14:14:12 20 delivering the vitamin D dose in a single drop,
14:14:15 21 right?

14:14:30 22 A You showed me an exhibit that -- the Harder
14:14:36 23 exhibit that showed -- that talked about a -- that
14:14:44 24 talked about an option of giving vitamin D in a less
14:14:56 25 reliable way that included one drop.

14:15:07 1 Q So you would agree with me that the patentee
14:15:09 2 did not invent delivering a vitamin D dose in a
14:15:14 3 single drop, right?

14:15:15 4 MS. FLORENCE: Objection, mischaracterizes
14:15:16 5 the testimony. Go ahead and answer to the extent
14:15:18 6 you can.

14:15:18 7 THE WITNESS: The Harder reference describes
14:15:39 8 Vigantol oil as being 500 IUs per drop, whatever
14:15:44 9 size that is. And that one drop is what Harder
14:15:54 10 prescribes and the rare exception when the infant
14:16:02 11 has bloating from taking tablets in water or a pre
14:16:09 12 -- what is it -- predisposed to allergy.

14:16:23 13 Q So is it fair to say that certain
14:16:25 14 circumstances were known in the art in which a
14:16:29 15 vitamin D dose could be delivered in a single drop?

14:16:34 16 MS. FLORENCE: Objection, mischaracterizes
14:16:35 17 the testimony. Go ahead and answer to the extent
14:16:37 18 you can.

14:16:38 19 THE WITNESS: A person of ordinary skill in
14:16:54 20 the art would probably not -- would not look to a
14:17:01 21 resource such as Harder. But if they did, they
14:17:06 22 would find that in a rare circumstance, one drop of
14:17:11 23 Vigantol oil is what she recommends to deliver
14:17:19 24 vitamin D to an infant according to the
14:17:27 25 translation.

14:17:47 1 BY MS. KRANING:

14:17:48 2 Q I'm going to go back to your declaration.

14:17:52 3 And I'm looking at paragraph 7a. You say here, "The
14:18:13 4 reader is left to guess what side of the tip she
14:18:18 5 means for the supplement to be placed." Right?

14:18:23 6 A Yes.

14:18:24 7 Q Would you agree with me that there's only
14:18:29 8 two sides of a spoon?

14:18:37 9 A Well, there are two ends of a spoon and the
14:18:40 10 spoon can be either the bowl with the mouth upward
14:18:45 11 or the bowl with the mouth downward.

14:18:53 12 Q You say here — you use the phrase "what
14:18:56 13 side of the tip." How many sides of the tip are
14:18:59 14 there?

14:19:00 15 A I would say there are two sides to the tip.

14:19:09 16 Q We talked a little bit ago about your
14:19:27 17 opinion that at least 90 percent of the drop that's
14:19:32 18 placed on a surface should be administered to an
14:19:36 19 infant to be consistently effective — strike that.
14:19:43 20 Let me ask a better question. You can tell it's
14:19:46 21 getting near the end of the day here.

14:19:48 22 I think we talked earlier about how your
14:19:52 23 understanding is that for a dose of vitamin D oil to
14:19:56 24 be consistently and effectively delivered, at least
14:20:00 25 90 percent of the drop needs to be administered —

14:20:04 1 needs to be received by the infant. Is that fair?

14:20:10 2 MS. FLORENCE: Objection, form. Go ahead

14:20:11 3 and answer to the extent you can.

14:20:12 4 THE WITNESS: I think I'll refer to the

14:20:17 5 patent actually that says according -- that says

14:20:24 6 under -- in column 7, if you want to go there. I

14:20:29 7 don't know.

14:20:29 8 BY MS. KRANING:

14:20:29 9 Q Yeah, I'll pull it up. Column 7. We're now

14:20:32 10 in Exhibit 1001 going to column 7.

14:20:37 11 A Go down to -- four lines from the bottom.

14:20:42 12 "Government regulations mandate that vitamin

14:20:45 13 supplements for humans must provide between 90 and

14:20:49 14 120 percent of the labeled doses."

14:20:54 15 Q And for the record, that's column 7, lines

14:20:58 16 64 to 66. So then is it fair to say that you are

14:21:06 17 assuming -- an assumption that you're making is that

14:21:10 18 the invention requires that the infant receive

14:21:15 19 between 90 and 120 percent of the drop that's placed

14:21:20 20 on the surface?

14:21:23 21 MS. FLORENCE: Objection, outside the scope

14:21:25 22 of testimony. Go ahead and answer to the extent you

14:21:30 23 can.

