Exhibit 11

I. Khan

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF GEORGIA

ATLANTA DIVISION

Civil Case No. 13-cv-03675-WBH-JCF

UNITED STATES OF AMERICA,)
Plaintiff,)
v.)
UNDETERMINED QUANTITIES OF ALL)
ARTICLES OF FINISHED AND IN-PROCESS)
FOODS, RAW INGREDIENTS (BULK POWDERS,)
BULK CAPSULES) LISTED BELOW, WITH ANY)
LOT NUMBER, SIZE, OR TYPE CONTAINER,)
WHETHER LABELED OR UNLABELED: BLACK)
WIDOW, et al.,)
Defendants,)
and)
HI-TECH PHARMACEUTICALS, INC., et al,)
Claimants.)

DEPOSITION OF IKHLAS A. KHAN, Ph.D.

Washington, D.C.

October 26, 2016

Reported by: Mary Ann Payonk; Job No. 114500

I. Khan

October 26, 2016
9:41 a.m.

Deposition of IKHLAS A. KHAN, Ph.D., held at the offices of the U.S. Department of Justice, 450 Fifth Street, N.W., Room 6400 South, Washington, D.C., pursuant to Notice before Mary Ann Payonk, Nationally Certified Realtime Reporter and notary public of the District of Columbia.

APPEARANCES:

ON BEHALF OF PLAINTIFF:

JOSHUA DAVENPORT, ESQ.
United States Food and
Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

ON BEHALF OF CLAIMANTS HI-TECH PHARMACEUTICALS, INC., and JARED WHEAT:

SHEILA WOOLSON, ESQ.
EPSTEIN BECKER & GREEN
One Gateway Center
Newark, NJ 07102

ALSO PRESENT:

Andrew McDonough

IKHLAS A. KHAN,
called as a witness, having been duly sworn, was examined and testified as follows:

EXAMINATION

BY MS. WOOLSON:

Q. Good morning, Dr. Khan. We met a few moments ago, and we're here today to take your deposition. Have you -- have you ever been deposed before?

A. Several years ago, yes.

Q. Okay. And approximately how many years?

A. Seven or eight.

Q. Okay. And what kind of matter were you deposed in?

A. That was on hoodia case.

Q. A what?

A. Hoodia.

Q. Okay. Since it's been a little while since you've been deposed, I'm just going to review for you some basic instructions.

We are here today to take your deposition. Although we're in an informal

setting, my questions and your answers are being transcribed in a booklet. You're answering them under oath. So it's important that you make sure you understand the questions I'm asking and that you hear them.

If you don't understand a question, let me know and I'll rephrase it. If you don't hear it, let me know and I'll repeat it.

If you answer a question, I'm going to assume that you've heard it, understood it, and are asking it to -- answering it to the best of your ability.

It's important that you keep all of your responses verbal, because the court reporter can't take down gestures or nods of the head.

And as the court reporter mentioned before we got started, let me finish my question before you begin your answer. And likewise, I'll let you finish your answer before I begin my next question. That way, we have a clean record.

From time to time your attorney may interpose an objection to a question. If he

does, just refrain from answering until we've worked it out and he'll instruct you whether to answer the question.

Do you understand those instructions?

A. Yes.

Q. If you need to take a break at any time other than when a question's pending, let me know and we'll take a break. Okay?

A. Yes.

Q. Great.

What did you do to prepare for your deposition today?

A. I'm not sure exactly what you mean.

Q. Okay. In order to prepare for your deposition today, did you review documents?

A. Yes.

Q. What documents did you review?

A. Mostly the expert reports, mine and Dr. Simone.

Q. Okay. Any other documents that you reviewed that you recall?

A. And also look into the manuscripts provided in the literature that has been cited just to try -- try to refresh my memory.

Q. Were there any particular manuscripts that you looked at that you recall?

A. Lately, I look into the manuscript of -- of Dr. Li and the Fleming paper --

Q. Okay.

A. -- and some other papers that have been reported.

Q. And other than looking at documents, did you meet with anyone to prepare for your deposition?

A. Yes.

Q. And who did you meet with?

A. With the attorneys --

Q. Okay.

A. -- yesterday.

Q. I don't want to know what you discussed with your counsel.

Was there anyone there other than your counsel and yourself?

A. No.

Q. Okay. And when did you meet with your counsel?

A. Yesterday.

Q. Okay. And can you briefly tell us

your educational background?

A. I did master's in organic chemistry from Aligarh -- Aligarh Muslim University in India, then I did my Ph.D. in pharmaceutical biology -- biology from the Ludwig Maximilian University in Munich.

Q. Okay. And did you have a thesis when you were working for your -- toward your Ph.D.?

A. Yes.

Q. And what was it?

A. That was -- it -- it was on echinacea, so --

Q. And --

A. -- where we found -- where we found adulteration in -- in the -- that echinacea that --

THE REPORTER: Where we found?

THE WITNESS: Adulteration and isolated new components reported from --

THE REPORTER: I'm sorry, I'm having a hard time.

THE WITNESS: Isolated new components. Isolated.

THE REPORTER: Isolated?

THE WITNESS: New components.

THE REPORTER: New components? Thank you.

Q. And let me just say it's fine if, when you answer my question, if you want to face the court reporter --

A. Okay.

Q. -- so she can hear you better, that's fine. I won't be at all offended.

And is it fair to say that your -- your background, your specialty is not analytical chemistry but, rather, pharmacology?

A. No.

Q. What would you say your specialty is?

A. It's called pharmacognosy.

Q. Pharmacognosy? Okay.

A. Pharmacognosy, which is a component include everything from plant chemistry, natural product chemistry --

THE REPORTER: Sorry?

THE WITNESS: Natural product chemistry.

THE REPORTER: Thank you.

A. Analysis and pharmacology.

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Q. Okay. And can you briefly tell us your employment background?

A. So after doing -- finishing Ph.D. in 1987 I came to Mississippi working as a postdoc, '88-'89. Then I joined a group. It's called Swiss Federal Institute of Technology in Zurich for three years where I worked on isolation of components from plants from Papua New Guinea.

THE REPORTER: From?

THE WITNESS: Papua New Guinea.

THE REPORTER: Yes.

A. And then in December '92, I came to Mississippi again where I worked plants like taxon. Taxon, T-A-X-O-N.

And then '95, I got assistant professorship. And since then, I'm there.

Q. Okay. And what is Phytochemical Services, Inc.?

A. It's a -- a spinoff company from University of Mississippi and National Center for Natural Product Research.

Q. And what's your role there?

A. I'm the vice president.

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Q. And how long have you been vice president?

A. Since the inception.

Q. And when was the inception? I'm sorry. If you -- if you said it, I missed it. What date was the inception date?

A. Oh, I -- must have been 2009. I am not sure what the date --

Q. I'm going --

A. -- was at --

Q. -- to show you -- go ahead.

A. Yeah.

(Khan Exhibit No. 1 was marked for identification.)

BY MS. WOOLSON:

Q. I'm going to show you what's been marked as Exhibit 1.

MS. WOOLSON: And I'll pull out a copy for you, counsel.

Q. Just let me know when you're ready to proceed.

Have you seen Exhibit 1 before?

A. Yeah. This is my report.

Q. At the back of your report -- or,

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strike that.

Does your report also include a copy of your current --

A. CV?

Q. -- CV?

A. CV, yes.

Q. If it would be helpful, you can turn to that and -- and take a look at it as we talk about your background. If I can find it, I'll turn to it too.

Who else works with you at -- at Phytochemical Services, Inc.?

A. Mahmoud ElSohly, the president.

Q. Okay. And anyone else?

A. And Waseem Gul --

Q. And --

A. -- and --

Q. -- what's his role?

A. Analysis and communication with the people who send samples.

Q. Okay. Is there anyone else that works there?

A. PSI is not a -- a -- a company that can ask for people to help since there is no

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full-time employee other than Waseem.

Q. Okay. So -- so in answer to my question, then, those are the only three employees, yourself, Dr. ElSohly, and Waseem?

A. Part of the company.

Q. When you say "part of the company," what do you mean?

A. I would not call them employee.

Q. So you -- would you call them interns?

A. Yeah.

Q. And where do you get the interns?

A. Well, these people are not working full-time for PSI.

Q. Understood. These people who are -- are -- let's back up. When you say they're not working full-time, are they part-time employees, so they're getting paid for part-time --

A. So --

Q. -- work?

A. -- Dr. ElSohly is the president.

Q. Uh-huh.

A. And he's not employed per se right

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now because he does not get paid.
Q. Okay.
A. I'm the vice president. I do not get paid. So we are not paid employees.
Q. Okay.
A. It is a -- a small startup company. Waseem Gul get partially paid.
Q. He gets partially paid? You mean he gets paid for part-time work?
A. Yeah.
Q. Okay. Any other employee or person get paid for part-time work there?
A. I believe some other people get paid, but I don't remember on what basis because I -- I -- I -- I don't know the finance. Mahmoud ElSohly might answer that question.
Q. Okay. And so what are your duties as vice president?
A. This is a -- my duties is that we can perform the analysis on anything that people inquire and we say that it can be done over there. So yes, my duties are can or cannot be done, or this is something that we should be doing it. It -- it fits with our expertise.

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Q. And how many clients, or customers shall we say, does Photochemical Services have now?
A. I cannot give you exact number.
Q. Can you estimate?
A. We do not have permanent clients. How many requests we have got for work for I show as several.
Q. Well, let me rephrase the question.
Are -- is -- is Phytochemical Services, Inc. currently performing services for any clients?
A. Yes.
Q. How many?
A. Again, I can't give you an exact number.
Q. Can you estimate?
A. I will say three to five.
Q. Can you tell me who they are?
A. No. I -- I don't remember.
Q. Can you tell me if any of them are governmental agencies?
A. No, I don't think so.
Q. To your knowledge, has Phytochemical

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Services, Inc. done work for any governmental agencies?
A. They have done work for -- but that's not a government agency, USADA.
Q. Done work for who?
A. USADA.
Q. US --
A. U.S. Anti-Doping Agency.
Q. Okay.
THE REPORTER: Repeat.
THE WITNESS: U-S-A -- USADA. U-S-A -- U.S. Anti-Doping Agency. USADA.
THE REPORTER: Well, I can get it later, but I -- I'm not understanding. But I will do research later to -- to find those terms.
MS. WOOLSON: That's okay.
Q. And what type of analysis has Photochemical Services performed for -- for U.S. for -- the U.S. Anti-Doping Agency?
A. The question that whether DMAA is present in geranium or not.
THE REPORTER: I -- I -- I'm sorry,

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I -- I'm struggling with every answer, and I -- I'm -- I apologize for that, but I --
THE WITNESS: Let -- let me sit close to you.
THE REPORTER: Well, I -- but -- but we -- sitting close, I just -- I'm struggling with every answer. And every single word is important, so I -- I hate to stop on every one. I -- I don't know what else to do because I -- I didn't understand your answer at all.
MR. DAVENPORT: You can sit back here, Dr. Khan. The -- the agency is the United States Anti-Doping Agency. I don't want to --
THE REPORTER: The question was what type of analysis, and so --
THE WITNESS: I said DMAA --
THE REPORTER: Yes.
THE WITNESS: -- in geranium plants.
THE REPORTER: Engineering implants?

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THE WITNESS: No.

THE REPORTER: See, I -- I am really --

MS. WOOLSON: I understand. It was DMAA in geranium, like the flower.

THE REPORTER: Oh. I don't want you to be mad at me, but we're going to be this way all day long because I'm struggling so hard to understand.

MS. WOOLSON: I understand. Everybody's doing the best they can. It's all we can do.

THE REPORTER: Okay.

MR. DAVENPORT: That's what he said.

THE REPORTER: Okay.

MR. DAVENPORT: That was counsel's interpretation, "DMAA" and "geranium."

THE REPORTER: Okay. Thank you.

BY MS. WOOLSON:

Q. And how -- strike that.

When did Phytochemical Services, Inc. start doing analysis for the USADA regarding DMAA in geranium plants?

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A. If I recall, it must have been around 2011.

Q. And is that work continuing through today?

A. No.

Q. When did it end?

A. After first publication.

Q. And when you say "first publication," what do you mean?

A. The -- the ElSohly paper which was reported DMAA in the first report, and that was partially sponsored by USADA.

Q. Okay.

A. That's -- that's -- that's the -- that's the end of the relationship.

Q. And we'll come back to that report a little bit later.

A. Uh-huh.

Q. Other than USADA, are there any other agencies or clients for whom Phytochemical Services, Inc. has done research or analysis on DMAA?

A. No.

Q. And how about you personally?

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Leaving aside the Phytochemical Services, Inc. analysis that we just discussed, have you personally done any analyses for any governmental agency or -- or anti-doping agency regarding DMAA in geranium plants?

A. Yes. We analyze -- the question to answer whether it's there or not, we did do analysis of DMAA.

Q. And by whom were you hired to do that analysis?

A. We were not hired by anybody.

Q. Okay. Perhaps I misunderstood, because my first question was did you personally do any analysis for any governmental agency or any -- any anti-doping agency regarding DMAA in geranium plants aside from the Phytochemical Services work that you talked about. And you said yes.

A. Yes. So if you look at the first paper, we did analyze the samples to confirm the identity of DMAA.

Q. Uh-huh.

A. That work was done in the center but it was not paid by -- well, not -- or we were

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not hired, center was not hired to do the DMAA analysis. It's just a question of scientific curiosity and finding whether it is there or not. That's what we did.

Q. And -- and this is still the first paper that you're talking about?

A. Yeah.

Q. Okay. Who funded the research that was done in that first paper?

A. In center we get funding from many agencies.

Q. Which ones funded the research in the first paper?

A. That's the USADA.

Q. Okay. So USADA funded the research that was in the first paper, the first ElSohly paper?

A. Yeah.

Q. Okay. What about other studies or analysis of DMAA subsequent to the first paper?

A. That's the second paper.

Q. Okay. And the second paper, was that undertaken -- well, strike that.

Who undertook the analysis for that

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second paper?

A. That's a multicenter study so it -- it was done by four centers.

Q. Okay. And who provided the funding for that study?

A. No direct funding for that.

Q. No one provided funding for that study?

A. No direct funding.

Q. So where did the money come from to support the study?

A. We -- we are part of the National Center for Natural Product Research where we have mandate to do the research. And the research funding as a whole is come from multi institutions. So basically -- basically when we talk about a project, a specific project, a specific question to answer is funded.

But general scientific question, that's very difficult to say where the funding is coming from because we have funding coming from states, funding coming from -- from USDA. Funding is coming from NIH, funding is coming from FDA.

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Q. So you said funding is coming from USD --

A. A.

Q. USDA, NIH and FDA?

A. Yeah.

Q. Okay. Aside from those three agencies, what other funding did you receive that underwrote the analysis that was performed in the second paper?

A. If you look at the second paper, there's no acknowledgment of a particular agency.

Q. You said there was an acknowledgment of a particular agency?

A. No.

Q. No? Then I'm sorry, I didn't understand.

A. No -- no acknowledgment of a particular agency.

Q. That wasn't my question.

The question was, other than those three agencies we've just talked about, were there any other agencies that provided funding?

A. No.

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Q. We talked about the first paper and the second paper briefly. Was there any other research or analysis or studies that you personally have been involved in regarding DMAA?

A. Yeah. We had subsequently published a paper on different technique called DART.

Q. Uh-huh.

A. That paper has been published. And then we have published a paper of biological activity for insecticidal property. That paper has been published too, but that was not about DMAA.

Q. So the paper on insecticidal properties was not about DMAA?

A. Specifically.

Q. Okay. And the third paper that you discussed, the -- the -- I think you called it DART --

A. DART.

Q. -- analysis, what agency or agencies provided funding for that analysis?

A. Again, this -- this is part of the center so it's -- it's not can be connected

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to --

Q. Okay.

A. -- funding.

Q. So let's talk about the center then very briefly.

A. Okay.

Q. You've mentioned -- you said you had a mandate, the center had a mandate.

A. Yeah.

Q. Who is the mandate from?

A. That's -- it's a center mandate. It's a vision that we should discover and develop natural product for the benefit --

THE REPORTER: Develop?

THE WITNESS: Develop natural products.

THE REPORTER: Yes.

THE WITNESS: For the benefit of health and agriculture.

Q. Okay. So this was a -- a --

A. Yeah.

Q. -- self-imposed mandate by the center.

A. Yeah.

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Q. Okay. And how does the center fund the studies that it does regarding this mandate?

A. Funding wherever we can get the funding, but major funding comes from Mississippi State, Department of Agriculture, of NIH, FDA, and -- and DOD, and some industrial partner if they want us to work with us. So, I mean, it changes year to year, but --

Q. And of those sources you've just listed for me, Mississippi State, Department of Agriculture, NIH, FDA, and DOD, who provides the majority of the funding for the center?

A. These are the major one. I -- I will not say the one is major. It mean it -- how it distributed to the budget. The major portion of the funding comes from this agency. You would like to have numbers?

Q. Yes.

A. That can be provided. I don't remember.

Q. Okay.

A. If -- if it is --

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Q. We will make a request in writing on that.

Do you know the percentages, the relative percentages, if not the numbers?

A. I think it will be better to deal with the number instead of percentages. As I said, it's always changing year to year. It depends on the funding, so I do not want to quote anything which is not right.

Q. Would you agree that the majority of the funding for the center comes from those four agencies I just identified? Yes?

A. That's right.

Q. And what is your role at the -- the center?

A. Center, I'm right now associate director, one of the associate director.

Q. How many associate directors are --

A. Two.

Q. -- there?

A. Two.

Q. Two? Who's is the other one?

A. David Pasco.

Q. When did you -- what are your duties

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as associate director?

A. I take care of mostly chemistry part, analytical part, medicine plant garden, and --

THE REPORTER: Medicine?

THE WITNESS: Plant garden. Plant.

THE REPORTER: Plant? Garden?

THE WITNESS: Yes.

THE REPORTER: Thank you.

A. And all the necessary things which come with the --

Q. And -- and the --

A. With the --

Q. I'm sorry. When you say you -- you -- you're responsible for those areas, what do you mean? What do you actually do to be responsible for those areas?

A. Of course I'm here to keep looking at the funding opportunities, plus we want to make sure that all the people are working in a -- in a well-defined or in a -- in a cohesive manner like any organization, and to make sure the people who are in the lab have what they are supposed to have to get the job done. So that's administrative position's all about.

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Q. Okay. And how many people work at the center?

A. Center, we have I will say around 80. It fluctuate. Plus we have Department of Agriculture people in the same building, which is around 30, 35. So total, we have more than 100. I would say close to 120 people.

Q. And what -- what's the relationship between the -- the folks that work for the center and the folks that work for the agricultural department?

A. We -- their focus, looking for natural product for using --

THE REPORTER: Looking for?

THE WITNESS: Natural products.

THE REPORTER: Natural products?

A. For trying -- trying to find the natural sources for herbicides, pesticides, and from natural -- or insecticide from the natural sources. So they -- they are -- their job is also doing science in natural product --

THE REPORTER: Also doing?