14:21:30 24 THE WITNESS: Yes, I believe so. In that

14:21:52 25 same section, by the way, just above it talks about

14:21:55 1 the 4 percent plus or minus 2 percent standard
14:21:58 2 deviation of the vitamin D and its HPLC, ethanol
14:22:08 3 extract that demonstrate that, which if we went back
14:22:11 4 to the lab notebook, I think there was a page on
14:22:15 5 HPLC. Sorry to digress like that, but you asked
14:22:23 6 earlier --
14:22:23 7 BY MS. KRANING:
14:22:24 8 Q No, you're fine.
14:22:24 9 A I just saw that.
14:22:26 10 Q So column 7 -- for the record, column 7 at
14:22:30 11 lines 55 through 59. So this is some of the
14:22:36 12 experimental data that you were looking for in the
14:22:39 13 lab notebook we looked at earlier, is that right?
14:22:43 14 A That's right. It actually extends down to
14:22:45 15 line 64 because it talks about after 30 seconds it's
14:22:52 16 reproducible, that that's what's left over and the
14:23:00 17 amount that's transferred in the next sentence after
14:23:03 18 that that we just talked about.
14:23:09 19 MS. KRANING: I think this is a good time
14:23:11 20 for a break.
14:23:13 21 MS. FLORENCE: That sounds fine to me.
14:23:15 22 Casey, how much longer do you think you have so we
14:23:20 23 can just maybe do a five-minute break?
14:23:26 24 (Short recess.)
14:23:27 25 ///

14:29:28 1 BY MS. KRANING:

14:29:42 2 Q Dr. Horowitz, going back to when you first
14:29:46 3 started recommending the use of the Ddrops product,
14:29:56 4 you didn't know at that time how much of the
14:30:02 5 vitamin D oil was being delivered to the infant,
14:30:08 6 right?

14:30:11 7 MS. FLORENCE: Objection, form. Go ahead
14:30:13 8 and answer to the extent you can.

14:30:15 9 THE WITNESS: Are you asking me if I knew
14:30:20 10 exactly how much vitamin D infants were getting
14:30:24 11 before and after starting using vitamin D drops?

14:30:29 12 BY MS. KRANING:

14:30:29 13 Q So what I'm trying to ask, perhaps
14:30:32 14 inartfully, is that when you started having
14:30:38 15 familiarity with these single drop vitamin D
14:30:41 16 supplements and you were recommending their use, if
14:30:49 17 you had a pacifier and you put a drop on a pacifier
14:30:52 18 and gave it to the baby, you were not sure whether
14:30:56 19 the baby actually received all of the dose, right?

14:31:05 20 A Because I'm not measuring it, I couldn't
14:31:07 21 know for an absolute fact, but I had confidence that
14:31:12 22 they were getting it. And there's evidence even in
14:31:17 23 the patent that shows that that was confirmed in
14:31:25 24 testing.

14:31:29 25 Q Right. I think we established earlier that

14:31:31 1 you had not seen the '958 patent when you started
14:31:36 2 recommending the use of the vitamin D oil drops,
14:31:40 3 right?

14:31:41 4 A That is true. Just like I have not seen the
14:31:46 5 patent supporting the use of many antibiotics and
14:31:52 6 other medications that we use. We make choices for
14:31:58 7 our patients based on a lot of factors. And I have
14:32:09 8 confidence that administering the Ddrops one drop
14:32:18 9 per day delivers what it says on the packaging.

14:32:23 10 Q So it's fair to say that you rely on what
14:32:28 11 the label discloses?

14:32:32 12 A In some cases, yes.

14:32:34 13 Q Okay. Let's go back to your declaration.
14:32:59 14 And I just want to look at something on your CV. So
14:33:03 15 I will share my screen. We're going to go to
14:33:14 16 page 23. So I've turned to -- I guess to start
14:33:22 17 here, Dr. Horowitz, this is the part of your CV
14:33:26 18 that's attached to your declaration, right?

14:33:28 19 A Yes.

14:33:29 20 Q And then on the page that's marked 23, at
14:33:41 21 the bottom -- I'll blow this up -- it says in 4 you
14:33:48 22 were a recognized contributor to "The Complete and
14:33:51 23 Authoritative Guide Caring for Your Baby and Young
14:33:54 24 Child Birth to Age 5" by the American Academy of
14:33:59 25 Pediatrics, 4th edition?

14:34:00 1 A Yes.

14:34:00 2 Q Is that accurate?

14:34:01 3 A Uh-huh.

14:34:02 4 Q And so I'm going to mark a new exhibit.

14:34:08 5 This one's going to be marked Exhibit 1028.

14:34:12 6 (Exhibit 1028 marked for identification.)

14:34:12 7 BY MS. KRANING:

14:34:13 8 Q I'm going to drop it in the chat. And then

14:34:22 9 I will pull this up on the screen.

14:34:30 10 Dr. Horowitz, do you recognize this

14:34:32 11 document?

14:34:32 12 A Yes.

14:34:33 13 Q And is this the document that's identified

14:34:36 14 on your CV as "The Complete and Authoritative Guide

14:34:41 15 Caring For Your Baby"?

14:34:42 16 A Yes, I think that's the one except that this

14:34:47 17 one says "compliments of your State Farm agent"

14:34:50 18 which I've never seen before.

14:34:51 19 Q And this is put out by the American Academy

14:34:56 20 of Pediatrics?

14:34:56 21 A Yes.

14:34:57 22 Q And do you consider the American Academy of

14:35:02 23 Pediatrics a reliable source?

14:35:04 24 A Yes.

14:35:05 25 Q I'm going to turn now to page 5.

14:35:12 1 MS. FLORENCE: Counsel, has this been
14:35:13 2 produced in this action?
14:35:16 3 MS. KRANING: It has not, no.
14:35:18 4 MS. FLORENCE: Are we going to be getting
14:35:20 5 the production of it? We'll object to the
14:35:21 6 presentation and relevance of this evidence, but if
14:35:26 7 you would produce it that would be great. Thank
14:35:27 8 you.
14:35:28 9 MS. KRANING: Yes, we will produce it,
14:35:30 10 absolutely.
14:35:31 11 BY MS. KRANING:
14:35:31 12 Q I've turned to page 5 of what I have marked
14:35:34 13 as Exhibit 1028 and I just wanted to point out that
14:35:39 14 this does say the fourth trade paperback edition
14:35:42 15 June 2004, updated May 2005. So this is the fourth
14:35:48 16 edition of this document, correct?
14:35:50 17 MS. FLORENCE: Objection. We don't have the
14:35:51 18 full version in front of us. There's no way to
14:35:54 19 authenticate this so we will object on that basis.
14:35:58 20 Go ahead and answer to the extent you can.
14:36:00 21 THE WITNESS: It says fourth trade paperback
14:36:03 22 edition on what you're showing me, yes.
14:36:06 23 BY MS. KRANING:
14:36:07 24 Q And I'm going to page 7 of this document.
14:36:12 25 You confirm that is your name listed as a -- under

14:36:16 1 the -- let's see, contributor section on page 6,
14:36:21 2 your name is listed on page 7 as a contributor, is
14:36:25 3 that right?
14:36:25 4 A Yes.
14:36:26 5 Q I'm going to go back to your declaration. I
14:36:41 6 just want to turn now to your Exhibit B which is the
14:36:47 7 material reviewed in the preparation of this report
14:36:51 8 in addition to footnotes. Is that right?
14:36:54 9 A Yes.
14:36:59 10 MS. FLORENCE: Objection to form.
14:37:00 11 BY MS. KRANING:
14:37:00 12 Q Did you -- did you compile this Exhibit B to
14:37:08 13 your declaration?
14:37:13 14 A I had assistance from counsel.
14:37:17 15 Q And I was trying to assess what in this list
14:37:27 16 -- strike that.
14:37:28 17 My understanding is that this list that's on
14:37:31 18 page 28 of your declaration, these are all materials
14:37:35 19 that are not included as additional exhibits at the
14:37:41 20 end of your declaration. Is that accurate?
14:37:47 21 A I don't think I follow your question.
14:37:52 22 Q So you attached some documents as actual
14:38:01 23 exhibits to your declaration, right?
14:38:02 24 A Yes.
14:38:03 25 Q My understanding is that these documents on

14:38:07 1 page 28 are in addition to the other documents that
14:38:15 2 you label as exhibits and append to your
14:38:21 3 declaration?

14:38:21 4 MS. FLORENCE: Objection, foundation.
14:38:22 5 Mischaracterizes the facts and testimony.

14:38:28 6 BY MS. KRANING:

14:38:28 7 Q I'm just trying to figure this out. I was
14:38:30 8 just trying to get a sense of what this was. So are
14:38:33 9 you saying that these documents are the documents
14:38:35 10 that are attached as additional exhibits?

14:38:41 11 MS. FLORENCE: Counsel, can I help you
14:38:43 12 there?

14:38:44 13 MS. KRANING: I would love for you to help
14:38:46 14 me, yes, please.