THE WITNESS: Also looking for natural product for agriculture uses.

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THE REPORTER: Thank you.

A. And our one is more focused on the health side, looking for health benefits.

Q. So do the people who work for the center actually collaborate with the people who work for the Department of Agriculture on studies?

A. Yes.

Q. Are you an editor or an advisor to any analytical chemistry journal?

A. I have to look into that. I was coeditor of Planta Medica, which does include analysis of analytical component, but it's called Planta Medica.

Q. Plant America?

A. Planta Medica.

Q. Planta Medica? Thank you.

Okay. And other than Planta Medica, can you think of any other --

A. Yes, I'm --

Q. -- journal that --

A. -- I am on the editorial board of several one. So specifically which one is analytical one, I have to look at the list to

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tell you --

Q. Okay.

A. -- to specify.

Q. Okay.

A. If you look at this page, editorial and advisory boards, many of them listed, including USP. I'm part -- on Planta Medica, I work for USP which deals on the monograph, which are analytical. At AOAC, committee on dietary supplement, expert committee. I have been part of the product quality working group which now they call NCCIH.

Q. So of these publications you've identified, is it your testimony that these publications are focused primarily on analytical chemistry? Or is it that analytical chemistry is a portion of what those journals focus on?

A. As I described the pharmacognosy, when we talk about plant, especially the medicinal plants, it has all the component from botany, analytical chemistry, isolation of components, and also pharmacology.

Q. Okay. And would you agree with me

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that the discipline of analytical chemistry is of itself its own special unique -- strike that.

Would you agree with me that the discipline of analytical chemistry is its own unique specialty?

MR. DAVENPORT: Objection, form. You can answer.

THE WITNESS: I'm sorry.

MR. DAVENPORT: Yeah, you -- I'm sorry. You may answer.

THE WITNESS: Okay.

MR. DAVENPORT: I was just interposing an objection to the form of the question.

THE WITNESS: Yeah.

A. Analytical chemistry, you have to be specific when you mean analytical chemistry. It -- it -- analytical chemistry itself can be divided in many, many, many portions of analytical chemistry.

Analytical chemistry does not only mean analysis of natural product. Analytical chemistry has many form and shapes and

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disciplines which can be broken down into different expertise. So it's a very broad question to -- to answer.

Q. Okay. Have you ever testified as an expert before?

A. As I mentioned, I was part of this deposition.

Q. So if we received a -- a statement saying that you had never testified as an expert before, that would be incorrect?

A. Last --

MR. DAVENPORT: Objection to the form of the question. Assumes facts not in evidence. You can answer.

A. Again, at the beginning I mentioned I was deposed in -- several years ago.

Q. Yes. And do you recall the name of the case?

A. Not on top of my head.

Q. And do you recall for whom you were acting as an expert?

MR. DAVENPORT: Objection to the form of the question.

A. A law firm.

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Q. A law firm?

And do you know who your client was?

A. The law firm who asked me to depose as expert in that case. I don't remember the name and detail.

Q. Do you remember the name of the law firm?

A. Not exactly. That was earlier, so -- but yeah, that information can be made available.

Q. And do you recall -- you said you were asked to testify as an expert. What was the subject matter of your testimony?

A. As I mentioned in the beginning, subject matter was hoodia, H-O-O-D-I-A.

Q. And do you know -- well, let me back up.

Do you know if you were being asked to testify on behalf of a private company or a governmental agency?

A. No.

Q. You don't know?

A. I would -- it was from the lawsuit from the law firm, so it was not a government

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agency.

Q. But you don't recall the name of the party for whom you were acting as an expert?

A. Not right now.

Q. Okay. Do you recall what the issue was?

A. Hoodia.

Q. Well, what about it?

A. Hoodia is present in the product or not.

Q. And what was the product?

A. I don't know.

Q. Do you have records regarding that testimony?

A. No, I don't have it.

Q. Do you have a copy of your deposition transcript?

A. Not with me.

Q. What was that?

A. Not with me.

Q. Not with you here, but do you have it at -- at -- at your office or at your home?

A. I'm sure it can be obtained if you ask for it, but I -- I do not have any -- no.

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No, I don't have it with me.

Q. Okay. Couple more questions for you about the center.

A. Yeah, uh-huh.

Q. Do you work with people at FDA in your role as associate director at the center?

A. Yes.

Q. And who do you work with?

A. Specifically, we -- we work with CFSAN. CFSAN is -- is a part of FDA's -- C, yeah, CFSAN, C.

THE REPORTER: I can get the spellings later.

THE WITNESS: Yeah.

THE REPORTER: I'll mark them to get them later.

Q. And what does that group do?

A. This is a food safety group within the FDA.

Q. And who at FDA personally, names of people do you know that --

A. Right now, the program officer is Cara Welch, C-A-R-A, W-E-L-C-H.

Q. Okay. Anybody else that you work

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with at FDA?

A. She is our program officer.

Q. And when you say "program officer," what do you mean?

A. She -- she's a program officer. I mean, she's the director responsible for making sure that projects are -- are funded and working and -- and accordingly. I mean, just an oversight officer in any government agency. That's her role.

Q. Does anyone at FDA review any publications or studies or potential articles that are prepared by the center before they're published?

A. General practice is that we send the publication to Cara Welch to look at it.

Q. Do you know what Cara Welch does with it? Does she send it to someone else?

A. I don't know internal process.

Q. Okay. And how long has Cara Welch been the program officer?

A. I will say three years. It might be plus/minus couple of months, but around three years.

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Q. Okay. And did you deal with someone in the -- the role of program officer before Ms. Welch?

A. Yes.

Q. And do you know who that was?

A. Daniel Fabricant.

Q. And did you follow the same policy of sending him articles or studies to be reviewed before they were published?

MR. DAVENPORT: Objection to the form of the question. You can answer.

A. No.

Q. So this process of -- of having -- of sending an article to FDA to review before publication started with Ms. Welch?

MR. DAVENPORT: Objection to the form of the question. Assumes facts. You can answer.

A. Anytime that we write publications that -- I mean, it was done but not it was done that every paper was provided to them.

Q. I'm sorry, what did you say?

A. It was done but not on regular basis.

Q. So what would determine when you

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would provide a copy of a study or an article to them before it was published?

A. Oh, the content of the paper.

Q. And what about the content of the paper?

A. I mean, it's -- some paper is -- have -- might have some quality issues identified by FDA. We just wanted to make sure that that was coming since they are being acknowledged.

Q. And of the -- the three papers we've discussed regarding DMAA, were any of those supplied to FDA before they were published for review?

A. No. That was not funded by FDA so they did not.

Q. What about NIH?

A. NIH does not require to review papers.

Q. Well, you said "NIH does not require to review papers." Does FDA require to review papers?

A. No.

Q. Okay. So then did NIH -- have you

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sent any papers -- strike that.

Has the center sent any papers or studies or articles to NIH to be reviewed before they were published?

A. No.

Q. How about the U.S. Anti-Doping Association? Has the center sent any papers, articles, or studies to the U.S. Anti-Doping Agency to review before they were published?

A. Except the paper which was partially sponsored by them, no other paper has been now reviewed by USADA.

Q. And that was the first paper we talked about?

And did the U.S. Anti-Doping Agency make any revisions to that first paper, to your knowledge?

A. Revisions mean editing?

Q. Uh-huh, yes.

A. They probably contributed to it. I can't specifically recall what corrections or editing they made.

Q. And the -- including this first DMAA study, the -- of the studies that we've

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discussed, to your knowledge, were those -- were those, the results of those studies, papers that were to be published, were they reviewed by anyone outside of the center or Phytochemical Services, Inc. or your research group before they were published, leaving aside the journal to which they might have been submitted?

A. Do you mean the publication reviewed among ourselves?

Q. So what I'm asking is, is there anyone outside of the group of people who actually performed the research for those papers? Did anyone review those articles or studies before they were submitted for publication?

A. "Outside" means?

Q. Other than the scientists who actually were performing the research.

A. Yeah. So the first paper was where the USADA was -- gave the editing, no one else.

Q. And what about the other DMAA studies?

A. DMAA studies were not shared by

anybody.
Q. Who do you work with at NIH?
A. Right now I do not have any NIH direct funding. I was part of a center grant which was funded through University of Illinois at Urbana-Champaign. And Craig Hopp, H-O-P-P, was our program officer.
Q. And with whom do you work at the Department of Defense?
A. I directly don't work at. This is a -- a project that our director, Larry Walker, is director. He's the PI and he communicates with them. I do not have personal or direct communication with them.
Q. Okay. You said this person's name is Lanny Walker?
A. Larry, L-A --
Q. Oh, okay.
A. -- R-R-Y.
Q. Okay. Larry Walker.
A. He's the director of the center.
Q. Last but not least, who do you work with at the Department of Agriculture?
A. Again, Larry Walker is the director.

He's the PI of this cooperative development and I'm one of the co-PI. So he's the one who actually deals with direct relationship with USDA. I don't have any directly.
Q. So that means you don't know the answer to my question about who's dealt with?
MR. DAVENPORT: Objection to the form of the question. You can answer the question.
Q. I mean, do you know the name of the people that the center deals with at the Department of Agriculture?
A. No, I don't.
Q. Okay. We've mentioned a few times this chemical, DMAA. Can you give me the -- the common chemical name for it?
A. Methylhexanamine.
Q. And when I've seen the -- the chemical described in literature, it talks about 1,3?
A. 1,3.
Q. 1,3-dimethylhexanamine? Is that the proper name?
A. For one of them which is reported,

yes.
Q. When you say "for one of them," what do you mean?
A. Because in some paper it say 1,3-dimethylamylamine and 1,4-dimethyl, so --
Q. Do you understand them to be two different isomers of the same compound?
A. They're two different components.
Q. Two different compounds? Okay.
And when you've been talking about DMAA, what are you referring to, 1,3 or 1,4?
A. 3. 1,3.
Q. Okay. So just to make everybody's life easier going forward, we're going to call it DMAA, and we'll know that we're talking about 1,3-dimethylhexanamine. Okay.
If we need to distinguish that, we'll talk about the other one as 1,4 just so we're clear.
A. Okay.
Q. What is a chiral molecule?
A. Chiral molecule, any -- any carbon which has a -- four different bonding connections can create a chirality.

Q. So let me paraphrase to see if we're on the same page.
My understanding of chirality is that it's talking about a carbon bond that has four different connections.
A. Exactly.
Q. Okay. And sometimes they talk -- they talk about chiral molecules as having handedness, right-handed, left-handed --
A. That's on --
Q. -- so it's superimposable mirror images. Okay.
Is DMAA chiral?
A. Yes.
Q. And how many chiral centers does it have?
A. Two.
Q. Okay. And we talked about sort of the mirror images, the -- the -- the right-hand and the left-hand images. Do they have a name, that pair of images?
A. It's called enantiomers.
Q. If you have a chiral molecule that has two chiral centers, you'll have two pair of

enantiomers?
A. Four.
Q. I'm sorry, pair.
A. Pair. Two pairs.
Q. Okay. You'll have four --
A. Enantiomers.
Q. Okay.
A. Yeah.
Q. And those enantiomers are called what? Those two -- the -- the two pairs?
A. Diastereomers.
THE REPORTER: Repeat.
THE WITNESS: Di -- diastereomers.
Q. Now, what's the difference between -- well, strike -- what's the difference between a diastereomer and an enantiomer?
A. Diastereomers are composed of enantiomers.
THE REPORTER: Composed of?
THE WITNESS: Enantiomers.
THE REPORTER: Thank you.
Q. Chemically, is there a difference between diastereomers and enantiomers?
A. Yeah.

Q. And what's the difference?
A. The different diastereomers, as is mentioned left and right, and so they are together is called diastereomers. And you separate them, they're enantiomers.
Q. So when you -- well, let me back up. When you separate diastereomers, you have to use a chiral column; correct? Or some -- some method of chiral chemistry to separate the two of them?
A. That's right.
Q. Right. Do you need to do that to separate the pairs of enantiomers?
A. To -- if I'm the -- correct, you are asking about separating enantiomers?
Q. So, for example, you have -- in DMAA, you have two chiral --
A. Center.
Q. -- centers, you have four diastereomers, and two pair of enantiomers; correct?
A. No. 1,4 DMAA has a -- two diastereomers, okay? And every diastereomers is going to give you two enantiomers, so two --

two pair of enantiomers. So in order to do enantiomeric separation, you need the chiral column or some chiral derivatization.
THE REPORTER: Or some chiral?
THE WITNESS: Derivatization.
Q. Okay. Well, let me -- let me try and ask it a -- a different way.
If you were to run a gas chromatography, liquid chromatography on DMAA that wasn't chiral --
A. Uh-huh.
Q. -- would it be possible to separate the two pair of diastereomers from one another?
A. I'm not getting your question.
Q. Okay. We -- we will come back to it later.
What's a racemic mixture?
A. Racemic mixture is having enantiomers together.
Q. And when you say "having enantiomers together," what do you mean?
A. I mean a mixture of two enantiomers.
Q. Any mixture of two enantiomers?
A. Actually -- actually, what I mean,

racemate generally is a 50/50.
Q. It's what? It's a 50/50 mixture of enantiomers?
A. Yeah.
Q. And when we're talking about natural products --
A. Yes.
Q. -- do natural products have a racemic mixture of enantiomers if they're chiral?
A. Not to my knowledge.
Q. They can never have a racemic mixture?
A. Not biosynthetically, kind of impossible or highly unlikely to have racemic mixture in the ratio of 50/50.
Q. Do you know a Joseph Betz?
A. Yes.
Q. Who is he?
A. He's a -- I don't know exact title, but he's in office of dietary supplement. He's a director of -- I -- I don't know what, but I know him well. He's in office of dietary supplements. I can't give you his exact title.
Q. Okay. Do you know a John Cordelia

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(phonetic)?
A. Cardellina.
Q. Cardellina?
A. Yeah.
Q. And who is he?
A. John Cardellina, you -- has worked with NCI for many, many years. He's well-known natural product chemist.
Q. Okay.
(Khan Exhibit No. 2 was marked for identification.)
BY MS. WOOLSON:
Q. Dr. Khan, I'm showing you what's been marked as Exhibit 2. Take a look at it and when you're ready to proceed, let me know.
THE WITNESS: Should I read the whole thing?
MR. DAVENPORT: You should review the entire document.
Q. Ready to proceed? Okay. I'm showing you what's been marked Exhibit 2, which is a compilation of emails that were produced in this case. Specifically, I'm drawing your attention to the first page. The very last

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email at 8-9-12, 3:47 p.m., from John Cardellina, who says that "Racemates are known from nature as natural products. Something to remember in trying to dissect this."
Correct?
A. Yeah.
Q. So Mr. Cardellina doesn't think that it's impossible to have a natural product that's a racemic mixture, does he?
A. He has not given any evidence in that regard having racemic mixture. Racemic mixture, I can -- based on experience, I can say that racemic mixture, one, is a biosynthetic pathway, and the way the plant makes --
THE REPORTER: Is a?
THE WITNESS: Biosynthetic. Biosynthetic pathway.
THE REPORTER: Uh-huh.
THE WITNESS: That plants make a compound, and one is a chemical reaction can happen and compound can racemize.
THE REPORTER: Compound can?
THE WITNESS: Racemize.

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THE REPORTER: Lathemize (phonetic)?
THE WITNESS: Racemize.
Q. That's not what Mr. Cardellina said, though, did he? He said racemates are known from nature. Isn't that what he said?
A. Natural products reported in racemates, when you go back and you look at the biosynthetic pathway, in most of the time or most all the time it finds out that it has been done in the process.
Q. I understand that's your opinion. I'm asking you, am I correct, did I just read this email correctly that John Cardellina said "Racemates are known from nature (as natural products)"?
MR. DAVENPORT: Objection.
Q. Is that what he said?
MR. DAVENPORT: Objection to the form of the question.
Q. Is that what he said in the email? It's a yes or no question. Is that what he said in the email?
MR. DAVENPORT: Objection. You can

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answer, Dr. Khan.
A. Supported in racemate and it has been cited and reported that you can find the racemate but you have to qualify if the plant can make racemate or not. This email does not say that plants make racemate. It said can be found.
Q. And what he said, racemates are known from nature; correct?
MR. DAVENPORT: Same --
A. As --
MR. DAVENPORT: -- objection. You can answer.
A. As natural products.
Q. Correct. That's what he says.
A. He's -- he didn't say "nature." He says "as natural products."
Q. Fine.
A. So there's a fine difference.
Q. And what is that difference, in your -- your mind?
A. In my mind, it is that he is not saying in this statement that nature makes racemate. Can be found as natural products, is

a compound which can racemize by several factors.

Q. So it is entirely possible that you can have a natural product that has a racemic mixture; correct?

A. No.

Q. And Mr. Cardellina's email on the bottom of page 2 is in response to comments by Dr. ElSohly, correct, who's saying that he finds the identical -- he finds it -- strike that.

He says "Ikhlas is right about the isomers. It's very unusual to have an isomeric ratio of a synthetic material look identical to that of a natural product."

Correct?

A. Yes.

Q. And then in response to that, Mr. Cardellina says "Racemates are known from nature as natural products." Correct?

A. As -- he qualified it as "natural product." He didn't say "nature."

Q. And I understand that's your argument. I was asking you what the email

said.

A. I mean, that's what is written in the bracket is "natural product."

Q. Okay. So he's saying there can be natural products with a racemic mixture; correct?

A. Not natural, but can be found as a natural product in the racemate.

Q. Okay. We're moving on.

Do you agree that the chemical composition of various geranium plants can vary? Strike that.

Do you agree that the chemical composition of geranium plants can vary?

A. To certain extent, yes.

Q. And what factors will affect the chemical composition?

A. Like any other plant, the season, growing conditions, age of the plant, environmental conditions, fertilizers, sunlight.

Q. Do you also agree that the enantiomeric mixture of a plant can vary?

A. You mean in concentration, or

composition?

Q. You tell me.

A. In concentration, yes.

Q. And what do you mean by "concentration"?

A. Well, one enantiomer is -- for example, is 3 percent versus 5 percent. But composition, that one has one-to-one ratio, that's not possible.

Q. Well, would you agree that it's possible to have a plant, one plant of the same species that has an enantiomeric mixture of, say, yeah, 60/40 and another that has the same -- that has the mixture at 70/30?

A. I'm not sure about the percentage but yes, the ratio can be variable.

(Khan Exhibit No. 3 was marked for identification.)

BY MS. WOOLSON:

Q. Let me know when you're ready to proceed, Dr. Khan.

A. Yes.

Q. Ready to proceed? Have you seen Exhibit 3 before?

A. Yes.

Q. And what is Exhibit 3?

A. A publication done by our group.

Q. And you're one of the author -- cited authors in the publication; correct?

A. Yes.

Q. And the article is discussing comparison of chemical and stereochemical tests for the identification and differ -- differentiation of Pelargonium graveolens --

A. Uh-huh.

Q. -- correct?

A. Yes.

Q. And is that the fancy scientific name for geranium plants?

A. It's the botanical name for the plant.

Q. Okay. If you would turn to the second page of the article, first full paragraph, you see where it says "Many factors can influence the composition of essential oils, including those involving the plant (location, age, climate --"

A. Uh-huh.

Q. "-- cultivars, temperature and growth regulators)"?

Do you agree with that?

A. Yes.

Q. And do you agree also that other factors that can affect the composition of the plant include the sampling process?

A. Yes.

Q. Do you agree that another factor that can affect the composition of plants is also the -- the preparation and handling in the study itself?

A. Can you explain to me what you mean by that?

Q. Sure. For example, if the sample -- the plant is -- sample is treated a certain way in the laboratory, certain chemicals are used on it, certain solvents are used to extract it, you can affect what -- ultimately, the composition of the sample that is then analyzed; correct?

A. Different solvent give it a different components, yes.

Q. And similarly, if you are not careful

when you are distilling something or evaporating something and you have a volatile component, you could inadvertently drive off the volatile component before you do the analysis; correct?

A. In some instances. Not as a common rule.

THE REPORTER: Not as a?

THE WITNESS: Common rule. Common. A common rule.

MS. WOOLSON: A common rule?

THE WITNESS: Yeah.

THE REPORTER: Thank you.

Q. I also want to have you look at what has been marked -- it's page 28184 at the bottom.

A. Yeah.

Q. This is discussion of citronellol enantiomers.

MS. WOOLSON: We'll get the spelling to you later.

THE REPORTER: I'll -- I'll get them from the documents. Thank you.

Q. Would you agree with me that that

paragraph discusses differing enantiomer ratios for that particular geranium oil?

A. What's the question?

MS. WOOLSON: Would you read the question back?

(The reporter read from the record as follows: "Would you agree that that paragraph discusses differing enantiomer ratios for that particular geranium oil?")

A. Yes.

BY MS. WOOLSON:

Q. At the last sentence of that paragraph here, it states: "The presence of the R isomer or a racemic mixture may indicate adulteration."

Do you see that?

A. Yes.

Q. What's the basis for that statement?

A. Because again, it's equal ratio racemization, not one or the other --

THE REPORTER: I -- I'm sorry. It's an equal ratio?

THE WITNESS: Or racemization.

THE REPORTER: "Or"? Yes.

THE WITNESS: That's what it's talking about here.

Q. But what -- what is your basis for saying it -- it indicates adulteration?

A. Because the ratio is equal.

Q. And how would you test to show that that was adulteration versus the actual ratio in the product?

A. That's what in figure 3 is the [unintelligible] standards and --

THE REPORTER: I'm sorry. I don't understand at all.

THE WITNESS: This is in figure 3.

THE REPORTER: This is in figure 3.

THE WITNESS: That the peaks can be differentiated to see what the ratio is.

Q. Okay. That will tell you the ratio, but that won't tell you how that ratio came to be; correct?

A. Here. But again, racemization, 50/50 ratio is not present in the nature, so if you find it, you have to question it.

Q. Okay. So it's your position that any time there is a 50/50 mixture of enantiomers,

that is indicative of adulteration of a natural product?

A. That's right.

Q. That's your -- that's your testimony?

A. No, that's the -- that's -- that's what reading what was in Exhibit 2.

Q. Well, I -- I think you're talking about Exhibit 3; right?

A. This is -- yeah. I mean, the email is the same thing.

Q. What's crossover?

A. Crossover in plants is a hybrid -- hybridization that one species can be hybridized as a crossover.

Q. What's crossover in chromatography?

A. Crossover in chromatography, when the -- the one switches to another one.

Q. When one what switches to another one?

A. One component, one enantiomer is higher than the other.

Q. Have you ever heard of crossover chromatography that causes retention time reversal of compounds?

A. In what technique?

Q. In chromatography.

A. Chromatography, the reverse phase is always reverse. That's when column reverse phase retention time switches from normal phase to reverse phase.

Q. Well, I'm not talking about what you used, reverse phase column. I'm talking about a standard column.

Have your ever heard of crossover whereby the retention times will be reversed?

A. The same component?

Q. Yes.

A. Reverse with whom?

Q. So, for example, if you have a compound such as an essential oil or plant material that has a number of components --

A. Uh-huh.

Q. -- and you load the compound onto the column and you get crossover so that the components do not elute in the order in -- in which you expect, they would elute in a reverse order.

A. In the same conditions? I -- I'm

not -- I'm not aware of it. If you change the conditions in columns, it can happen.

Q. So you're not aware that that's a phenomenon that's common for essential oils?

A. Not for the same particular method.

Q. And I take it because you're not aware of it, you've never tested to see whether it occurred in any of the studies that you were involved in.

A. No. It should not be happening. Once you have a method developed, you would know the profile. If it keep changing every time you inject it, then it's not a method anymore.

So if you change the conditions, you change the columns and chromatographic conditions, can we see the reversal, yes. But by using the same method again and again and one time you see this way and the next time you see the reversal is scientifically not possible.

Q. So if I were to tell you that I read about crossover in the literature, you would tell me that's scientifically not possible?

A. Unless I see the evidence that really convincing me, but just -- just looking at the purpose of the method where you are [unintelligible] try and compound and you are --

THE REPORTER: Where you are?

THE WITNESS: Identifying.

THE REPORTER: Yes.

THE WITNESS: Compound, and the next time that compound has gone somewhere else, if somebody has done it, I would love to see that, but it just, as a conventional method, doesn't look like it.

Q. Okay. How many articles have you authored or coauthored related to DMAA?

A. If you include DART, it's three.

Q. Okay. I'm going to go through those in a -- in a little bit.

Let's turn back to Exhibit 1, which is your report. And specifically, I'd like you to look at paragraph 3 of your report.

You say: "I have concluded that available scientific evidence does not support

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Hi-Tech's assertion that DMAA occurs naturally in geranium plants or oil."

Do you see that?

A. Yes.

Q. Okay. And when you say "available scientific evidence," are you referring to the studies that then follow in your report?

A. Both, because one so far has been published in geranium plant and the rest of the studies follow, yes.

Q. So, I'm -- I'm sorry. I may not have understood your answer correctly.

A. Well --

Q. Is there something outside of the reports that are listed in -- strike that.

Is there something outside of the articles and scientific studies that are listed in your report that you're relying on?

A. No. The published paper. Before DMAA started analysis, there is lot -- many publications we reported geranium analysis which never reported it, plus the one that really specifically talked about DMAA, so that include both.

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Q. Okay. And I -- and I take it when you're saying there's one that specifically talked about it, you're talking about the Ping study.

A. Ping, Zhang, all the studies have been done on DMAA.

Q. Okay. And all those studies are what your report talks about?

A. That -- that's based on that one, yes.

Q. Okay. Just want to make sure that we -- we understand what -- what the basis for your opinion is.

And so these studies that you're relying on would include the studies that you yourself participated in; correct?

A. Also.

(Khan Exhibit No. 4 was marked for identification.)

BY MS. WOOLSON:

Q. Have you had a chance to look at Exhibit 4?

A. Yes.

Q. What is Exhibit 4?

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A. The first paper published by Mahmoud ElSohly.

THE REPORTER: Published?

THE WITNESS: By Mahmoud ElSohly.

THE REPORTER: Thank you.

Q. And -- and earlier this morning when we were talking about the various studies, this would be the first study; is that correct?

A. By us.

Q. Okay. And it lists as authors Dr. ElSohly; Dr. Gul, whom you've spoken about.

Kareem ElSohly, who is he?

A. He is working in PSLI.

Q. And what does he do there?

A. He contributes -- help Waseem Gul.

Q. Okay. Is he --

THE REPORTER: Contributes?

THE WITNESS: Work with Waseem Gul.

THE REPORTER: Thank you.

Q. So is he like a lab technician or something like that?

A. Yeah.

Q. Okay. And then there's a name that I'm not even going to attempt to pronounce, but

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it's A-R-O-O-N-A.

A. Yeah, Aroona Weerasooriya. He -- he's a part -- he -- he was with us as a botanist in medicine plant garden.

Q. Okay. And then there is Amar?

A. Amar. Amar Chittiboyina is a chemist working in the center.

Q. Okay. And then we have --

A. Bharathi Avula. She is -- does all the analysis. She's in the center.

Q. Okay. And then we have you?

A. Yes.

Q. And then we have Amy Eichner. And who is she?

A. She's in USADA.

Q. So the U.S. Anti-Doping Association?

A. Yeah.

Q. Did she -- was she actually in the lab doing work?

A. No.

Q. Okay. How about Larry Bower?

A. No. He's also in USADA.

Q. Was he in the lab doing any work?

A. No.

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Q. Why are their names on the paper?

A. Because they contributed to -- to the -- to the hypothesis and the -- the -- the -- scientifically. Like, I was not in the lab. I'm the office, so --

Q. But they don't work for the labs that did the work, "they" being Amy Eichner and Larry Bowers; correct?

A. Yes.

Q. And you were responsible for overseeing the work that was being done by the people that worked for you; correct?

A. Yeah.

Q. Okay. And is Amy Eichner a scientist?

A. I believe so.

Q. What about Larry Bower?

A. I think he's also scientist.

Q. But you don't know?

A. I -- I don't know their --

Q. Okay.

A. -- credentials.

Q. So when you say they contributed, other than money, what did they contribute?

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MR. DAVENPORT: Objection to the form of the question. You can answer, Dr. Khan.

A. Yeah, I mean, as I said, I mean, we talk about the issue. That the first thing that Amy Eichner contacted us. There's an issue. Then we talk about is -- what it is they would like to -- what the question is. Would they ask that can we analyze whether DMAA's in the plant or not, and then they contributed into the text of the manuscript.

Q. So just so I'm clear, so the -- the U.S. Anti-Doping Association came to you and Dr. ElSohly and asked you for help?

A. Yes.

Q. Okay. And what specifically did they want you to do?

A. They -- since we are national center for natural product, they wanted us to look into the question whether DMAA's naturally occurring in geranium plant or not.

Q. Why did they want you to look into that?

A. Because they -- I think they took

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legal action on it, and the question came that they are naturally occurring but there was no credible science at that time.

Q. This is after the Ping study; correct?

A. Ping study was done in 1996.

Q. So that -- that would be yes, after the Ping study?

A. Yes.

Q. So they came to you with this -- this question.

A. Yeah.

Q. And how did you go about finding a -- a solution? What was your solution?

A. When we -- this question we pose all the time since we work on natural product and we do isolate and identify [unintelligible] novel component all the time and --

THE REPORTER: Identify?

THE WITNESS: And isolate and identify.

THE REPORTER: Did you say "a novel component"?

THE WITNESS: Yeah.

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THE REPORTER: Thank you.

A. So that's -- the question is in order to do that, first you start with authentic sample where you have to -- the plant that you've chose is well identified. It's -- so you look into that plant is there or not. And then you develop a analytical method to analyze it. And once the method is developed, then you analyze unknown samples. So that's the procedure we go for everything.

Q. And how did you go about developing the analytical method here?

A. No, I think this one, we had only -- we took the geranium plant first and also the standard to DMAA, which we did all the parameters required to evaluate the methods and then analyze the samples.

Q. Okay. So where did you get the standard for the DMAA?

A. DMAA standard was from Fisher Scientific.

Q. If I could direct you to the page that's numbered 27841. It's the third page.

A. Yes.

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Q. Under Materials and Methods, it says "MHA standard."

A. Oh, that was bought from Sigma-Aldrich. The solvent was from Fisher.

Q. Okay.

A. The standards were bought from Sigma-Aldrich.

THE REPORTER: From Sigma?

THE WITNESS: Yeah.

MS. WOOLSON: Aldrich, A-L-D --

THE REPORTER: Aldrich? Thank you.

MS. WOOLSON: -- R-I-C-H.

THE REPORTER: Thank you.

Q. So you purchased this compound from Sigma-Aldrich, and you were going to compare that to the geranium plant; correct? The substances in the geranium plant?

A. Yeah.

Q. How many substances are there in a geranium plant?

A. Hundreds.

Q. Have they all been fully characterized?

A. Maximum, there's a report up to 95 --

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if I remember correctly, 90-some has been identified.

Q. And what are the major components of a geranium plant?

A. Citronellol, geraniol, and many others has been reported. So I can't give you the exact, but citronellol and geraniol are the main ones.

Q. And approximately what percentage of the composition of the geranium plant do the citronellol and geraniol make up?

A. A big portion. I cannot give you a percentage without looking into the documents, but --

Q. So would it be fair to say that if -- and I'm not saying it does -- I'm saying if DMAA were to be in a geranium plant, it would be a small percentage of the composition, overall composition of the geranium plant?

A. Based on the first study, Ping/Li --

THE REPORTER: Based on the?

THE WITNESS: Ping.

THE REPORTER: Based on the?

THE WITNESS: Ping.

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MR. DAVENPORT: Ping, P-I-N-G.

THE REPORTER: Ping?

THE WITNESS: Ping/Li study --

THE REPORTER: Study? Yes.

A. It's not a minor component.

Q. So it's not a minor component?

A. Based on Ping/Li study, it's not a minor component.

Q. Okay.

A. .6 percent in it.

Q. So what did you do to separate the DMAA from the 90 or so other components of the geranium plant --

MR. DAVENPORT: Objection to the --

Q. -- if anything?

MR. DAVENPORT: -- form of the question. Assumes facts not in evidence. You can answer.

A. This paper is asking one question, is only one thing, the DMAA is there or not. So the whole focus has been the presence or absence of DMAA. So our target is already fixed what we're looking for.

THE REPORTER: So?

I. Khan

THE WITNESS: Our target --

THE REPORTER: "Our target"?

THE WITNESS: -- is already fixed.

THE REPORTER: Thank you.

Q. So is it your testimony that you didn't attempt to separate the DMAA from the other components of the geranium plant --

MR. DAVENPORT: Object to the form --

Q. -- as part of --

MR. DAVENPORT: -- of the question.

Q. -- this study?

THE REPORTER: I didn't hear the end of your question.

MS. WOOLSON: As part of this study.

THE REPORTER: Thank you.

A. Not sure what you mean by "separation."

Q. I -- I'll -- I'll rephrase the question.

You told me that the geranium plant has at least 90 different --

A. Yes.

I. Khan

Q. -- components.

A. Yes.

Q. What did you do with the geranium plant in order to analyze it for the presence of DMAA?

A. Yeah, so we have a standard. We develop a method. We know what to look for. That's what we did in geranium plant sample.

Q. So you --

A. Now, the thing is separation is totally different thing than focusing on one component there or not.

Q. Okay. So I just want to be sure I understand what you did in this 2012 study.

A. Yeah.

Q. What did you do to the geranium plant in order to determine whether or not DMAA was present or not present?

A. Yeah, so we compared -- we develop a GC method, an LC method --

THE REPORTER: "We develop"?

THE WITNESS: GC.

THE REPORTER: A GC matter?

THE WITNESS: Method.

I. Khan

MR. DAVENPORT: GC. Capital G, capital C.

THE WITNESS: Method.

THE REPORTER: A GC method? Is that what you're saying?

THE WITNESS: Yeah.

THE REPORTER: Thank you.

A. And LC method to find a -- the particular component, which happened to be DMAA.

Q. Okay. And correct me if what I'm about to say is wrong but I just want to summarize this to make sure we're all on the same page.

And that method that you developed involved taking the standard that you had purchased and running it through the GC, or gas chromatograph, and LC, the liquid chromatograph, and finding peaks for it; correct? Or signal for it?

A. Looking for it.

Q. But we're talking about the sample, the standard.

A. Yeah, the standards.

I. Khan

Q. Right.

A. Yes, yes.

Q. So you would run it through the columns and you would see where you got a peak --

A. Yes.

Q. -- for the standard; right?

A. Right.

Q. Okay. And then what did you do with the plant?

A. Plant sample was processed, which goes through extraction, spiking, recovery, and then inject, same method where we have determined the DMAA analysis.

Q. Okay. And when you say you extracted the plant, what do you mean?

A. The plant material has to be extracted with a solvent to -- in order to get the component, because in any chromatographic condition, it has to be injected in the liquid form.

Q. Okay. So you took the plant matter and you essentially dissolved it in a solvent?

A. We don't call it dissolve because

I. Khan

it -- really, plant material don't dissolve, but you extract them.

Q. Okay. So you chopped up the plant material, put it in a beaker, put some solvent on top of it, stirred it around?

A. Yeah.

Q. Filtered it?

A. Filtered it.

Q. You took the filtrate, and that's what you injected onto the columns?

A. Yeah, that's right.

Q. Okay. And as part of the study at any point did you see what else -- did you check to see if there were any other components in the filtrate besides the DMAA, if it were there?

A. No.

Q. Okay. So you took the filtrate, you inject it onto the gas chromatogram and in -- through the liquid chromatogram, and then what did you do?

A. Analyze it and write the report.

Q. And when you say you analyzed it, what do you mean?

I. Khan

A. The -- the method which is already established with their standards, so you have one sample, which is a standard, and then you have your extracted samples that you go through the same process and then you see the response.

Q. And so you would compare the peaks that you got from the plant material with the peaks you got from the standard?

A. That's right.

Q. Okay. And did you also spike the plant material?

A. Yes. As -- as part of the process of method development, you have to spike, you have to do the recovery, you have to do the position.

Q. Uh-huh, okay. How -- when you did the extraction of the plant material, what steps, if any, did you take to determine if the extraction was successful for DMAA?

A. That's called recovery.

Q. Okay. And what did you do to test your recovery?

A. For recovery, you spike the samples and see how much you're getting back, and based

I. Khan

on that one, you see what the recovery is.

Q. You used, I'm sorry, five samples? Is that what you said?

A. Spiked.

Q. Spiked samples?

A. Yes.

Q. Spiked samples.

So you would take plant material, you would spike it with DMAA, you would do the extraction, you would measure your recovery; is that --

A. Yeah.

Q. -- fair? Okay.

What was the recovery?

A. Recovery, I believe it was 35 percent, or something like that.

Q. So less than 50 percent?

A. Less than 50 percent.

Q. Okay.

A. But that recovery was higher than 19 percent reported by Fleming.

Q. Fleming used a different procedure than you used in this paper; correct?

A. Yeah.

I. Khan

Q. Okay. What was the level of detection in the study?

A. GC method was .1 ppm.

THE REPORTER: Point one?

THE WITNESS: Ppm, and -- yeah.

THE REPORTER: Thank you.

Q. You said GC. What about the LC?

A. LC was -- I believe it was 10 pp -- let me see. What was that? LC was 2.5 ppb.

THE REPORTER: Pp?

THE WITNESS: B.

THE REPORTER: Thank you.

Q. And just so I'm clear, you didn't run any analysis to determine what other components may have been in the extract; correct?

A. That's right.

Q. So what was the result of this study?

A. We did not find MHA in all the samples except products.

Q. When you say you didn't find MHA -- and let me just back up.

MHA is DMAA; right?

A. Yeah.

Q. Okay. In any of the samples except

I. Khan

products, you mean actual supplements or manufactured products?