14:38:48 15 MS. FLORENCE: I think that it is just
14:38:49 16 following the rules in the USPTO of items that are
14:38:54 17 attached to declaration versus items that have been
14:38:56 18 looked at and referenced as part of the opinion.
14:39:00 19 Does that make sense? So not necessarily referenced
14:39:05 20 to in the declaration, but items that have been
14:39:07 21 referred to or looked at that helped create --

14:39:10 22 MS. KRANING: Okay.

14:39:11 23 MS. FLORENCE: -- the declaration. Does
14:39:12 24 that help?

14:39:13 25 MS. KRANING: Yes, that's very helpful.

14:39:16 1 Thank you.

14:39:16 2 MS. FLORENCE: Okay.

14:39:19 3 BY MS. KRANING:

14:39:19 4 Q So now that I understand that, so just to

14:39:23 5 get a sense of what's in here, so this page on

14:39:26 6 page 28 shows a variety of different documents that

14:39:31 7 you reviewed while you were working on the report,

14:39:33 8 right?

14:39:35 9 A Yes.

14:39:36 10 Q And if I turn to page 29 of this document,

14:39:42 11 now there's a list of IPR filings and documents.

14:39:46 12 And you reviewed those in connection with preparing

14:39:50 13 your declaration?

14:39:53 14 A I looked through a lot of documentation and

14:39:59 15 this seems to be all part of it.

14:40:03 16 Q And it continues onto page 30, there's

14:40:06 17 additional documents from the IPR that you reviewed?

14:40:15 18 A That's right.

14:40:17 19 Q And at the bottom of this page and going

14:40:21 20 onto the next page, I understand this is a list of

14:40:24 21 all of the exhibits that have been filed in the IPR

14:40:30 22 at least up until your declaration was filed. And

14:40:34 23 did you review all of these exhibits?

14:40:39 24 A I believe I saw all of these exhibits. Some

14:40:48 25 of them I looked at more carefully than others.

14:40:51 1 Q Sure, sure.

14:40:52 2 A But I can't reconcile the list that you're
14:40:56 3 showing me right now with -- you know, to answer
14:40:58 4 your question. Did you have a specific question
14:41:05 5 about something on the list?

14:41:06 6 Q No, not yet. Then next at the bottom of
14:41:11 7 this page 31, it says, the Ddrops company --
14:41:17 8 basically this is the litigation documents and that
14:41:19 9 goes on to page 32. I see there's different
14:41:29 10 litigation. So did you review all the documents in
14:41:34 11 these lists from these litigations?

14:41:37 12 A Yes. I looked at material from previous
14:41:41 13 cases.

14:41:47 14 Q And going on to page 33, it looks like
14:41:50 15 additional discovery from litigation and at the
14:41:54 16 bottom of page I see a list of Ddrops and these are
14:42:01 17 Bates numbered documents?

14:42:02 18 A I see that.

14:42:02 19 Q And that goes onto the next page 34, the
14:42:08 20 next page 35, and did you review all of these
14:42:11 21 documents that have the Ddrops and/or the Vieth
14:42:16 22 Bates number?

14:42:17 23 A I believe I did.

14:42:18 24 Q And then going on on page 35 to the list of
14:42:25 25 Mommy's Bliss Bates numbered documents, the list

14:42:29 1 here that extends onto page 36 and 37, do you see
14:42:34 2 that?
14:42:34 3 A I see that.
14:42:35 4 Q And did you review all of these documents?
14:42:40 5 A Yes, I believe I did. Some of it I looked
14:42:43 6 at more carefully than others.
14:42:45 7 Q How much time did it take you to look at all
14:42:48 8 of the documents on your materials considered list?
14:42:54 9 A A lot of time. I can't give you an
14:42:57 10 estimate.
14:43:00 11 Q There's thousands of documents listed here,
14:43:04 12 right?
14:43:05 13 A Which is why some of them I looked at more
14:43:08 14 carefully than others. Did you want to ask me about
14:43:20 15 one of them?
14:43:20 16 Q No. Okay. We went over your background
14:43:24 17 earlier and just to kind of clarify a couple of
14:43:29 18 things, you do not have a doctorate in
14:43:34 19 pharmaceuticals, right?
14:43:35 20 A I am not a pharmacist, no.
14:43:38 21 Q And specifically, you don't have a doctorate
14:43:42 22 in pharmaceuticals, right?
14:43:43 23 A I've never heard the word pharmaceuticals.
14:43:50 24 Q Let me ask it this way. Do you have a
14:43:52 25 Ph.D. ?

14:43:54 1 A No, I don't.

14:43:55 2 Q You have an MD, right?

14:43:58 3 A Yes, I do.

14:43:59 4 Q And have you ever formulated a medicine?

14:44:08 5 A Yes, I think I have.

14:44:11 6 Q And can you tell me a little bit about that?