A. Yeah, these are the three products listed here.

Q. Okay. And you're looking at table 2; correct?

A. That's right.

Q. Okay. How many different plant samples did you analyze as part of this test?

A. Okay, so we had sample from Mississippi that was a dry samples, mature leaves, fresh leaves. Then we had authentic samples from India. And then we had commercial oils which say they have --

THE REPORTER: We had commercial?

THE WITNESS: Oils.

THE REPORTER: Oils? Yes.

A. Which says it contains Pelargonium graveolens. So I think it was all 20 samples.

Q. Okay. Let me -- let me rephrase the question.

How many actual different plant -- plant material samples did you have?

A. I will say three or more. And if you

I. Khan

count this dried and this, so I will say at least three authentic samples.

Q. Okay. Because when -- when I look at the Materials and Methods section of this article, page 3, it says you obtained leaves and oil from the Indian Institute of Integrated Medicine, and leaves and stems from medicinal plants --

A. Yeah, in --

Q. -- in National Center for Natural Products Research --

A. Yeah.

Q. -- in Mississippi.

A. Yeah.

Q. So I only see basically two sources for the plants.

A. Yeah, and one oil.

Q. Okay. And none of those plants came from China; correct?

A. In this study, yes.

MR. DAVENPORT: Counsel, while you're looking at that, I'm going to propose that we go to noon. Is that okay with you?

I. Khan

MS. WOOLSON: Yeah.

MR. DAVENPORT: Okay.

MS. WOOLSON: That's fine.

MR. DAVENPORT: And then we'll take a lunch break and --

MS. WOOLSON: Resume.

MR. DAVENPORT: -- resume. Very good. Okay.

(Khan Exhibit No. 5 was marked for identification.)

BY MS. WOOLSON:

Q. Have you seen Exhibit 5 before?

A. Yes.

Q. Okay. And what is Exhibit 5?

A. Talking about sample analysis.

Q. Okay. And when you say talking about sample analysis, this -- this, Exhibit 5, is a compilation of emails between Dr. ElSohly, yourself, Larry Bowers, and Amy Eichner; correct?

A. Yes.

Q. And the date of the -- the email exchange appears to be late May, early June 2011; correct?

I. Khan

A. Yes.

Q. And that was after you had done the analysis that we had discussed in Exhibit 4; correct?

A. Looks like analysis is -- was not completed.

Q. It's not completed? Okay.

Now, if you go to the third page of the email, at the top of the page there's an email from Dr. ElSohly to Amy Eichner; correct?

A. Yes.

Q. And you're copied on that email; correct?

A. Uh-huh.

Q. And it says: "We analyzed the samples you just sent to me by the LC/MS/MS method and they do contain low levels of DMP (in the nanogram per milliliter range)."

Correct?

A. Yeah.

Q. What samples are those?

A. This was in the products.

Q. So these were products?

A. Yes.

I. Khan

Q. Okay. And these were the products that you analyzed in Exhibit 4?

A. Yeah.

Q. And which products?

A. I can't recall that.

Q. And when you say -- strike that.

If you look at table 2 on Exhibit 4, there are three products listed. Table 2, the last page of the report.

A. Yeah.

MR. DAVENPORT: I apologize, I've got a -- I'm missing --

THE WITNESS: No, the last page.

MR. DAVENPORT: You're talking about figure 14?

THE WITNESS: Oh, you're missing one page?

MR. DAVENPORT: Yeah, I'm actually missing -- regarding Exhibit 4, as I see it -- you kept referring to -- I've got 2, 4, page numbers 2, 4, 6, 8, so I don't have the full copy.

MS. WOOLSON: Hang on. I might have an extra copy.

MR. DAVENPORT: That's all right. Hold on. Pause for a minute.

(Discussion held off the record.)

BY MS. WOOLSON:

Q. Back to table 2 of Exhibit 4, there were three products listed there; correct?

A. Yes.

Q. And they are all listed as having concentrations in the milligram per gram --

A. Yes.

Q. -- range; correct?

A. Yeah.

Q. Not microliter -- nanogram per milliliter; correct?

A. Yeah.

Q. Okay. And you still think those are the products that you're talking about in this particular paragraph?

A. Likely.

Q. Likely? Are you sure?

A. I'm -- I'm -- again, I -- I can't recall unless I look at -- back.

Q. Okay. And what would you look at to determine which products were tested on or

about May 27, 2011, and had low levels of DMP in them?

A. These are the products that should be cataloged in ElSohly's, so he should have all this information.

Q. And he should have it in what?

A. They do a chain of custody when they receive it. They should have it.

Q. And so let me ask you, when you look at table 2 and you go up to the -- the fresh plant material, rather, the plant material --

A. Uh-huh.

Q. -- the first four --

A. Uh-huh.

Q. -- samples say that there's concentration of less than 10 nanograms per milliliter; correct?

A. That's the -- for the detection limit.

Q. But it doesn't say not detected. It says less than 10 micro -- nanograms per milliliter; correct?

A. This -- this is a scientific practice. Always, you -- whatever the value

you are measuring, you -- below that, you just don't say it. You put your limit.

Q. Okay. And then below it, though, for all the rest of the products, you have "nondetect"; correct?

A. Yeah.

Q. Okay. So you didn't say nondetect for the top four?

A. Yeah.

Q. Correct.

And in this email that we're talking about, we're talking about products that were sampled at the LC/MS/MS method and have low levels of DMP, in the nanograms per milliliter range; correct?

A. This is the product?

Q. I'm talking about the email.

A. Okay, I'm talking about the email. This is not about the geranium plant material.

Q. Just let me finish my question, sir.

The email talks about samples that were analyzed by the LC/MS/MS method that do contain low levels of DMP in the nanogram per milliliter range; correct?

A. Yeah.

Q. That's what the email says.

And what's reported in table 2 are four plant samples that have a limit of less than 10 nanograms per milliliter; correct?

A. Can -- can I answer? These products --

Q. It's a yes or no question.

MR. DAVENPORT: Objection to the form. He -- he's allowed to answer the question.

MS. WOOLSON: But he's not.

MR. DAVENPORT: Okay.

MS. WOOLSON: That's the problem. It's a yes or no question.

MR. DAVENPORT: It's -- it -- it -- your yes or no question -- the question may not, you know, determine a yes or no answer.

A. These samples, if you are referring to these samples, they are not the same.

Q. But you already told me you don't know, didn't you?

A. Yeah, but these are the product.

I. Khan

They never send us any authentic samples of any geranium plant. That for sure I know.

Q. Okay. You would agree with me nevertheless that table 2 reports a concentration for the four plants as nanograms per milliliter; correct?

So less than 10 nanograms per milliliter; correct?

A. That was our detection --

Q. Right.

A. -- limit.

Q. And the other plants, they say nondetect; correct?

A. Yeah.

Q. Okay. And for the samples, the products that you say are the subject of this email, those concentrations are reported in milligrams per gram?

A. Yeah.

Q. Not nanograms per milliliter --

A. Yeah.

Q. -- correct? Okay.

And if you found low levels of product in -- low levels of -- of DMAA in the

I. Khan

products, you said you went -- then went back and analyzed all of the samples using this new LC mass spec/mass spec method; correct?

A. Yeah.

Q. And this LC mass spec/mass spec method was a new method that you guys -- excuse me -- your lab had -- had developed; correct?

A. That particular method, yes.

Q. Okay.

A. LC method has been reported earlier.

Q. If you go to the email immediately preceding the email that we were just looking at in Exhibit 5, this is from Ms. Eichner to Dr. ElSohly. It's on page 4273.

A. Yes.

Q. You see where she says: "If it is in there at a measurable level, then our message will obviously change slightly. We will focus more heavily on synthetic DMP not being a dietary ingredient, but DMP extracted from a plant meets the definition of a dietary ingredient."

Correct?

A. That's what it reads, yes.

I. Khan

Q. So she's talking about what to do if DMAA is actually found in the plant material; correct?

A. Yes.

Q. Okay. And then Dr. ElSohly's response to her is that: "In the next couple of days, we will conclude all our testing and we will have a very clear picture. Anyway, it appears that the levels are really low, in the parts per billion range."

Correct?

A. That's what the email says.

Q. And then if you go to the very top of the -- the -- the email, it's the first email on the first page, Dr. ElSohly is now talking about: "If the samples show 2 to 8 ppb, we can comfortably say absent with a detection limit of 10 ppb, or something like that."

Correct?

A. Yeah.

Q. And micro -- micrograms -- excuse me -- nanograms per milliliter, is that ppb? Parts per billion?

A. Yes.

I. Khan

Q. So what Dr. ElSohly is talking about is reporting a detection limit of 10 ppb, which would prevent -- excuse me, which would allow him not to record detections below that; correct?

A. No, because there was a follow-up identification of [unintelligible] that --

THE REPORTER: I'm sorry. There was a follow-up?

THE WITNESS: Follow-up method developed and checked with Q-TOF, Q-T-O-F --

THE REPORTER: "There was a follow-up method"?

THE WITNESS: Yes.

THE REPORTER: "Developed and"?

THE WITNESS: To confirm.

THE REPORTER: "To confirm."

THE WITNESS: The identity.

THE REPORTER: Thank you.

A. If his intention was to hide the results, he would not have used the Q-TOF method to confirm it, so --

THE REPORTER: He would not have

I. Khan

used the?

THE WITNESS: The Q-TOF method to --

MR. DAVENPORT: It's -- it's Q-T-O-F?

THE WITNESS: Yes.

MS. WOOLSON: Q-T-O-F?

THE REPORTER: Okay. "The Q-TOF method to confirm it." Yes, thank you.

Q. And -- and when you say "Q-TOF," you're talking about the LC mass spec/mass spec method?

A. That's --

Q. Okay.

A. -- correct. So the thing is this is -- it can be implied that Amy is asking him to hide it and he said we will hide it, but then why we are going to do the confirmation?

Q. But he's actually talking about the results of the Q-TOF method that you just talked about; right?

That's what he's talking about in that paragraph?

A. No, he is talking about the

I. Khan

LC/LC/MS -- LC/MS/MS level.

Q. And isn't that the new method?

A. Then this is -- then it use the Q-TOF method, which in the paper, which it says we also give the high resolution mass spec to confirm --

THE REPORTER: "We also give"?

THE WITNESS: High resolution.

MS. WOOLSON: High resolution.

THE REPORTER: Oh, high resolution. High resolution. "We also give the high resolution"?

THE WITNESS: Mass spec --

THE REPORTER: Yes.

THE WITNESS: -- to confirm --

THE REPORTER: "To confirm"? Thank you.

THE WITNESS: -- the identity of the component.

Q. And when you say you gave the high resolution mass spec to confirm the component, you're talking about the high resolution mass spec of the full extracted material from the plant; correct?

I. Khan

A. Yeah, in the -- in the geranium sample.

Q. In the geranium sample.

Without any effort to isolate DMAA if it was in that sample; correct?

A. I -- I do not -- how do -- how do you isolate when you're identifying? So I'm little confused with this question.

Q. Well, I'll -- I'll state it again. What you were running the -- the -- the NMR on; right --

A. Yeah.

Q. -- was the extract from the plant material --

A. That's right.

Q. -- correct?

A. Yes.

Q. With all the components, the 90-plus components in there?

A. Yes.

Q. Okay, thank you. And -- and you would agree with -- strike that.

Can you point to me the NMR for the standard DMA solution?

I. Khan

A. It's not there.

Q. Okay, thank you.

Now if you go back to Exhibit 5, which is the email, the second email on the first page from Dr. Bowers, he's expressing some concern about relying on the LC mass spec/mass spec method to verify presence of a substance.

Do you see that?

A. Yeah.

Q. But he seems to think that it's okay to rely on it to -- to show the absence of a substance; correct?

A. Wrong interpretation.

Q. Pardon me?

A. He doesn't say that.

Q. Does he say at the bottom of the sentence --

A. He is talking about the limitations of the method.

Q. The limitations of what? The method?

A. Method.

Q. Okay. But he says: "The absence of characteristic ions at the expected retention

I. Khan

time, however, is helpful in establishing the absence of a compound"; correct?

A. Yes. He is talking about the -- using more ions for the confirmation.

Q. Well, he's talking about using the absence of ions to establish the absence of a compound, not more ions to confirm the presence of a compound, in that sentence.

A. In that, that -- that's the interpretation.

Q. Okay. Did Dr. Bowers and Dr. Eichner see this report, Exhibit 4, before it was published?

A. Yeah.

Q. And did they make revisions to it?

A. No.

Q. No revisions at all?

A. As far as I know. Dr. ElSohly can provide you more information.

(Khan Exhibit No. 6 was marked for identification.)

BY MS. WOOLSON:

Q. Have you seen Exhibit 6 before?

A. No, I did not.

I. Khan

Q. Okay. Understanding you haven't seen it before, would you agree with me that this is an email from Dr. Bowers to Dr. Gul and Dr. ElSohly and Dr. Eichner discussing paragraphs that he wants to be added to the article that we've been talking about as Exhibit 4?

MR. DAVENPORT: I'm going to object to the form of the question, but you may answer, Dr. Khan.

A. As I mentioned earlier, that they have provided editing and provided their comments being part of the manuscript, and that's very usual, to have a discussion.

Q. And is it usual to have a discussion where two people who were involved in the funding of the study are suggesting conclusions for the study?

A. Funding is -- having a scientific discussions, like in previous exhibit they talk about the limitation of LC/MS/MS, that's -- that's very usual among authors to discuss a manuscript, provide the correct information.

Q. And -- and again, by "authors,"

I. Khan

Dr. Bowers and Dr. Eichner didn't perform any of the studies involved; correct?

A. So I did not do either.

Q. And they didn't supervise anybody who performed any of the studies; correct?

A. That's right.

Q. Okay.

MS. WOOLSON: It's about 12. Do you want to break?

MR. DAVENPORT: That'll work.

(Recess taken.)

BY MS. WOOLSON:

Q. Dr. Khan, what is ChromaDex?

A. ChromaDex is a company selling standards and involved in contractual services related to natural products, reference standards, analysis --

THE REPORTER: I'm sorry?

THE WITNESS: Analysis.

THE REPORTER: What analysis?

THE WITNESS: General analysis.

THE REPORTER: General? Okay. Just -- I just didn't hear the word. Okay. "General analysis."

I. Khan

THE WITNESS: Yeah. Of nature products.

Q. And what is your relationship to ChromaDex?

A. ChromaDex initially started as in collaboration with University of Mississippi, I believe in 1998, around that time.

Q. And how were you involved with ChromaDex?

A. Initially they funded research to isolate the standard compounds to University of Mississippi and I was the PI of that project.

Q. And by "PI" you mean principal investigator?

A. That's right.

Q. Okay. And following your role as principal investigator, have you continued to have a relationship with ChromaDex?

A. No, no financial project after that that I did.

Q. Do you own any shares of stock of ChromaDex?

A. Yes, I do.

Q. And how many shares of stock do you

I. Khan

own?

A. They recently changed to another exchange so I don't know exactly, but it should be around one-third of what I had, which was 238,000, I believe.

Q. And do you know if you are one of the principal shareholders of ChromaDex?

A. No, I'm not.

Q. You're not?

Do you know who the principal shareholders of ChromaDex are?

A. I certainly know that Frank is, but I -- I'm not sure who else is there right now. I don't follow.

Q. And what's Frank's last name?

A. Jaksch, J-A-K-S-C-H.

Q. Okay. And when did you become a ChromaDex shareholder?

A. Once they issued the shares, I remember it was.

Q. Okay. And do you sit on the board of ChromaDex?

A. No.

Q. Okay. Have you ever sat on the board

I. Khan

of ChromaDex?

A. No.

Q. Do you know how many shareholders ChromaDex has?

A. I don't follow it. I really don't know. But they are changing so quickly so fast so I'm not sure.

Q. When you say they are changing so quickly so fast, what do you mean?

A. I mean the business is growing very fast, they are acquiring, they are having other companies, so I can't anticipate the -- the whole complex deal.

Q. And I take it you are not employed or do not have a contract with ChromaDex. Is that correct?

A. That's right.

Q. Okay, okay. I'd like to have you turn back to Exhibit 4 again. I have a couple more questions for you. So on page 27847, the text at the bottom of the page, there's a discussion of -- where is it? -- it says "extract of .1 milligrams of a powdered commercial product alleging P. graveolens as

I. Khan

the source of MHA and the F -- HFB derivative of the IS showing a small amount of MHA."

Do you see that?

A. Yes.

Q. And then two pages over, on figure 9, you have -- the legend at the bottom of the -- the graphic says: "GC mass spec selected chromatograms for the HFB derivative of the IS showing a small amount of impurity of MHA."

Do you see that?

A. Yeah.

Q. Okay. And where -- can you point to me on the chromatogram where the MHA shows up?

A. These are the ions for the MHA.

Q. And when you say "these are," what are -- what are you pointing to?

A. This left side.

Q. The left side? Okay.

And how did -- did you ever determine how the IS -- excuse me, how this -- this particular compound came to be contaminated with MHA?

A. Yes. There is a -- a small overlapping [unintelligible] --

I. Khan

THE REPORTER: A small?

THE WITNESS: Overlapping.

Q. Overlapping?

A. Yes. They found impurity there which later on was confirmed not to be MHA.

Q. But as far as this paper goes, that -- that information's not in this paper; correct?

A. That's what is written, yes.

Q. Well, what's written is that the impurity was MHA; right?

A. A small amount of impurity, but yeah.

Q. All right. And if it wasn't MHA, what was the impurity determined to be?

A. Something else, not MHA.

Q. And did you publish any papers about determining the identity of that impurity?

A. No.

Q. And who did the work to determine that the impurity was not MHA?

A. Dr. ElSohly's lab.

THE REPORTER: Repeat the term.

THE WITNESS: "ElSohly's lab."

THE REPORTER: Okay, thank you.

I. Khan

Q. So they did the work, but they never published that work; correct?

A. That's what they are talking about ion, missing ion, yes. They give the evidence in the second paper.

Q. Okay. So you're saying in the second paper, they confirmed that this impurity was not MHA?

A. Yeah. It -- it was confirmed in this paper too, but they highlighted again because of the question raised about three ions.

Q. Okay. Well, you say it was confirmed in this paper, but this paper says the impurity was MHA.

A. Yeah.

Q. Doesn't say it was something else. It says it was MHA; correct?

A. The MHA impurity was confirmed with the [unintelligible] for three ions --

THE REPORTER: Confirmed with the?

THE WITNESS: Three ions.

THE REPORTER: Oh.

Q. Okay. So let's -- let's back up. We've confirmed based on what you've just said

I. Khan

that the impurity was MHA based on those three ions. Okay?

And my initial question to you was did your lab ever determine how the sample became contaminated with MHA. And I thought your answer was it wasn't MHA, it was something else.

A. Yeah, after confirmation.

Q. Okay. So let's back up again. In this paper, the impurity is identified as MHA; correct?

A. Looks like it.

MR. DAVENPORT: Object to form.

Q. Yes.

MR. DAVENPORT: Okay.

Q. Yes?

A. Looks like MHA.

Q. Okay. And as you sit here today, to your knowledge, did anyone make a determination of how the sample became contaminated, whether the contaminant was actually MHA or later determined to be something else?

A. Yeah, that's where the three ion confirmation we started off.

I. Khan

Q. No, I'm asking you how it became contaminated. Do you know how --

A. No, I --

Q. -- the sample became contaminated?

A. -- don't. I don't know.

Q. As you ran the studies in this paper, did you notice any change to the level of detection or the sensitivity of the equipment?

A. Not that I'm aware of.

Q. Do you know if the equipment was cleaned between each sample?

A. That should be written, cleaning procedure.

THE REPORTER: I'm sorry? Repeat it.

THE WITNESS: That should be written [unintelligible] cleanup procedure.

THE REPORTER: I -- I don't -- I don't understand.

MR. DAVENPORT: That should be written in the cleaning procedure.

THE REPORTER: Thank you.

Q. I don't see any section of this paper

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called Cleaning Procedure, so --

A. Okay. That should be provided by ElSohly's lab.

Q. So it's not in this paper?

A. Yeah.

Q. Do you know if standards were ran -- excuse me -- standards were run between each sample?

A. Again, this protocol, I don't recall it, but yes. Whether it was run after each sample or after three sample, I don't know, but should be run.

Q. It should be done?

A. Yeah.

Q. And again, this paper doesn't discuss that; correct?

A. Yes.

Q. Okay.

(Khan Exhibit No. 7 was marked for identification.)

BY MS. WOOLSON:

Q. Take a minute to review it and let me know when you're ready to discuss it.

MR. DAVENPORT: I'm not sure I have

the complete report again.
(Discussion held off the record.)
BY MS. WOOLSON:
Q. So I'm showing you Exhibit 7, Dr. Khan. Have you seen it before?
A. Yes.
Q. And what is it?
A. This is multicenter study.
THE REPORTER: I'm sorry?
A. Multicenter study.
Q. And is this the second paper that we talked about this morning?
A. That's right.
Q. Okay. And I see Dr. ElSohly, I see Dr. Gul, I see your name on there.
Who is Candice Tolbert?
A. Candice is -- is tech person in ElSohly's --
Q. Okay.
A. -- lab.
Q. We talked about Kareem ElSohly.
A. Yeah.
Q. Who is Timothy Murphy?
A. He's -- he's a senior analytic --

analyst in that -- ElSohly's lab.
Q. We talked about Dr. Avula?
A. Yeah.
Q. And we've talked about Dr. -- I'm going to go with "Amar" because --
A. Yeah, yeah.
Q. -- it's just easier for me to say. Who is Dr. Wang?
A. Wang is also analytical chemist, works on -- in our center.
Q. So he -- she -- he or she?
A. She.
Q. She works at the center?
A. Yeah.
Q. Okay. And who is Dr. Yang?
A. Dr. Yang works with Dr. De-an Guo in Shanghai Institute of Materia Medica.
THE REPORTER: Sir?
THE WITNESS: Shanghai Institute of Materia Medica.
Q. And Dr. Zhang and Dr. Su?
A. They work in Second Military School -- School of Pharmacy, Second -- Second Military Medical University Shanghai.

Q. Okay. Now, tell me how this study came to be.
A. This one came because after publishing first paper, the criticism was that we analyzed sample from India and we did not analyze any sample from China. And according to Dr. Khan, the natural variation can be -- from different region can produce different sample.
Q. According to doctor who?
A. Dr. Khan.
Q. Dr. Khan?
A. That's me.
Q. Okay.
A. That's what's referred to in the paper.
Q. I wanted to make sure there wasn't another Dr. Khan out there.
A. No, this is -- has been heavily referred that -- my paper, that the natural variation does occur. So since we are seriously investigating is there or not, so that criticism [unintelligible] was taken seriously, and --

THE REPORTER: So that?
THE WITNESS: That criticism.
THE REPORTER: Criticism?
THE WITNESS: And suggestions.
THE REPORTER: And suggestions?
THE WITNESS: Yeah. Were taken, and we thought it better to do a study and include the sample from China.
Q. Okay. And the samples that you got from China, what region of China did they come from?
A. This sample was collected by the same person who collected the sample for the studies for Fleming and Li, and they come from Yunnan (phonetic) province.
Q. And the samples that Dr. Fleming, Dr. Li both tested and confirmed had DMAA in it, what region of China did those samples come from?
MR. DAVENPORT: Objection to the form of the question. You can answer.
A. They found DMAA in dia -- in the -- in diastereomeric form, sample they analyzed, so I hope it does not imply that they found

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naturally. Having said that --

THE REPORTER: It -- it does not?

THE WITNESS: "Imply."

THE REPORTER: That they found?

THE WITNESS: Naturally.

THE REPORTER: Oh, "naturally."

THE WITNESS: Right.

A. But the samples were, if I recollect, they were Yunnan (phonetic), Guizhou (phonetic), and Changzhou (phonetic) region, which are almost three -- close to 2,000 kilometer apart from each other.

Q. So you didn't collect any samples for your study from the Changzhou region; correct?

A. No, because we asked the person in China -- for us to analyze the sample, we have to contact somebody where we can get the sample from, and that person was the one that provided from the Yunnan province sample, so we assumed that he is going to provide the similar region sample.

Q. You assumed. What did you do to confirm that?

A. Because that's what the Yunnan sample

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that came from provided by the same person.

Q. But you didn't get a sample from the Changzhou region; correct?

A. Yes, we did not got the sample from Changzhou.

Q. Okay. And -- and you didn't run the sample from the Yunnan region against the sample from -- against a sample from the Changzhou region; correct?

A. We asked the person in China to provide us the Pelargonium samples. If he would have provided from 10 different places, we would have taken 10. We did not tell them to provide only from Yunnan.

Q. Okay. But you didn't also ask him to provide you one from Changzhou either, did you?

A. There is no reason for us to because we are not trying to repeat somebody's study. We are trying to find out -- collect as many sample as we can to see whether is a -- that objection that we did not have a sample from China, is it valid or not.

Q. Okay. And if you were trying to do a comparison of your study to the Li study or the

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Fleming study, it would be helpful to have plants that come from the same region; correct?

A. It -- yes. And Yunnan is the same -- same area there where they got the sample from. So we do have representative sample.

But if you look at the Fleming and Li, they are contradicting each other also.

Q. Well, when you --

A. So -- so unless -- unless you're talking about a particular sample that questioned that we did not try to do it, even we got the sample from Yunnan, that is, we didn't get from Changzhou. So I think this -- this is -- I'm not sure what your question is.

We did try to do our best to collect the sample, representative sample from the same region. We didn't go somewhere else.

Q. But you -- my question was a very simple question, which was you didn't run a sample comparing -- you didn't run a study comparing your sample from the Yunnan province with a sample of a plant from the Changzhou region. You didn't do that; right?

A. We didn't have sample from Changzhou.

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Q. Was there any reason why you couldn't get a sample from the Changzhou region?

A. We contacted the person who provided a sample for this study. We said we would like to have sample, and he provided from Yunnan.

Q. That wasn't my question.

My question was: Is there any reason why you couldn't get a sample from the Changzhou region?

A. We had to have somebody to collect and provide the sample to us.

Q. So your testimony is you didn't get a sample from the Changzhou region because you couldn't find someone to provide you with a sample?

A. The Chin He (phonetic), who collected a sample, provided us only from Yunnan.

Q. And did you say to that person, we would also like a sample from the Changzhou region?

A. No.

Q. All right. So tell me about the method that you used in -- or methods that you used in this study.

A. So one of the criticism was that our recovery rate is slow, which is -- if you look at the Fleming paper, they had a 19 percent recovery. So we used the Li methods and adjusted based on the ratio of the plant. So extraction procedure was done accordingly as reported by Li.

Q. Okay, let me stop you there. When you say you did the sample -- the method or sample preparation according to Li, did you do it at the exact same quantities and volumes as Li?

A. No. As I mentioned, as I mentioned earlier, volume were adjusted based on the concentration we were using.

Q. And you were using less plant material, basically -- basically like tenfold less plant material than Li?

A. In the -- but we had the one -- the one-tenth of the volume, also, so --

Q. I'm just asking the question. Did you use tenfold less material than Li?

A. With the tenfold less solvent, so concentration is the same.

Q. Okay. So am I correct that you used about a gram of plant material and Li used about 10 grams of plant material?

A. We used 1 gram in 5 milliliter, he used 10 gram in 100 milliliter, so the concentration should be double than what he had.

Q. Your concentration was double?

A. Because we used 1 gram into 5 ml.

Q. So you --

THE REPORTER: Into 5?

THE WITNESS: Ml. Milliliter.

THE REPORTER: Ml? Ml. Thank you.

Q. So you doubled the concentrations that Li used? Is that what you're saying?

A. No, not in this paper. What I'm saying is if you look at the volume, if your question is they used 10 gram and we used 1 gram --

Q. Uh-huh.

A. -- they used 10 gram in 100 milliliter, we used 1 gram in 10 milliliter, which is equivalent.

Q. I agree with you. But that's not

what you said previously so I just wanted to clarify that. Okay.

When you're dealing with small volumes --

A. Uh-huh.

Q. -- of material and you're dealing with low recoveries to begin with, doesn't that affect your overall recovery of the sample and the -- and the compound that you're trying to isolate?

A. That's why the recovery experiments are run, to determine it.

Q. Okay. But my question is if you are starting with something that's difficult to recover to begin with, where you have a low recovery rate, and you're self-limiting to using only a gram of material; right? So aren't you -- inherently, isn't your yield going to be less? Just in a sheer gram, not a percentage-wise, but sheer number of gram-wise of the product than Li or Fleming?

A. Once you extract the sample, you get a certain volume and you inject certain volume. So ratio, as mention earlier, if you take 10

gram in 100 milliliter --

Q. Uh-huh.

A. -- or 1 gram in 10 ml, it's the same. End of the day when you are -- when you inject it, they should have the same concentration.

Q. I'm not talking about the volume. I'm asking you a question strictly on a basic level of grams of material.

You would agree with me, if you -- you start with less grams, you're going to end up with less grams? Not talking about the concentration, I'm just talking about sheer weight of material. Right?

A. Yeah, sample -- sample extract, if you are talking about how much extract we are going to get from 10 versus 100, yes, that will be different.

Q. Okay. And would you agree with me that the error rate between laboratories working on a small scale of sample can be as high as 50 percent?

MR. DAVENPORT: I'm going to object to the form of the question. You can answer, Dr. Khan.

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A. You are talking about within the laboratory, or you are talking about the other laboratories?

Q. Between laboratories.

A. Between laboratories, everybody is going to determine their limits, so --

Q. Well, that -- that wasn't my question. My question was, do you agree with me that if you had two laboratories working with the same compound, doing the same procedure, that the error rate can be as much as 50 percent between the two laboratories?

A. Should not be. If they have done the full method validation.

THE REPORTER: The full?

THE WITNESS: Method validation.

THE REPORTER: Yes, thank you.

Q. So you think that two laboratories should be 100 percent the same?

A. I mean, that's why we run them several labs, to compare the results from each lab. And it should be comparable. And if it is a big different, then it should -- has to go back and look at where it happened. That's

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what the method validation -- interlevel (phonetic) method validation is all about. So you are trying to see the vary -- variation in different labs, but everybody has their own method validation done.

Q. What was the -- well, when you say everybody has their own method of validation done, what was the difference between the method of validation for your lab and the Shanghai Institute and the School of Pharmacy in this study?

A. That's where it's written in tables. So table 2 is describing for Shanghai -- Second Military Medical University, Shanghai. Table 3 is for Materia Medica. And 10 nanogram per milliliter --

THE REPORTER: 10?

THE WITNESS: Nanogram.

THE REPORTER: Per?

THE WITNESS: Milliliter.

THE REPORTER: Thank you.

Q. And where are you looking?

A. This last paragraph.

Q. Last page?

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A. 786, yes.

Q. And where? Is the paragraph "Finally, figure 7"?

A. Yeah.

Q. Well, I'm not sure what you're trying to -- to -- to -- to tell us because that's talking about comparison to a control sample at 10 nanograms per milliliter.

A. Figure 7 shows the example of [unintelligible] --

THE REPORTER: I'm sorry, sir? Shows?

A. Figure 7 shows example of the LC-MS-TOF chromatograms for -- for two extracts of two oil samples as well as those of sample of young and mature leaves in one stem sample as compared to that of control sample.

Q. So how does that tell me your -- your level of detection? I -- I'm sorry, your detection validation?

A. Yeah, let me see. "Qualification procedure is --"

THE REPORTER: I'm sorry, sir. If you are reading for the record, you need

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to read to me, and slowly.

A. 10 milligram.

Q. Okay. That paragraph says: "The LOD and LOQ of the instrument were deduced by a standard solution --"

A. Yeah.

Q. "-- of 10 nanograms per milliliter --"

A. Yes.

Q. "-- with S/N 3.1 and 10.1 respectively. The LOD and LOQ of the method were deduced by a recovery sample. The results are shown in tables 2 through 5."

Tables 2 through 5 only deal with the Shanghai Institute and the Military --

A. Uh-huh.

Q. -- Military Medical University. I don't see any tables regarding the work that was done by ElSohly or Phytochemical Services or the Natural Product Center -- National Center for Natural Products.

A. Yeah. So MHA showed fragmentation ion, and the limit of detection for this method was estimated as 10 ppb.

Q. And where are you now?
A. It's -- it's the last line of the second page.
Q. Last line of the second page. And this is -- I'm sorry. Can you show me where?
A. It's under it.
Q. Okay.
A. Here.
Q. Okay. Again, this is the limit of detection for the LC --
A. TOF.
Q. -- Q-TOF method.
A. It was --
Q. Okay.
A. -- done by -- by the center.
Q. Okay. So your method -- your limit of detection was 10 ppb; correct?
A. Yes.
Q. Okay. And then if we go over and we look at table 2 --
A. Yeah.
Q. -- which is the level of detection for the Military Institute --
A. Uh-huh.

Q. -- that says 8?
A. Yeah.
Q. .8 what?
A. Limit of detection. Picogram.
Q. Picogram?
A. Yeah, yeah.
Q. And then if we look at table 3 --
A. Yeah.
Q. -- it says 28 and 5, right, for peak 1?
A. Yeah.
Q. So 28 micrograms per kilogram. That's parts per billion?
A. Ppb, yes.
Q. Okay. And 5 parts per billion?
A. Yes.
Q. And your method was 10 parts per billion?
A. Yeah.
Q. Okay. So you found a range of anywhere from 5 to 28 parts per billion was acceptable level of detection for the three different laboratories?
A. That's -- being four different labs,

that -- that's the purpose of -- if you find that much variation within the lab, that should not be acceptable. But four different methods, four different techniques, then you have to come up with [unintelligible], yes.
THE REPORTER: Then you have to?
THE WITNESS: Come up with a range.
THE REPORTER: "Come up with a range"? Thank you.
Q. So there can be a wide range of differences between laboratories performing the same analyses; correct?
MR. DAVENPORT: Objection to the form of the question. You can answer, Dr. Khan.
A. That's not the rule.
Q. I'm basing this on the results we just looked at.
A. No, I -- I'm --
Q. We go from 5 --
A. Yes.
Q. -- to -- to 28 parts --
A. That -- that -- that's --
Q. -- per billion; correct?

A. That's why the multi-lab validation is good to have, because you'll see the variation lower or higher. But as long as people are using the same sample, we each extract it. So minimize that variation, but use a different technique so you get the results, which should be comparable. Or, if not, then we can discuss why not.
Q. Okay. And in this case, you've got three labs performing analysis on plant material. Did they all use the same exact --
A. Same exact --
Q. Let me finish the question. Same exact preparation method?
A. Yes.
Q. Did they all use the same exact analytical method?
A. No. They are -- they are using all different methods.
Q. Okay. And so they are using all different methods, and we have a range of levels of detection from 5 parts per billion to 28 parts per billion; correct?
A. By this report, yes.

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Q. Now, did all three labs analyze all of the samples?

A. Yes.

Q. Does -- anywhere in this report, do you list the results for all of the samples for all three labs?

A. In this lab -- let me read it, because it says it's provided in supplemental data, so I'm sure it -- it should be there.

Yeah. "Examples of chromatogram Pelargonium samples as it -- as is and again spiked with MHA are provided in the supporting document." So it should be available.

Q. But it's not in this paper; correct?

A. Supporting document generally is not included in the paper.

Q. Okay. And do you know if you gave the supporting documentation to your counsel?

A. This is coming from -- from ElSohly, so I cannot -- should have, but I'm not --

Q. Okay.

A. I mean, the -- all the data has been provided, so should be included.

Q. Okay. We're going to make a request

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for the supplemental material.

In the interim, let me go back. I need to clarify one thing with you. The tables on -- tables 2 through 5, I think I inadvertently said that they included levels of detection for the Shanghai Institute. But that's not correct, is it? These are all for the Military Medical University.

A. Yes, but it -- it should be part of the supplemental we did.

Q. Is there some reason why the level of detection for the Shanghai Institute was not reported?

A. Should not be any reason.

Q. Did the Shanghai Institute report finding DMAA in any of the samples?

A. All the samples are negative.

(Khan Exhibit No. 8 was marked for identification.)

MS. WOOLSON: Hopefully, all the pages are there.

MR. DAVENPORT: I'll check. You have a three-page document?

MS. WOOLSON: Yes.

I. Khan

MR. DAVENPORT: Okay. Exhibit 8?

THE REPORTER: Yes, sir.

MR. DAVENPORT: Thank you.

BY MS. WOOLSON:

Q. Have you seen Exhibit 8 before?

A. Yes.

Q. And what is Exhibit 8?

A. This is about communication between ElSohly and De-an Guo.

Q. And who?

A. No, wait. No, this is -- there are two emails here.

Q. So let's talk about the first one on page 1. Well, actually, I guess it's the second one on page 1. This was an email exchange between Dr. ElSohly and Dr. Yang; correct?

A. Dr. Guo. Yeah, yeah, Dr. Yang, yeah. Same group.

Q. Okay. And Dr. Yang is saying that in the earlier work she -- it's a she? Dr. Yang is a she?

A. He.

Q. He? Dr. Yang said in his earlier

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work he analyzed the samples using the same extraction method with that of the literature but none of them showed detectable MHA, so he improved the extraction method and obtained the results sent to you previously; correct?

A. That's what it says.

Q. Okay. And if we go to the next page, it says -- this is Dr. ElSohly writing to Dr. De-an, and he says: "Your writeup shows fresh samples 1 and 2 to show a peak at the same RT of MHA but below LOQ." Correct?

A. Yeah.

Q. Meaning MHA was detected below the level of detection -- below level of quantification; correct?

A. Partially correct, but the next sentence, what he's trying to convey, he's talking about that having a peak does not mean [unintelligible] MHA.

THE REPORTER: I'm sorry? Having a?