14:44:15 7 A About 15 years ago, I formulated a diaper

14:44:23 8 rash cream that had certain properties. I don't

14:44:28 9 even remember the details anymore, but I had a

14:44:31 10 compounding pharmacist make some up and we tried it

14:44:37 11 on some babies. That's all I can think of right

14:44:45 12 now. It did work pretty well, but not well enough

14:44:48 13 to do anything with it commercially or anything like

14:44:51 14 that.

14:44:52 15 Q So other than that, the one diaper rash

14:44:58 16 formulation product, have you formulated any other

14:45:01 17 medicines?

14:45:04 18 A Not that I can think of.

14:45:06 19 Q Fair to say that you do not have several

14:45:13 20 years of experience in formulating a medicine,

14:45:15 21 right?

14:45:18 22 A Yes, that is fair to say.

14:45:20 23 Q And have you ever formulated a nutritional

14:45:25 24 supplement?

14:45:27 25 A No, I don't think so.

14:45:29 1 Q So fair to say that you do not have several
14:45:35 2 years of experience in formulating a nutritional
14:45:38 3 supplement?

14:45:39 4 A Yes, that is fair to say.

14:45:41 5 Q And fair to say you're not a patent lawyer,
14:45:47 6 right?

14:45:49 7 A That is very fair to say.

14:45:52 8 Q It's a good thing, trust me. And before
14:45:58 9 this case, you had never offered an opinion on a
14:46:01 10 patent before, right?

14:46:05 11 A That is correct. I hope it's not that
14:46:09 12 obvious in the lay person's parlance.

14:46:14 13 Q And have you ever interpreted the meaning of
14:46:24 14 a claim term in a patent?

14:46:31 15 A No, not before this.

14:46:41 16 MS. KRANING: Okay. Let's go off the record
14:46:43 17 for just a minute.

14:46:45 18 (Short recess.)

14:46:48 19 MS. KRANING: I have just a couple more
14:47:55 20 questions. It should be very, very short.

14:47:59 21 MS. FLORENCE: Okay.

14:48:00 22 BY MS. KRANING:

14:48:06 23 Q Dr. Horowitz, how did you prepare for
14:48:08 24 today's deposition?

14:48:12 25 A I met with counsel. I reviewed a video. I

14:48:20 1 read over my notes and some of the exhibits.

14:48:26 2 Q What video did you review?

14:48:30 3 A Something Bender, Matthew bender maybe. Is
14:48:38 4 that the name?

14:48:40 5 Q And what was --

14:48:42 6 A I think so.

14:48:43 7 Q What was the video about?

14:48:46 8 A Giving expert deposition.

14:48:53 9 Q Hints and tricks for how to answer
14:48:56 10 questions?

14:48:59 11 You said you met with counsel. How many
14:49:02 12 times did you meet with counsel in preparation for
14:49:04 13 your deposition today?

14:49:08 14 A Somewhere around three times, plus or minus;
14:49:19 15 once in person and a couple times on Zoom.

14:49:23 16 Q And when did you meet in person?

14:49:29 17 A About two weeks ago. I can tell you exactly
14:49:36 18 when. Maybe it was a week ago. I think it was on
14:50:13 19 the 12th.

14:50:14 20 Q Okay. That's fine. When you met in person,
14:50:18 21 how long did you meet for?

14:50:20 22 A About -- I don't know. Hold on. I think I
14:50:30 23 can get pretty specific on that.

14:50:35 24 Q You're welcome to ballpark it.

14:50:39 25 A I don't know. Maybe about four-and-a-half

14:50:45 1 or five hours, something like that.

14:50:47 2 Q And who all did you meet with for that four-

14:50:55 3 to five-hour in-person session?

14:50:58 4 A Alan Anderson.

14:51:01 5 Q Anyone else?

14:51:03 6 A No.

14:51:04 7 Q I think you said that you met a couple other

14:51:09 8 times over Zoom for preparation?

14:51:15 9 A That's right.

14:51:16 10 Q About how long were those preparation

14:51:18 11 sessions?

14:51:20 12 A They ranged from 10 minutes to 45 minutes or

14:51:26 13 an hour.

14:51:28 14 Q And was Mr. Anderson on those Zoom calls?

14:51:36 15 A I think he was on one of them.

14:51:38 16 Q Who else was on the Zoom calls?

14:51:45 17 A Reagan, L. Reagan Florence.

14:51:54 18 Q And just Reagan?

14:51:56 19 A Yeah, as far as I remember.

14:51:59 20 Q And did you speak with counsel at any of the

14:52:08 21 breaks today?