THE WITNESS: Having a peak.

MR. DAVENPORT: Peak.

THE REPORTER: "Peak"?

THE WITNESS: Peak. Does not mean this is MHA.

Q. So in response to Dr. ElSohly's email saying finding a peak does not mean that you have MHA, Dr. Yang goes on, responding, saying this is what I found and this is what I did.

A. Oh, yeah. Dr. ElSohly's asking him to confirm it. He is not saying you hide it. What he's saying is if you found it, you have to confirm it. Then he goes and improves it and follows the same protocol and then he doesn't find it.

Q. No. Actually, when he improved the protocol, he found it; correct?

A. But what he found as MHA, he did not confirm this is MHA.

Q. I -- I'm -- I'm not saying he confirmed it; I'm saying this is what he's saying he found after he improved the protocol.

A. Yeah, but you have to confirm. Other people have reported finding it too, but it doesn't mean it's there.

Q. And what, if anything, did you do -- "you" meaning your laboratory -- do to prove it

wasn't there?

A. Wasn't there?

Q. Uh-huh.

A. It's already not there.

Q. Oh, so you did nothing to -- to --

A. That's --

Q. -- confirm --

A. -- why --

Q. -- that it --

A. -- you --

Q. -- was --

A. -- the protocol.

THE REPORTER: I'm sorry. I didn't hear the end of the question.

Q. So you did nothing to confirm that that was not MHA that was detected?

A. That's why you do the MRM, to confirm it.

Q. And where is there an MRM on Dr. Yang's sample?

A. It should be provided. It should be included. I don't have it here, but yes, what they are asking you, if you find it, you have to confirm it. That's what ElSohly is saying

in this email.

Q. And so there's no NMR -- MRM for Dr. Yang's sample in your report --

A. There's all this data --

Q. -- and there -- and there's no mention of the detection; correct?

A. Yeah, detection limit is 10 ppb. That's what it says in the paper up front.

Q. So in other words, if you detect something that could be MHA below the detection limit, you're not going to report it in your paper?

A. You have to confirm it before you report it.

Q. Okay. And again, I asked you, what steps did you do to confirm it?

A. Yeah, you take the MRM, you analyze it, you do the high resolution mas spec to see whether --

THE REPORTER: You do the?

THE WITNESS: High resolution mass spec --

THE REPORTER: Yes.

THE WITNESS: -- to confirm it.

Q. Okay. And that's not in this paper?

A. That's not in the paper.

Q. Okay.

(Khan Exhibit No. 9 was marked for identification.)

MS. WOOLSON: Tell me when you've had a chance to look at 9.

MR. DAVENPORT: You have a six-page document?

MS. WOOLSON: Yes. The last page is 2272.

BY MS. WOOLSON:

Q. Have you seen Exhibit 9 before?

A. Yes.

Q. What is Exhibit 9?

A. This is email exchange sent to De-an Guo and to me from -- from Min Yang.

Q. Thank you. This is regarding the work that we looked at that was in Exhibit 7? The 2014 paper?

A. Yeah.

Q. This one.

A. No, this one -- related to, yes, Exhibit 7.

I. Khan

Q. Okay, okay. And in the first email, Dr. Yang is saying that "Checked the data and found that 2 nanograms per milliliter in DMAA in methanol control solution could be detected by the MRM method." Correct?

A. Yeah.

Q. And then he says: "I think 2 nanograms per milliliter could be detected in the samples." Correct?

A. That's what it reads, yeah.

Q. And then immediately below that is an email from you to Dr. Yang saying you found 10 -- 2 nanograms in samples, but it doesn't match the report from Professor Dong's lab --

A. Yeah.

Q. -- correct?

A. Yeah.

Q. So you're acknowledging that Dr. Yang found 2 nanograms of DMAA in some of the samples?

A. Reporting. There's no confirmation at this point. That's why the exhibit --

Q. So he's reporting that. Okay.

A. He is saying that's what I found --

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Q. Uh-huh.

A. -- and since we are multicenter study, we [unintelligible] --

THE REPORTER: And since we?

THE WITNESS: Multicenter study.

THE REPORTER: Yes.

THE WITNESS: We would like to confirm the results.

THE REPORTER: Yes.

THE WITNESS: And that's where this Exhibit 8 even was, can you confirm it.

Q. Uh-huh. And -- and you -- and you wanted him to confirm it using an MRM; correct?

A. Yeah.

Q. Okay, let's turn to page 3. These are MRMs of the plant samples taken by Shanghai Institute; correct?

MR. DAVENPORT: We're at 2270?

MS. WOOLSON: Yes.

A. Yes.

Q. Yes?

A. Yes.

Q. And it says that DMAA was detected in samples 1 and 2; correct?

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A. They are what it says.

Q. It says that the isomer of DMAA was detected in five samples; correct?

A. That was written here.

Q. Okay. Was any of that in the paper that was published? Exhibit 7?

A. So --

Q. Yes or no?

MR. DAVENPORT: Objection.

Q. That's the answer, yes or no. Was it in the paper or was it not in the paper?

MR. DAVENPORT: Same --

Q. I haven't asked you why yet.

MR. DAVENPORT: Same objection to the form of the question.

A. This method -- this is still work in progress. The email was sent to him to confirm it. His confirmation was that no, I did not find it. So this one, because somebody was working on it without confirmation, shouldn't become a part of the publication. It generally does not happen.

Q. Okay.

A. Unless you have a confirmation, you

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do not write into scientific paper.

Q. Okay. You told me earlier that the confirmation would be an MRM, which you have in Exhibit 9; correct?

A. Yeah, but this is the same when we asked him and he went back and he -- he was not able to confirm it.

Q. No, this is the confirmation; correct?

A. No, this is in April, and this is in May.

Q. Okay. And in May --

A. May's the one that ElSohly's asking him to repeat it, confirm it. That was in April.

Q. And where is the test where he repeated it and couldn't find it?

A. That should -- all should be available to you. I'm sure that all -- in discovery all the documents would be available.

Q. I don't see where Dr. Yang is talking about doing any other tasks. What he said was I improved the -- the extraction method and I found the results I sent to you previously,

which were these in Exhibit 9; correct?
A. This is -- this is in April. The last email when Mahmoud ElSohly was asking him to confirm it, you don't have that data right now, but that data should be available to you.
Q. I -- I don't see anywhere where he's talking about redoing the -- the analysis. What he says was, I rewrote my works; correct?
A. Without doing it?
Q. I'm -- I'm asking you. This email --
A. No --
Q. Where does it --
A. -- I -- I'm --
Q. -- say he's doing an analysis? It doesn't, does it? It says, I rewrote my paper.
A. If you're questioning the integrity of the Shanghai Institute of Materia Medica, that people are just, like, printing the results?
Q. I am not questioning the integrity of the Shanghai Institute. No, I'm not.
A. So I'm sure the data should be available.
Q. Well, if it is, we would certainly

like to see it, and we will request that it be produced.
Now, notwithstanding that, my question was, with regard to Exhibit 7, which was published in August of 2014, so over a year later, there's no reference anywhere in this paper to the results that were detected by the university of Shanghai, are there?
A. What do you mean by "detected"? We confirm we did not find it.
Q. Where --
A. The same --
Q. -- is the confirmation?
MR. DAVENPORT: Hold on.
A. The confirmation of what?
Q. Where --
A. That we -- this is the confirmation. We wrote in the paper that we did not detect it. That's the confirmation.
Q. You didn't --
A. Now you do not have the detailed results that you're asking that should be available to you. But where is the confirmation of what? Is already confirm in

the paper, and they did not find it.
Q. Where in the paper does it discuss the fact that there was a detection that was subsequently eliminated? Nowhere; correct?
Nowhere in this paper does it discuss there was a possible detection that was eliminated?
A. This is -- is work in progress.
Q. This is a published paper.
A. This is published paper. If it says they did not find it, they better have the results. They better have [unintelligible] or it's not --
THE REPORTER: They better have?
THE WITNESS: The results to show it, the data to show it.
Q. But my question to you is where in this paper is there a mention that we found this detection and we ruled it out using thus and such method? There's no discussion anywhere in this paper about that, is there?
A. Yeah, but this -- this paper, this short communication, it says the data is provided in supplemental. These are the papers

are very concise and precise, and you provide the final data. Unless somebody is being accused of hiding the data and misinterpreting it, there's no way that these final results are presented here that something is -- somebody's going to hide anything.
Q. Where in this report is there a single chromatogram or result from Shanghai Institute?
A. All should be available in supplemental data. If you want, you can -- I'm -- I'm sure it will be available. If you found these emails, I'm sure you should have all the data too.
Q. So I guess the answer to my question is it's not in the paper; correct?
A. Paper is also the final four studies. One study [unintelligible] publish in --
THE REPORTER: One study? I'm sorry.
A. One study required several paper, full publication. This is summarizing the finding of four labs in one paper. So generally, in scientific community you provide

the supplement data and do not make it very heavy publication with all the details. So yes, details are not available but it should be made available in supplemental data.

Q. Uh-huh. And in -- in the conclusion to your report is: "27 different samples of the Pelargonium plant material and oils from a variety of sources were analyzed by four different laboratories. None of the laboratories found any MHA in any of the samples at the detection levels of the methods used. These results support previous reports that MHA found in dietary supplements is not of natural origin." Correct?

A. Yes.

Q. Correct. But yet we have an MRM in Exhibit 9 that shows the detection of DMAA in plant material; correct?

MR. DAVENPORT: I'm going to object to the form of the question. You can answer, Dr. Khan.

A. No, we did not find.

Q. Isn't that what this Exhibit 9 says? Isn't that what the MRM says? That MHA was

detected?

A. This is confirmation. This is in April. In May, he asked you to -- to look at your data back. You read the email with it saying -- not saying that you -- to hide the results. He is saying confirm, because you are finding something, so you better confirm it. And that's a confirmation.

Q. I -- tell me in this email where you see any effort to do additional research to confirm.

A. How do you confirm without doing additional research?

Q. That's what I'm asking you.

A. That -- that's what I'm saying. They should -- data should be there.

Q. Well, if you can find the data, we'd love to see it.

A. Yes.

(Khan Exhibit No. 10 was marked for identification.)

BY MS. WOOLSON:

Q. Before we get to Exhibit 10 I just have a follow-up -- actually, go ahead and look

at Exhibit 10.

MR. DAVENPORT: This is a three-page document?

MS. WOOLSON: Yes. It's 27811 to 13.

BY MS. WOOLSON:

Q. Exhibit 10, have you seen that before?

A. Yes.

Q. And what is Exhibit 10?

A. This is a different technique for detecting a DMAA.

Q. This is the third study that we talked about this morning?

A. Yes.

Q. Is this the last study that you've done on DMAA?

A. On DMAA, yes.

Q. Okay. Are you currently doing any other studies on DMAA?

A. No, we published an insecticide electivity which came, I believe, after this.

Q. And the --

A. But that was on geranium, the plant,

not the DMAA.

Q. Okay. And we -- we talked about that this morning. You said it wasn't specifically about DMAA.

A. Yeah.

Q. How does this method differ, if at all, from the method you used in Exhibit 7?

A. This method is a DART. Without processing the sample, you can do the direct analysis. So this is being -- right now, being a new technique, people are trying to use this technique to identify the contaminations in -- where they were looking. They were looking like pharmaceuticals, food. So this is a new technique they're trying to utilize and look at the detection limit.

Since we bought this equipment of the detector, we wanted to see so we had a sample sent and tried to see how reproducible it is.

Q. Okay. And you had plant samples. How many plant samples did you have for this?

A. I will say -- commercial sample so I'm sure we had at least minimum of -- plant sample?

Q. Uh-huh. If -- if it's helpful, on -- on the first page it says "Chemical and plant samples."

A. Yeah, so it -- it does have a plant -- alternative plant samples. Stem and leaves. So whatever was in our collection must have been how many -- let me see. Should have been couple of plant material.

THE REPORTER: Couple of?

THE WITNESS: Plant material.

THE REPORTER: Plant material? Thank you.

Q. If you look at the second page, figure 1 shows the mass specs.

A. Yeah.

Q. And I guess if you look on the bottom of that chart, it's got geranium plant 1, 2, 3, 4, so perhaps there were four samples?

A. Yeah, couple of -- three or four, probably.

Q. Okay. And where on this chart is the DART analysis for the standard of DMAA? Is that the thing at the top?

A. Yes.

Q. Okay. And that's at 114?

A. Yeah.

Q. And --

A. No, 116.

Q. 116 in the middle?

A. Yeah.

Q. Okay. All right. So when you're looking at these mass spec of the -- the plant material in particular --

A. Uh-huh.

Q. -- I'm only seeing basically two peaks at 114 and one at 113, it looks like.

A. Yeah, you are seeing this. It was probably, yeah, 114.

Q. So explain to me how the plant material was prepared for analysis.

A. These are the sample. You put the sample in the probe --

Q. Okay.

A. -- and that's -- so it's no bad section processed.

Q. Okay. And when you say you put the sample directly on the probe, are you saying you put, like, a leaf on the probe, or you do

something to the leaf and then you put that on the probe?

A. No, you just -- there's a sample holder between the DART analysis, so you -- you keep the sample in between, hold the sample when it's being bombarded.

Q. Okay. So then do you take a piece of the leaf and put it in the holder and then bombard it, or do you have to dissolve the leaf or --

A. No, you --

Q. -- do something else?

A. -- don't have to dissolve.

Q. You don't dissolve the leaf? Okay. And so you injected the whole plant or you -- injected's the wrong word. You bombarded the entire plant material?

A. Uh-huh.

Q. And you got one peak or two peaks in the mass spec?

A. Yeah.

Q. And we talked earlier this morning about the fact that geranium plants have at least 90 different components; correct?

A. Yeah, but this is not analysis. We are looking at targeted. This is not chromatographic separation at all.

So whatever is being -- at that time, with that energy, whatever is going to excite, you are going to record it. So this is not to be confused with chromatographic method where you separate the components.

So this one, when you do the laser, you do it -- this is called what is being excited, so you're going to do it very selective.

Q. Uh-huh.

A. So generally, the DART technique is used to find a particular component, not a regular screening of plant composition.

Q. And -- and -- and I understand that. But what I'm asking you is you did this particular analysis on a plant material that's supposed to have 90-odd components, and even allowing for the range at which you set the instrumentation, you found one, possibly two spikes, and that's it?

A. Whatever you find it. But again, you

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are not trying to look for 90 component. This is not a -- this technique is not replacement of all the other chromatograph technique because there is no separation going on in the peaks.

Q. Okay. And do you know what that peak is at 114?

A. No. It can be many, many possibilities.

Q. And there were -- just so I'm clear, there were no other papers between Exhibit 7 and Exhibit 10; correct? On DMAA?

A. From us?

Q. Yes.

A. No.

Q. That you know of.

A. No, that's right.

Q. Okay.

(Khan Exhibit No. 11 was marked for identification.)

BY MS. WOOLSON:

Q. Have you seen Exhibit 11 before?

A. Yes.

Q. And what is Exhibit 11?

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A. This is about the detection limit of DMAA.

Q. And is this regarding the detection limit on the study we just looked at, the DART study?

A. Yes.

Q. Okay. In this email from Dr. ElSohly to Dr. Avula, which you're copied on, at the end it says: "Furthermore, our results were corroborated by several other investigators (references) who reported absence of DMAA in --" what I assume is supposed to be poly -- I can't pronounce it now --

A. Yeah.

Q. Geranium oil.

A. Yeah.

Q. "-- in multiple sources collected from various parts of the world and several oil samples bought on the open market."

And the question I have for you about that sentence is are there any other DART studies out there regarding DMAA of which you're aware?

A. No, as far as I know, there is no

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other studies.

Q. Okay. You can put that aside now.

In your report you reference a number of these studies that I assume are similar to the studies that Dr. ElSohly was referring to in his email, and I want to review them with you. If we can do it without marking the studies, fine. I have them, we can mark them if you want to look at them all. Whatever you and your counsel are comfortable with.

And so the first study I wanted to talk about was the Shellie study. You published papers with Dr. Shellie; correct? I'm on page 16 of your report. Paragraph 32.

A. Dr. Shellie. The question was have I published with her?

Q. Yeah, have you published with Dr. Shellie, yes. I'm not talking specifically about this article, this report in 32. I just want to know if you've ever published with her.

A. I don't recall it, but I can look at my CV. But I don't recall publishing with her.

Q. That's fine. We can come back to that.

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Was the Shellie study that you are referring to in paragraph 32, was it specific to DMAA?

A. No. This is the Pelargonium analysis.

Q. So it was identifying a whole host of compounds that were in the --

A. Yeah.

Q. -- the plants?

A. That's right.

Q. Do you know what they did to prepare the sample for analysis?

A. I don't recall it.

MS. WOOLSON: Okay. Do you want to take a short break? We've been going for like an hour and change. And I can have the court reporter mark all the various studies. That way we can just flip through them real quickly.

MR. DAVENPORT: It's your deposition.

MS. WOOLSON: Just a suggestion.

MR. DAVENPORT: That's fine. All right. We can go off the record.

(Recess taken.)
(Khan Exhibit No. 12 was marked for identification.)
(Khan Exhibit No. 13 was marked for identification.)
(Khan Exhibit No. 14 was marked for identification.)
(Khan Exhibit No. 15 was marked for identification.)
(Khan Exhibit No. 16 was marked for identification.)
(Khan Exhibit No. 17 was marked for identification.)
(Khan Exhibit No. 18 was marked for identification.)
BY MS. WOOLSON:
Q. So I'm showing you Exhibit 12, which is the Shellie report that is cited in your expert report; correct?
A. Yes.
Q. Okay. Take a second and look at it and let me know when you're ready to go.
A. Yes.
Q. Okay. So Exhibit --

A. 12.
Q. Exhibit 12 is the Shellie, Marriott paper that is cited in your report.
A. Yes.
Q. Was the paper -- the study, rather. Excuse me. Was the study specific to DMAA and its detection?
A. No.
Q. And how did the authors identify the various compounds that they found in their chromatograms?
A. Based on retention time and molecular weight.
Q. Did they also look at the library spectra for those compounds?
A. Yes. And they also reported the matching to more than 90 percent or more.
Q. And the matching of the compounds to their spectrum in the library is similar to what Ping did; correct?
A. No, that's not correct.
Q. Isn't that what Ping did?
A. Ping did not report quality matches. Ping paper has wrong name, wrong molecular

weight.
Q. Okay.
A. Ping paper did not match and give the quality of percentage which probably determined the probability of component being there. Ping -- none of it done in Ping paper.
Q. My question was, didn't Ping match spectra of -- of the compounds that it found to the library spectra?
A. We don't know which library he use. He certainly did not use the library that we -- we generally use so I can't comment on which library did he use.
Q. Okay. What library do you usually use?
A. Generally, NIST.
Q. Pardon me?
A. NIST, N-I-S-T.
Q. N-I-S-T?
A. Yeah.
Q. Is that the library that -- that Shellie used?
A. Here, this is the library, some of the library.