14:52:09 22 A No. She told me that my microphone was

14:52:14 23 unmuted for a quick second at the first break. And

14:52:19 24 I'm a quick learner so I didn't do that again.

14:52:23 25 MS. KRANING: Okay. Great. I have no

14:52:24 1 further questions. Thank you for your time today,
14:52:28 2 Dr. Horowitz.
14:52:29 3 MS. FLORENCE: I have a couple of redirect
14:52:30 4 if that's okay.
14:52:32 5 REDIRECT EXAMINATION
14:52:32 6 BY MS. FLORENCE:
14:52:33 7 Q Dr. Horowitz, I don't know. Can I pull up
14:52:37 8 -- Casey, are you able to pull up for me the Vieth
14:52:41 9 patent?
14:52:44 10 MS. KRANING: Yeah. The '958 patent?
14:52:47 11 MS. FLORENCE: Yes, please. Thank you.
14:52:49 12 MS. KRANING: Sure, no problem.
14:52:50 13 MS. FLORENCE: Sorry about that. I don't
14:52:52 14 think I have control. Do I have -- I don't think I
14:52:58 15 have scroll capabilities here either. I just want
14:53:01 16 to go to the very, very top, please. Very first
14:53:04 17 page.
14:53:06 18 MS. KRANING: Oh, first page.
14:53:09 19 MS. FLORENCE: First page. Sorry about
14:53:10 20 that. Sorry, Casey. Wait. Do I have control now?
14:53:16 21 I guess I do now. I do. I did have it. Okay,
14:53:27 22 there we go.
14:53:27 23 BY MS. FLORENCE:
14:53:28 24 Q Okay. So Dr. Horowitz, I am going to show
14:53:31 25 you what has previously been marked and you see this

14:53:35 1 is the '958 patent, correct?

14:53:38 2 A Yes.

14:53:38 3 Q And do you recall earlier when counsel was
14:53:43 4 asking whether the patent had to be administered to
14:53:51 5 an infant to meet the claims? Do you recall that?

14:53:56 6 A I don't think I understood her question to
14:53:58 7 be did it have to be to an infant to meet the
14:54:02 8 claims. I think she asked if giving it to an infant
14:54:07 9 helped meet the un -- helped solve the unmet need.

14:54:12 10 Q Okay. So is it your testimony then that the
14:54:17 11 '958 patent is for more than just infants?

14:54:23 12 A Absolutely.

14:54:24 13 Q Okay. And I'd like to go down and have --
14:54:30 14 if I can. Excuse me. Sorry. I'm trying to scroll
14:54:35 15 down and it's not -- I just want to go to the
14:54:38 16 abstract. Excuse me. It's not letting me. I
14:54:43 17 apologize, Casey.

14:54:44 18 MS. KRANING: So is this on the first page?

14:54:47 19 MS. FLORENCE: It's like the very bottom --
14:54:49 20 there we go. It's 57. If you'll zoom out so that
14:54:54 21 he can read this.

14:54:59 22 MS. KRANING: Zoom in further?

14:55:01 23 MS. FLORENCE: Well, at least --

14:55:03 24 THE WITNESS: I can see it.

14:55:04 25 ///

14:55:04 1 BY MS. FLORENCE:

14:55:04 2 Q Can you read it all? So can you read for us

14:55:07 3 -- oh, my goodness.

14:55:08 4 A I can read it.

14:55:09 5 Q Can you read for us the abstract? I'm not
14:55:11 6 going to touch it. Please go ahead.

14:55:13 7 A "Composition of vitamin D in medium-chain
14:55:16 8 triglycerides and use thereof in delivering a
14:55:19 9 nutritional or therapeutic amount of vitamin D to a
14:55:22 10 human being, particularly an infant. The
14:55:26 11 compositions are applied to an object, such as skin
14:55:31 12 or in the case of an infant, to a woman's nipple or
14:55:35 13 pacifier from which the infant sucks off the
14:55:37 14 composition. The method provides a more suitable,
14:55:41 15 safer, and efficient way of providing the human
14:55:44 16 being with vitamin D. The compositions further
14:55:48 17 comprise a free fatty acid and/or monoglyceride,
14:55:53 18 oxidant preservative and, optionally, other
14:55:57 19 vitamins."

14:55:58 20 Q So, Dr. Horowitz, do you see anything in the
14:56:02 21 patent that suggests it's only for infants?

14:56:08 22 A No, I don't see anything that's exclusive in
14:56:11 23 that.

14:56:13 24 Q Okay, thank you. And the title of the
14:56:15 25 actual patent itself, could you read that for us?

14:56:18 1 If we could go up.

14:56:21 2 A "Vitamin D compositions and method of
14:56:26 3 administration to a human being."

14:56:28 4 Q Okay. Thank you. One more question I have
14:56:33 5 for you and that is regarding the materials on your
14:56:40 6 declaration that you referenced in Exhibit B, I
14:56:44 7 believe. Earlier counsel asked if you had reviewed
14:56:50 8 previous case files and previous cases, correct?

14:56:54 9 A Yes.

14:56:55 10 Q Okay. Isn't it true -- hold that. Sorry.
14:57:00 11 Scratch that.

14:57:02 12 You were hired prior to the IPR by Ddrops,
14:57:07 13 correct?

14:57:10 14 A My --

14:57:11 15 Q For the district court action? Excuse me.

14:57:14 16 A I was hired for the district court action
14:57:18 17 and the IPR -- now that I know what that means --
14:57:23 18 came up after I had agreed to be an expert witness,
14:57:29 19 if that's what you're asking.

14:57:31 20 Q That was. Thank you. And you reviewed
14:57:35 21 documents for the district court action as well when
14:57:41 22 you were hired, correct?

14:57:41 23 A Definitely.

14:57:43 24 Q And are some of the items you reviewed
14:57:46 25 listed in your Exhibit B to your declaration?

14:57:51 1 A I believe so, yes.

14:57:52 2 Q Okay. Might that explain the list of
14:57:55 3 documents being so cumulative in Exhibit B of your
14:58:00 4 declaration?

14:58:02 5 A Yes.

14:58:04 6 MS. KRANING: Objection, leading.

14:58:05 7 BY MS. FLORENCE:

14:58:07 8 Q Dr. Horowitz, is there any document that you
14:58:10 9 can think of that you did not list in your
14:58:13 10 declaration exhibits as you sit here today that
14:58:17 11 would help refresh your testimony?

14:58:29 12 A There was the question about the
14:58:34 13 transference being the 96 percent plus or minus
14:58:40 14 2 percent that I couldn't readily identify in
14:58:45 15 Dr. Vieth's notebook, but I think it was part of
14:58:48 16 that HPLC --

14:58:51 17 Q Okay.

14:58:52 18 A -- documentation. But that -- I also
14:58:56 19 referenced that one case of a patient who got an
14:59:01 20 overdose of vitamin D by getting too high a volume
14:59:07 21 for the concentration that wasn't part of our
14:59:11 22 exhibits, but I don't think that was really
14:59:13 23 material.

14:59:15 24 Q So let me ask you a question. So aside from
14:59:20 25 -- well, strike that.

14:59:22 1 So in writing your report, did you use more
14:59:26 2 than just Dr. Vieth's lab notebook?
14:59:31 3 A Absolutely.
14:59:32 4 Q Okay. What else did you look at to form
14:59:37 5 your opinion, aside from his lab notebook regarding
14:59:42 6 vitamin D concentrations?
14:59:46 7 A My personal experience and the exhibits that
14:59:51 8 were attached to my declaration.
14:59:54 9 Q And in those exhibits, what kind of
14:59:58 10 documents are they?
15:00:01 11 A There's a range of documents from peer
15:00:04 12 reviewed journals to consensus statements and
15:00:10 13 everything in between.
15:00:11 14 Q Okay. And those peer reviewed statements,
15:00:15 15 are they considered academic articles?
15:00:21 16 A Peer reviewed articles generally are
15:00:26 17 academic.
15:00:27 18 Q Okay. And would they be a trusted resource
15:00:31 19 for a medical professional to use as a reference?
15:00:39 20 MS. KRANING: Objection, leading.
15:00:40 21 THE WITNESS: I mentioned earlier -- should
15:00:45 22 I respond? I'm sorry.
15:00:49 23 BY MS. FLORENCE:
15:00:50 24 Q Let me rephrase. Let me rephrase this way.
15:00:57 25 In preparing your opinion, did you use scholarly

15:01:04 1 materials?

15:01:07 2 MS. KRANING: Objection, vague.

15:01:13 3 BY MS. FLORENCE:

15:01:14 4 Q You can go ahead and answer.

15:01:15 5 A Yes.

15:01:15 6 Q And in those — are they listed within your

15:01:21 7 witness statement?

15:01:22 8 A Yes.

15:01:23 9 MS. FLORENCE: Okay, thank you. I just need

15:01:25 10 about two minutes just to go over a couple of more

15:01:28 11 things and then I should be good. Actually I just

15:01:34 12 need one minute if that's okay. I just have to look

15:01:37 13 at one thing.

15:01:43 14 (Short recess.)

15:01:50 15 MS. FLORENCE: Okay, I'm ready.