Q. So there's more than one library that could be used?
A. Yes. So that the Agilent machines generally --
THE REPORTER: I'm sorry, what machines?
THE WITNESS: Agilent. Agilent.
MR. DAVENPORT: Agilent.
THE REPORTER: Agilent machines?
THE WITNESS: Yeah, they come up with the Wiley (phonetic) software.
THE REPORTER: With the?
THE WITNESS: Wiley software.
THE REPORTER: Wiley?
THE WITNESS: Yeah.
THE REPORTER: Wiley? Okay.
Q. So we've got the NIST --
A. Yes.
Q. -- laboratory. We've got the Wiley lab -- library -- excuse me. Not laboratory. Library. Any other libraries you can think of?
A. I'm sure there are some more databases that people have access to.
Q. So there's not just one library that

can be used then; correct?
A. Yeah, but there -- there are standard, well -- well-recognized. Some probably have their own in-house but generally NIST and Wiley libraries are used.
Q. Okay. Where did the sample come from? What was its geographic origin?
A. From Australia.
Q. Okay. You can put that paper aside. And now I'm going to show you Exhibit 13.
MR. DAVENPORT: Four pages, yes?
THE WITNESS: Yeah.
A. Yes.
Q. So Exhibit 14 is the Lisi study that's cited in your report?
A. 13.
Q. 13. Sorry. Yes, 13 is the Lisi study that was cited in your report; correct?
A. Yes.
Q. And where were these samples taken from, the plant samples?
A. Mostly from Australia, one from New Zealand.
Q. Okay. And these authors treated the

plant samples with a hydrochloric acid and tert-butyl methyl ether --
A. Yes.
Q. -- correct?
A. Yes.
Q. Okay. And that's a different solvent than the one that was used by either Fleming or Li; correct?
A. Yes.
Q. Can you find the level of detection in this report?
A. It did not mention it specifically, but based on Dr. Simone calculation, it was .1 ppm.
Q. So you're saying Dr. Simone calculated --
A. That's what it says in this report.
Q. But this paper doesn't have that information; correct?
A. Not specifically, yes.
Q. And a rigorous paper would include that information; correct?
A. Should be.
Q. I'm going to show you what's been

marked Exhibit 15. Exhibit 14 was a duplicate of Exhibit 13 so I'm just skipping.
MR. DAVENPORT: So there is no Exhibit 14?
MS. WOOLSON: Correct.
Q. So Exhibit 15 is the DiLorenzo article that is cited in your report; correct?
A. Yes.
Q. Okay. Where -- can you tell me where the plant samples came from?
A. From Italy.
Q. From Italy?
A. Yes.
Q. And the authors of this paper chose to derivatize the plant products; correct?
A. Yes.
Q. And they made them the O -- the ortho-thal -- aldehyde derivative; correct?
A. Yes.
MS. WOOLSON: We'll spell it for you later.
THE REPORTER: Got it.
Q. To your knowledge, are they the only authors that have chosen to use that particular

derivation method?
A. Because they are using HPLC UV, and you have to derivatize in order to use [unintelligible] to detect the --
THE REPORTER: In order to use?
THE WITNESS: To detect, they have to derivatize.
Q. That's because DMAA on its own does not fluoresce; correct?
A. It does not have any chromophore.
THE REPORTER: Does not have any?
THE WITNESS: Chromophore.
THE REPORTER: Thank you.
Q. Now, the conclusion of this paper, which is on the page marked government 20 -- sorry, 027970, states that "DMAA is either, one, absent from geranium; two, present at very low concentrations (below 1.2 micrograms per gram); three, occurs under rare and not yet described growing conditions; or, four, is present in very uncommon cultivars."
Do you see that?
A. Yes.
Q. So DiLorenzo didn't determine or

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didn't conclude that DMAA did not exist in plants; correct?

A. This is the correct way of talking about science. So he did not find under his detection limit, he did not find under his conditions in the sample. But being as good scientist, and there is nothing called absolute in the science, if he's saying that if we did find somewhere, it has to be extraordinary condition to find it.

So he's being, like, these are my results, we don't find it under these conditions, so if it's there, it has to be some reason, which can be uncommon cultivars, it can be growing conditions, the list we discussed in the morning. It can be anything.

So he is not closing that absolutely is not there because he doesn't have anything to support it.

Q. I'd like to show you -- show you Exhibit 16.

A. Yes.

Q. Here it's got Exhibit 17, but it's actually Exhibit 16, because I duplicated that

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one too.

MR. DAVENPORT: All right. This is the Zhang study, or Zhang article.

(Discussion held off the record.)

BY MS. WOOLSON:

Q. So Exhibit 16, this is the Zhang article or study that's referenced in your report, expert report; is that correct?

A. Yes.

Q. Did Zhang test any actual plant material?

A. Probably oils.

Q. And does he indicate from what region the oils came from?

A. The origin is in China, Egypt, so it's according to manufacturer, but --

Q. Okay. And we don't know what region of China the samples came from; correct?

A. These are oils.

Q. How did Zhang go about doing the analysis?

A. This one, they are looking in the chirality and the ratio of diastereomers to -- to the DMAA. So it's not about -- they are

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trying to see -- compare what occurs.

If it is natural, it should not have all four enantiomers, as we all agrees, including Li and Fleming. So everybody's unanimous for that one. Yes, we should have a different ratio. So they wanted to see whether they -- there's any variation in chirality or enantiomeric ratio.

Q. So it's your testimony that Li and Fleming both believe that you can't have a racemic mixture of a natural product?

A. According to their publication, yes.

Q. Okay. Well, we'll -- we'll get there.

A. Yeah.

Q. And so my question was, what was the method of detection?

A. Oh, they used a chiral -- the GC, and also they used the LC method.

Q. Okay. And did they inject the oil directly into the mass spec?

A. They derivatized with [unintelligible] --

THE REPORTER: I don't understand,

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sir. Speak up.

THE WITNESS: They derivatized.

THE REPORTER: Advertised?

THE WITNESS: Derivatized.

THE REPORTER: Derivatized.

Q. If -- if I can draw your attention to page 686 of the report under the "HPLC Analysis."

A. Yes.

Q. Do you see in the first paragraph under that subtitle it says: "When the underivatized extracted residue of geranium oils were directed -- were directly injected to these mass spectrometers, the signal of DMAA was greatly suppressed by the other geranium oil components remaining in the residue"?

A. It's probable.

Q. Pardon me?

A. It's probable.

Q. Is that something known as a matrix effect?

A. If we're looking at full -- fully scan mode, yes.

Q. I'm sorry. If you're looking to

what?
A. Fully scan mode. If you are looking for all the mass spec, the other chromatogram in there, but if you are looking for single molecule, then it should not be affected much.
Q. Okay. But according to them, the signal for DMAA, a single molecule, was greatly suppressed if they -- they directly injected the oil onto the mass spec; correct?
A. Yeah. Oil -- oil is already very concentrated anyway.
Q. So what's the practical effect of having a very concentrated sample directed to the mass spec?
A. You will not see very nice baseline separation.
Q. In the studies that you've done on DMAA, have you noticed any matrix effects as a result of the techniques that were used or the concentrations that were used?
A. That's what we do all the time. I mean, the matrix effect is always there. That's why we do the solvent extraction, we do [unintelligible] extraction, we --

THE REPORTER: "We do"? That term you just said.
THE WITNESS: Yeah, "solvent extraction."
THE REPORTER: Yes.
THE WITNESS: And selective solvent extraction.
Q. And every time you do an extraction, there's some loss of product; correct?
A. I don't know what you mean. You extract selectively so you leave lot behind, so if you interpret it as a loss --
Q. Let me rephrase the question. Extraction procedure is not 100 percent; correct?
You're not going to extract 100 percent of any compound in performing an extraction; correct?
A. Try to get close to that.
Q. But you're not going to get 100 percent; correct?
A. Yeah.
Q. And what's the -- the average efficiency of the extractions using the plant

material for DMAA in your studies?
A. I'll have to go back. I think it's more than 50 percent.
Q. Well, whatever it is, it should be in your papers; correct?
A. Yeah, it should be --
Q. Okay.
A. -- in there.
Q. Okay. The Zhang paper also talks about dansylation. What is that?
A. That's also derivatization for [unintelligible] --
THE REPORTER: I don't understand.
THE WITNESS: Derivatization.
THE REPORTER: Yes.
THE WITNESS: For LC method.
THE REPORTER: "Method"? Thank you.
Q. And what's the effect of that?
A. It's -- derivatization is increasing the sensitivity.
Q. It's increasing the sensitivity of the instrument to be able to detect the compound?

A. Yes, selectively.
Q. Does the paper include any information on the recovery of the column using dansylation?
A. The LOD for this method was [unintelligible] for --
THE REPORTER: The LOD?
THE WITNESS: Was 10 ppb for DMAA in geranium oil.
THE REPORTER: In?
THE WITNESS: Geranium.
THE REPORTER: Oh, "geranium oil"? Thank you.
MS. WOOLSON: That was not actually the question that I had, but that's okay.
Q. And so Zhang doesn't conclude that there is no DMAA in geranium samples; correct?
They simply say they didn't detect it above 10 ppb; correct?
A. They did not analyze geranium sample.
Q. I'm sorry. Geranium oil sample.
A. Geranium oil sample.
Q. So -- correct.

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A. Yes.

Q. Okay. Have you ever encountered or heard of a solvent effect masking DMAA?

A. In analysis?

Q. Uh-huh, yes. In terms of interfering with the ability to detect it.

A. I don't recall it.

MS. WOOLSON: Okay, I'm going to show you what's been marked 18. 18 should go from 183 to 187 in terms of pages.

MR. DAVENPORT: Doesn't have a Bates stamp on it?

MS. WOOLSON: No, it doesn't.

MR. DAVENPORT: Was it produced by you?

MS. WOOLSON: I don't know if it was produced by us. It wasn't part of Dr. Simone's -- I don't believe it was part of his reliance materials. It was something that was referenced in one of the papers that was I think produced by the government.

MS. JAMPOL: I think there was an

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agreement that if something was publicly available and it's referenced.

MR. DAVENPORT: No, that's fine. I haven't -- I'm not stating any objection on -- on the basis of by whom it was produced, I'm just wondering if it -- I didn't see a Bates number on it.

MS. WOOLSON: It's because I printed it out yesterday and it doesn't have a Bates number on the Internet, at least not yet.

MR. DAVENPORT: That would be a neat trick. That would be an odd situation if it did, but okay.

BY MS. WOOLSON:

Q. So Exhibit 18 is an article -- sorry -- is a study by Sean Vorce, Justin Holler, Brian Cawrse, C-A-W-R-S-E, and Joseph Magluilo, M-A-G-L-U-I-L-O --

A. Yes.

Q. -- Junior. And it was done for, looks like Department of Defense; correct?

A. Yes.

Q. Okay. And you would agree with me

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that in this study Vorce and his colleagues are reporting that DMAA eluted with a solvent peak and so they initially missed detecting it; correct? I'm at the top of page 187 if that's helpful for you.

A. Well, yes, this is coming with the solvent peak. Anytime you analyze something, you have a buffer and solvent peak, so it's eluting at that point. That -- that had been raised in several publication, that DMAA should be coming in the beginning, not end where the Ping/Li reported, because they are light and volatile compound

THE REPORTER: They are light and?

THE WITNESS: Volatile.

THE REPORTER: Volatile? Thank you.

Q. And so if it co-elutes with solvent, it's possible that it's not being detected even if it's there; correct?

A. That -- it all depends on your method. If -- if you have starting with nothing, you generally screen everything what is in the -- the chromatogram. But if you are

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not targeting it, yes, you can elute, co-elute with the solvent. And that's what happened. With LC, you retain [unintelligible] component with --

THE REPORTER: I'm sorry. With LC, you?

THE WITNESS: Retain a lot of component which is not eluted unless you wash the column. In GC it can come up front in the chromatogram with the solvent.

(Khan Exhibit No. 19 was marked for identification.)

THE WITNESS: Looks different.

BY MS. WOOLSON:

Q. I have the Chinese version as well but I didn't think that would be as useful to us. If somebody can read Chinese, I'm happy to mark it.

A. Somebody did read Chinese in order to confirm that they have DMAA.

Q. Well, that's not my point. My point is I have the Chinese version. Unless we can read Chinese, I don't think that's going to

help us.

A. If you talk about chromatogram, it might be useful in this one. But it depends on the question, so --

MS. WOOLSON: That's okay. I'll look to see if there's a chromatogram. You keep reading.

(Khan Exhibit No. 20 was marked for identification.)

MR. DAVENPORT: The one written in Chinese is Exhibit 20?

MS. WOOLSON: 20.

MR. DAVENPORT: Okay. Your Exhibit GOV-004569 looks very different than mine.

MS. WOOLSON: With the same numbers on it?

THE WITNESS: That's Chinese.

MR. DAVENPORT: Yes. It's the same document but you have a black line going through the chromatograph, I'm assuming, and the top.

MS. WOOLSON: Uh-huh.

MR. DAVENPORT: Can we go off the

record for a second?

(Discussion held off the record.)

BY MS. WOOLSON:

Q. So I'm showing you Exhibit 19 and Exhibit 20. I believe Exhibit 19 is the translation from Chinese of Exhibit 20 of the Ping paper that is cited in your report.

A. Yes.

Q. Okay. Now, in your report you discuss the fact that Ping matched spectra to a library of spectra. How did Ping go about doing that?

A. No idea. Probably --

Q. Okay. Well, in paragraph 20 of your report, which is Exhibit 1, I believe.

A. Yeah.

Q. Paragraph 20 on page 10. You say: "The conclusions" -- I'll wait until you get there. Sorry.

A. Yeah.

Q. You say: "The conclusions of the study were based on matching a peak spectrum of geranium oil with a library mass spectrum of DMAA." Right?

A. That's what we can guess.

Q. Then you say: "Most of the essential oils, however, contain several components and identification based solely on comparison of the spectra with the databases Wiley and NIST using a probability-based matching algorithms may lead to wrong structure or identification."

A. That's -- that's a fact.

Q. Okay. But as you sit here today, you can't say definitively that Ping made a mistake in his matching; correct?

A. Okay. Look at the Ping list, okay? And look at the chromatogram in the Ping method. We see, between 27 and 31, how many peaks we see?

Q. Uh-huh.

A. Only one. How many components here identified in the list? Four.

Q. I'm sorry, I'm not following you.

A. So if you see the chromatogram --

Q. Uh-huh.

A. -- it has 27 and 31. The other side.

Q. Oh, down here at this end? 27 and 31 --

A. Even --

Q. -- at the right-hand side --

A. Even --

Q. -- of the spectrum?

A. And even though the peaks are not known, how many peaks are there? Only one.

Q. Well, actually, I see one at 27, one between 27 and 31, one at 31.

A. If you look at the compounds, 27, 28, 29, 30, 31.

Q. So it's your conclusion -- your contention that based on that, Ping has made a mistake in matching the spectra?

A. The -- the paper is -- something is -- take the word from what Fleming says about this paper and to what Li says. Forget about what other people, because other people did not find, so they have no validity. But those people who found it, what they are saying, that both have agreed, in fact, the --

THE REPORTER: I'm sorry, both have?

THE WITNESS: Agreed that this paper is not something that can be taken

scientifically sound document.
Q. Okay. Well, you have --
A. If you just look at the chromatogram, 27, and look at the name --
Q. Uh-huh.
A. -- one for DMAA even is not mentioned except in Chinese. English name is wrong for 1,3-DMAA. Okay? But at least the molecular formula is 115. There is no mention, except it says in Chinese 1,4-DMAA, but no matching formula. It says 129 and wrong name. So somebody read the Chinese name and believe, even though it's -- the molecular weight is wrong, chemical name is wrong, but 1,4-DMAA is there.
Q. Well, 1,4-DMA isn't there.
A. It's not there.
Q. On that list. We're talking about 1,3-DMAA; correct?
A. Yeah, 1,4-DMAA is also reported in Ping/Li; otherwise, nobody has ever reported 1,4.
Q. So Ping has found 1,3 and 1,4-DMAA?
A. If they -- that's -- if you believe

in what is written in Chinese, not in English, not by chemical formula.
Q. Understood. And you don't speak Chinese, and you don't read Chinese; correct?
A. But I can read the chemical name, and I can read the -- the molecular weight, which does -- does not match when you refer to 1,4-DMAA.
Q. And did you look up the spectrum of 1,4-DMAA and compare it to this chromatograph that Ping published in his paper?
A. Nobody can reproduce it because the -- the previous one, this one that you have, Exhibit 18, okay, you say this paper eluted at the 50-degree temperature right there with the solvent system, that's right? That's we just talk about.
Q. Yeah. So what does that have to do with reproducing Ping?
A. Just look at the Ping paper. They use 50-degree temperature in English translation and their components coming in the end.
THE REPORTER: "Their components"?

THE WITNESS: Are coming in the end.
THE REPORTER: "Coming in the end"? Thank you.
THE WITNESS: The end of the chromatogram.
Q. And they are analyzing a complete sample of oil; correct?
A. They just analyzing oil, so --
Q. Right.
A. -- they did not try to find in the plant.
Q. So when one analyzes a complete sample of oil, one is analyzing a very complex molecule, correct, with a lot of components?
A. It's still a part of the geranium. They're not two different samples. One is a plant material; one is oil.
THE REPORTER: Oh, I'm sorry. One is a?
THE WITNESS: Plant material, one is oil.
THE REPORTER: A plant what?
THE WITNESS: Material.

THE REPORTER: Material? One is oil. Thank you.
Q. I -- I understand that. But my question to you was specific to the oils. Geranium oil is a very complex substance that contains many components; correct? We talked about this this morning, you told me there were at least 90 components to geranium oil.
A. Yeah.
Q. Okay. And if you overload a column with geranium oil, what happens?
A. What happens?
Q. Uh-huh.
A. You will not be getting a decent chromatogram.
Q. And you can also have significant matrix effects; correct?
A. Matrix effect in natural product is always there, so --
Q. So I'll --
A. -- this is --
Q. -- take it --
A. -- why some --
Q. -- as a yes.

I. Khan

A. Matrix effect is always there. I don't know what -- see, when people analyze geranium plant, it was too much matrix and they should have found in the plant. Ping did not do it, but we believe in Ping study because he report it, listed it, okay? Ping did not confirm it. Ping did not identify it. Okay? Li study that went around the MRM to find it out. Ping did not do any of these thing. As you said, 1,4 were not there.

Q. But --

A. So the thing is, taking that study --

Q. Uh-huh.

A. -- and saying this is the study which has been criticized, both of the people who found it, and there are so many -- everybody in the literature, any -- anything you see, Ping study, it -- they didn't do anything.

They talk about the detection limit. It's .6 percent. Then they are criticizing people to have find 1 ppm like Lisi study. I mean, if it is of a level you come out they're talking about in the Ping/Li study, everybody in the world should have been able to find it.