15:01:55 16 BY MS. FLORENCE:

15:01:56 17 Q Dr. Horowitz, do you recall when counsel

15:01:59 18 asked you about toxicity levels of vitamin D doses?

15:02:07 19 A Yes.

15:02:08 20 Q Now, you don't study toxicity, correct?

15:02:16 21 A That's right. I'm not a pharmacist or a

15:02:21 22 pharmaceutical company or anything of the sort.

15:02:25 23 Q In your opinion, did you make any assertion

15:02:31 24 that a pharmaceutical person would be an ordinary

15:02:35 25 person skilled in the art in this case?

15:02:40 1 A I don't follow you.

15:02:41 2 Q Excuse me. Does someone who has ordinary
15:02:46 3 skill in the art need to have a pharmaceutical
15:02:49 4 degree?

15:02:51 5 A No, not to be an expert in children the way
15:02:56 6 I am.

15:02:57 7 MS. FLORENCE: Okay. No further questions
15:03:00 8 from me.

15:03:03 9 MS. KRANING: Okay. I may have a brief
15:03:06 10 recross if you give me just a minute.

15:03:10 11 (Short recess.)

15:04:48 12 RECCROSS EXAMINATION

15:04:48 13 BY MS. KRANING:

15:04:49 14 Q I just have a very brief recross.

15:04:57 15 Dr. Horowitz, you recall a few moments ago
15:05:00 16 you testified when you counsel asked you about the
15:05:03 17 district court litigation that you were also hired
15:05:11 18 for?

15:05:11 19 A Yes.

15:05:12 20 Q Have you offered any opinions in either an
15:05:18 21 expert report or a declaration in that district
15:05:21 22 court proceeding?

15:05:22 23 A No.

15:05:28 24 MS. KRANING: I have no further questions.

15:05:29 25 MS. FLORENCE: I just have -- one more one

15:05:32 1 more follow-up really fast. Is that okay? Sorry.

15:05:35 2 RE-REDIRECT EXAMINATION

15:05:35 3 BY MS. FLORENCE:

15:05:35 4 Q Dr. Horowitz, isn't it true that the
15:05:38 5 district court action was stayed upon commencement
15:05:42 6 of this IPR?

15:05:44 7 A As I understand it, yes. That is --

15:05:48 8 Q Okay.

15:05:49 9 A You're about to get out of my scope of what
15:05:52 10 I understand here.

15:05:53 11 Q I was just going to say, might that explain
15:05:57 12 why you have not offered an opinion yet?

15:05:58 13 THE WITNESS: Yes.

15:05:59 14 MS. FLORENCE: Okay, thank you. That's it.

15:06:02 15 MS. KRANING: Great.

16

17 (Time Noted: 3:06 p.m.)

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I, PAUL HOROWITZ, M.D., being first duly
sworn, on oath say that I am the deponent in the
aforesaid deposition taken on March 19th, 2024; that
I have read the foregoing transcript of my
deposition, consisting of pages 1 through 148
inclusive, and affix my signature to same.

_____ as it now appears
_____ as it now appears with corrections

PAUL HOROWITZ, M.D.

SUBSCRIBED and sworn to
before me this _____ day of
_____, 2024.

Notary Public

1 C E R T I F I C A T E

2 I, Sandra L. Rocca, CSR, RMR, RDR, CRR, a
3 Certified Court Reporter within and for the States
4 of Illinois, Florida, Washington and Georgia, do
5 hereby certify:

6 That PAUL HOROWITZ, M.D., the witness whose
7 deposition is hereinbefore set forth, was duly sworn
8 by me and that such deposition is a true record of
9 the testimony given by such witness.

10 I further certify that I am not related to
11 any of the parties to this action by blood or
12 marriage; and that I am in no way interested in the
13 outcome of this matter.

14 IN WITNESS WHEREOF, I have hereunto set my
15 hand this 26th of March, 2024.

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20
21

Sandra L. Rocca, CSR, RMR, RDR, CRR

22
23
24
25

IL License 084-003435
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Illinois, D.C. and Florida Notary

1 ERRATA SHEET FOR THE TRANSCRIPT OF:

2 Case Name: MOM Enterprises vs Vieth

Dep. Date: 3/19/24

3 Deponent: PAUL HOROWITZ, M. D.

4

5 CORRECTIONS:

6

Pg.	Ln.	Now Reads	Should Read	Reason
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19

PAUL HOROWITZ, M. D.

20

21 BEFORE ME THIS ____ DAY

22 OF _____, 2024.

23

24

25 (Notary Public) MY COMMISSION EXPIRES: _____