I. Khan

Q. Where does Ping quantify the amount of DMA found?

A. .6 percent in the list. Here's the percentage.

Q. And -- and DMAA is where? Where are you? 29 and 30?

A. Yeah.

Q. So .23 and .65?

A. These are the different component, which nobody ever -- none of the people found this component.

Q. I -- I -- I understand you have --

A. Yeah, but --

Q. Sir?

A. -- these are the --

Q. Sir?

A. These are the --

MR. DAVENPORT: Hold on. Hold on.

Q. I understand you have a story you want to tell about Ping, but we're here today to take your deposition, which means I ask questions, you answer questions. You don't give a speech. Okay?

MR. DAVENPORT: Hold on. I think

I. Khan

he's trying to answer your question.

Wait for the next question.

Q. So according to this list, the concentrations of 1,3-DMAA and 1,4-DMAA are .23 and .66; correct?

A. .66 and .29.

Q. .66 and 29. Okay. And that's two out of 31 components, together they add up to less than 1 percent; correct?

A. Yes.

Q. Agree?

A. Yes.

Q. And just like you have supplemental material that's not in your articles, isn't it possible that Ping has supplemental material that's not in his article?

A. I cannot guess on it.

Q. In your report you also say that the Ping study does not describe the geographic location of the samples.

A. Yeah.

Q. Correct? Read paragraph 19 of your report.

A. Yes.

I. Khan

Q. So Ping did identify the geographic region for the samples, did he not?

A. That's where he was. They collected the sample, but that -- that's what -- everybody provided information in that regard, the specific information for finding something which was not there but required more detail.

Q. Okay. Well, requiring more detail and saying someone hasn't done something are two different things; correct?

A. It -- it all depend on what -- what -- what is asked for.

Q. Well, this was your report and your report said Ping didn't identify the geographic location of the samples, but in the immediate preceding paragraph you say that he did.

A. Yeah, I mean, that's very obvious that he was in China and going -- and more than that, I mean, it would have been -- provide a little bit more information would have been helpful for everybody.

Q. Well, we looked at a number of these reports that you're relying upon, and most of those just identify a generic region of the

I. Khan

country or a country where the samples come from; correct?

A. A short answer, but yes.

Q. Let's go to paragraph 24 of your report.

A. Yeah.

Q. In this paragraph you criticize the Ping study because it -- it detected a significant number of other amines in the geranium oil?

A. Yeah.

Q. And why are you criticizing Ping because of that?

A. The Ping study, whatever has been written in this one, all the main components. In geranium, for any analysis, before and after, regardless of DMAA, nobody found amine compound except Ping/Li. The question, if -- if it is reproducible, is found, it should have been detected by someone, somewhere.

Q. And when you're saying no one has ever detected any other amine compounds, didn't Fleming detect 1,4-DMAA?

A. Other than these two, 1,4 we're

I. Khan

talking about. In this paragraph, you're talking about everything else.

Q. Okay. But 1,4-DMAA is an amine; correct?

A. Yeah.

Q. Okay.

A. But which you already mentioned is not there in that paper.

Q. Now, you also criticized Ping for finding very high levels of DMAA, much higher than Li and Fleming; correct?

A. That's what reported, yeah.

Q. And the Ping paper was, what, 2006?

A. Ping? '96.

Q. 1996, excuse me.

A. Yeah.

Q. And the Li paper was when?

A. 2012, I believe.

Q. The Fleming paper was after that?

A. Almost same, same time, yes, 2012.

Q. And methods and detections have changed and improved since 1996 to the present; correct?

A. That's right.

I. Khan

Q. And again, Ping wasn't specifically looking for DMAA in his study, was he?

A. Can't speak for that.

Q. Well, you've read the study, haven't you?

A. Yeah. He did not mention in the paper. It is -- he's not looking for DMAA; he's analyzing geranium sample that has been --

THE REPORTER: He's analyzing?

THE WITNESS: Geranium samples which has been analyzed by many other investigators.

(Khan Exhibit No. 21 was marked for identification.)

BY MS. WOOLSON:

Q. Exhibit 21 is the Li study that's cited in your expert report; is that correct?

A. Yes.

Q. Okay. Now, the Journal of Analytical Chemistry Insights, is that a peer-reviewed journal?

A. I would believe so.

Q. And what is your definition of a peer-reviewed journal?

I. Khan

A. Generally, they are citation indexed. They are called scientific citation index. They -- they are listed there. Some of the paper are online publication which are becoming very common nowadays. They might have their own review process, but we can talk about it, what it is.

Q. So you don't know what the review process is; is that --

A. It's --

Q. -- correct?

A. It's -- yeah.

Q. Okay. Do you know who anyone on the editorial board at Analytical Chemistry Insights is?

A. No.

Q. If I told you that they were all Ph.D. scientists with Ph.D.s in biology or chemistry, would you be surprised by that?

A. No, not at all. Nowadays, there are many, many online publications coming up. So no, that does not surprise me. Only thing is you have to pay a lot of amount to get it published in the paper. So that's only thing I

know.
Q. And do you know for a fact that Professor Li or Dr. Li had to pay to publish in Analytical Chemistry Insights?
A. Unless they gave some kind of a waiver, I think that there is a fee for publication.
THE REPORTER: Gave some kind of a?
THE WITNESS: Waiver.
MR. DAVENPORT: Waiver.
Q. And so because there's a fee for publication, in your mind the articles that are published are less -- what's the word I want -- scientifically sound?
A. So generally -- the main factor is a citation index. Okay? So that's one thing. Other thing is you have publication that we don't know what the development process are, how stringent their review process is and how they select the paper, but --
Q. So you don't know what the review process is?
A. I don't want to comment on it, yes.
Q. Okay. And what's the review process

for drug test analysis?
A. They send it to three reviewers, or at least two reviewers, get independent reports from the expert in the field, and the editor does their own judgment.
Q. You mean the editorial board does its own judgment?
A. Yeah, chief editor does look at the -- I don't know how to say the -- whether these people have been commenting based on science or based on judgment, whatever. So then the editor will communicate with the author.
Q. Do you know who any of the people who reviewed your articles are?
A. No.
Q. Okay. Were the samples that Dr. Li used authenticated?
A. Based on the information that's provided that they got the sample from China, it's the same person from three different regions. Based on their information, I assume that they were authenticated.
THE REPORTER: That they were?

THE WITNESS: Authenticated.
THE REPORTER: Thank you.
Q. In fact, if you look at page 48 of the report, which is the second page, the bottom right-hand corner it discusses the authentication of the plants and the oils; correct?
A. Yeah.
Q. Now, in your expert report you purport to criticize the Li report because it found considerably lower concentrations than those reported by Ping; correct?
A. Let's look.
Q. Paragraph 41 of your report.
A. Yes.
Q. Okay. And why is that, since you criticized the concentrations that Ping found?
A. We have to start from somewhere. If Ping was right, they found a low concentration, and if you read the paper from the beginning -- I'm not giving a lecture --
THE REPORTER: I'm sorry. The paper from?
THE WITNESS: If you read the paper

in the beginning they said that Ping has identified, so they are starting their finding based on Ping Li. But if you go back and compare it, Ping Li found higher amount.
Q. Okay. And again, as we discussed a few minutes ago, the purpose of the Ping paper was not specific to detecting or quantifying DMAA; correct?
A. Yes.
Q. Okay. And the purpose of the Li paper was specific to detecting and attempting to quantify DMAA; correct?
A. Quantifying DMAA, yes.
Q. And it did so -- it used a different methodology than Ping did; correct?
A. Yes.
Q. And in your report you say: "When there are unprecedented findings of this nature, a more in-depth scientific study and application of additional scientific tools are usually required to confirm the accuracy of the findings, which were not done."
A. Yes.

Q. Do you see that?
A. Yes.
Q. So is it your testimony that Dr. Li should have done additional studies as part of this report --
A. Right.
Q. -- to confirm his detection?
A. So you used the right term. This is a report. Li paper is a technical report. Sample were sent by a company for -- to a contractual lab to analyze the sample. Is not about finding DMAA or not. If -- they already know the DMAA is there, they just only wanted to make sure it's natural or not. Can you analyze our sample?

So for the fee, there's a difference between research and analyzing somebody's sample. So Li finding, the method Li used, it -- there no question but they use a sample which was provided for service. Sample came to them. If they did find something unusual, then we should have confirmed with more test.
Q. Okay.
A. That's what it means.

Q. Let me stop you right there. Your first paper regarding DMAA involved your lab analyzing samples that were sent to you by the U.S. Doping Agency; correct?
A. Product.
Q. Product? Fine. Product. That's what you did as part of your first study; correct?
A. No, not all of it. Part of it.
Q. I understand. Part of it.
A. Yeah.
Q. Okay. And in the Li paper, Li is talking about actually testing plants not products.
A. Yeah.
Q. Okay. So that's the same thing; right?
A. The only difference is Li's finding, then they have to confirm it.
Q. We will get to the confirmation. It's just a question of you seem to be trying to cast aspersions upon what Li did because he supposedly analyzed a sample that someone sent to him.

A. That's what it is.
MR. DAVENPORT: Objection. There's no question pending.
Q. Now, earlier today you said that Li confirmed that racemic mixtures cannot possibly exist in nature. Do you recall that testimony?
A. Yes.
Q. So I'm going to have you go to page 56 of the Li report, and paragraph on the right-hand side that starts with "The results." You can read that to yourself and then I'll ask you some questions.
A. Yes.
Q. So Li doesn't say that the racemic mixture could not possibly be natural, does he?
A. Therefore, most likely only one enzymatic process -- "most likely only one chiral configuration would be present in a plant."
Q. And what's the next sentence say?
A. "Often referred to as natural form."
Q. The next sentence?
A. This -- "The results in the current study show that 1,3-DMAA in geranium plants and

geranium oil appears to be exception to the notion."
Q. And what's the sentence after that say?
A. "Indeed, this is not the first report demonstrating the presence of a racemate in a plant tissue. In fact, it's -- the presence of a racemate (nerol oxide) has been demonstrated once before in the geranium plant as well. Further study is needed to elucidate the biosynthetic pathway of DMAA in geranium plant."
Q. Right. So Li didn't conclude that the racemic mixture was incapable of being --
A. Li --
Q. -- naturally created, did he?
A. Li also missing the point. Nerol oxide is not a biosynthetic; is a cyclization, which is a chemical reaction. Sorry to give you lecture, but --
Q. I -- I understand you disagree with that conclusion. But that is what Dr. Li stated; correct?
A. Yeah, but this is what he said. It's

a exception to the notion.
Q. Uh-huh.
A. That's what he's saying.
Q. Right.
A. So that's what he said. He's agreeing with. He didn't say you would find the mixture. And we already discuss the racemization. Biosynthetic pathway, making a component racemization are two different things.
Q. Yes, but Dr. Li said, based on his findings, it appears that the 1,3-DMAA in the plants and oil is an exception to this notion that you cannot have a racemic mixture; correct?
A. Yes.
Q. Thank you.
(Discussion held off the record.)
(Khan Exhibit No. 22 was marked for identification.)
BY MS. WOOLSON:
Q. So Exhibit 22 is the Fleming report; correct?
A. Yes.

Q. That's what's referred to in your expert report?
A. Yes.
Q. Okay. And did Fleming detect DMAA --
A. Yes.
Q. -- in plant samples?
A. Yes.
Q. And where were the plant samples sourced from?
A. He detect only one out of three samples.
Q. And where was that sample sourced from?
A. I believe it came from the same location based on the information provided as in the Li paper.
Q. In fact, it was actually the sample that Li examined; correct?
A. One of the sample was -- came from Li. Three samples came from the same location, I believe.
Q. Okay. And if you look at table 3 of the report, which is on page 66, it lists four samples; correct?

A. I think I'm missing a page here. Yeah.
MR. DAVENPORT: He has the -- every other page.
MS. WOOLSON: Okay. Let me see if this one's got every page.
MR. DAVENPORT: The one I have --
MS. WOOLSON: This one's got every other page too.
MS. JAMPOL: Okay, here's one.
MS. WOOLSON: Is there something stuck behind it?
MR. DAVENPORT: The last page is 78?
MS. WOOLSON: Yeah, 78.
MR. DAVENPORT: Before we go forward, why don't we have this one then be the official one?
MS. WOOLSON: Yeah.
BY MS. WOOLSON:
Q. So this identifies four samples; correct?
A. Yes.
Q. Okay. And if you look at the

conclusion which is on page 70 and 71, it discusses finding 1,3-DMAA in the sample S11; correct?
A. Yeah.
Q. And that's the sample from Li?
A. That's -- I assume that's sample --
Q. Okay.
A. -- from Li.
Q. Now, when you did your studies on DMAA, did you ask Dr. Li for a sample of the products that he had used?
A. No.
Q. And I take it you never asked Dr. Simone for a sample of the product that his laboratory used.
A. No.
Q. Now, your report does not criticize the analytical methods used by Dr. Fleming or Dr. Li, does it?
A. Dr. Fleming I -- I -- I do have concern about these studies because these are the only two studies with finding it. But the variability presented in Fleming paper, it creates more confusion.

I. Khan

Q. My question was, in your report did you criticize the analytical techniques used by Dr. Fleming?

A. Yes. We talked about different concentration in number 45.

Q. So that is a criticism of the result of the study, not the method that's used; correct?

A. Yes.

Q. You would agree with me that the Fleming study was conducted according to U.S. Pharmacopeia guidelines?

A. No. EPA guidelines.

Q. EPA guidelines?

A. Fleming study, yes.

Q. Okay. So you think that the Fleming study is done by EPA guidelines?

A. I -- I think that's what -- Li study was done USP, but I think he talked about EPA and that's what it says in the table, I think. Yeah, US EPA MDL.

Q. And what are you looking at?

A. This is table 2, USP.

Q. Table 2?

I. Khan

A. Primary -- it's the EPA.

Q. Those are just the MDLs; right?

A. According to EPA.

Q. Right.

A. Yeah.

Q. Those were used to determine the detection limits, accuracy and precision of the studies; correct?

A. Of the method.

Q. Right. But you said the Li study was done pursuant to U.S. Pharmacopeia guidelines; correct?

A. That's what it says, yes.

Q. So both Li and Fleming detected 1,3-DMAA in the same sample; correct?

A. Different concentration, yes.

Q. I understand there's a different concentration, but they both detected it; correct?

A. I just want to be clear.

Q. They both detected it; correct?

A. Yeah.

Q. Okay.

A. Only in one sample.

I. Khan

Q. And were the concentrations that Fleming detected higher or lower than the concentrations that Li detected? It's in paragraph 45 of your report. I'm -- I'm not --

A. It is, but the Changzhou, which is -- so you're talking about the same sample?

Q. Yes, the S11 sample.

A. Yeah, S11 sample, it was reported 165, if I'm not mistaken, in Li. And in this Fleming study is giving a different concentrations.

Q. And they gave -- they gave 97 -- 499 in Changzhou S11 and they found 97 nanograms per gram in Changzhou 3; correct?

A. Yeah.

Q. Okay. And Li detected 365 -- oh, wait. I'm sorry.

A. No, that's from different sample, from Guizhou sample.

Q. Yeah, I'm sorry, I've got -- I've got it --

A. Yeah.

Q. Got it wrong.

A. Yeah.

I. Khan

Q. In any event, your criticism of the Fleming study is that it came up with a different concentration of DMAA than the Li study; correct?

A. Yes.

Q. Now, the Fleming study, did that have any different steps or additional steps that it performed or used in terms of preparing the samples different from the Li study?

A. Yeah. He uses a addition method, so table 3 is based on analysis set 1. Table 4 and 5 is based on analysis 2, set 2, but the sample in table 4 and table 5 are different. One is winter; one in summer.

Q. And what is your understanding of what the standard addition method is?

A. Is just a standard addition method is to add -- do the additional calculation to come up with the probable values.

THE REPORTER: The probable?

THE WITNESS: Probable values.

THE REPORTER: Values? Thank you.

Q. So the standard addition method is to help detection and quantification?

A. Yes.
Q. Did the Fleming study do any additional extraction procedures different from the Li paper?
A. Honestly speaking, it is very confusing because he has changed his procedure. In table 3 is different than table 4, and table 5 is different sample. So he said, according to this paper, it used limited but is improved, and that's what it says.
Q. Okay. And what was the improvement?
A. He uses the addition method.
Q. Did he also do an additional hexane extraction?
A. For the table 4?
Q. I'm asking in the paper generally not specific to any particular table.
A. He did differently. I can't -- yeah, he probably used hexane. I have to --
Q. Okay. I'll refer you to page 27872.
A. 27872? Yes, he used a hexane partition step.
Q. Okay. And we've talked about a number of methods that your laboratory used

and -- including, for example, GC mass spec, LC mass spec/mass spec. Each of those types of analysis, the LC, the GC, the mass spec, they are all different and independent methods of analysis; correct?
A. That's right.
Q. So the Fleming analysis and HP mass spec/mass spec, those are two different types of analysis; correct?
A. Yes.
Q. And the Li analysis, what did Li do in -- in terms of the methodology? Do you know -- recall?
A. No.
Q. You can look at Exhibit 21 if you need to. Probably page 49 maybe might help.
A. Yeah. You mean he was using the .5 hydrochloride?
Q. No, he was using liquid chromatography, mass spectrom- -- the LC/MS/MS method.
A. Oh. So talking about condition.
Q. Yeah, just the -- the methodology that was used, that's all.

A. Yeah.
Q. And -- and the LC is a separate and independent method of detection than the mass spec; correct?
A. Mass spec is used as a detector with LC, yes.
Q. My question was they are two different and independent methods of detection; correct?
A. Both are LC/MS/MS methods.
Q. Okay. Maybe I'm not being clear, but the LC method is a separate and independent method from the mass spec method. That's all I'm asking you.
A. Yes, for --
Q. Okay. And stay with Li for a second. And Li used two transitions, two ion transitions with mass spec? That's also on page 49 at the bottom.
A. Page 49.
Q. I'm sorry, I know I have you jumping back and forth.
A. Yeah.
Q. Okay.

(Khan Exhibit No. 23 was marked for identification.)
BY MS. WOOLSON:
Q. So this is your rebuttal report, which we've marked as Exhibit 23.
A. Yes.
Q. Take a second to review it. First of all, in your report you say that you have reviewed the declarations of Marvin Heuer, H-E-U-E-R, and Dr. Simone.
A. Yes.
Q. Your rebuttal report then does not mention Dr. Heuer again; is that correct?
A. Yes.
Q. Okay. And why is that?
A. Except mentioning in very general about DMAA, Ping study, but he goes into the safety part, which is not my area of -- my charge.
Q. So you're really not rebutting any of the assertions made by Dr. Heuer?
A. Except occasionally he said that Ping found it's a study that --
Q. Okay.

I. Khan
A. Yeah.
Q. But you're not offering any opinion on the safety of DMAA?
A. I'm not.
Q. Okay. Now, in your rebuttal report, you say that Dr. Simone failed to provide the concentration found for the split sample that he and the Li group tested. Isn't that information in the Fleming report? The Fleming study that we marked as Exhibit 22?
A. Sample number are not matching, are not clearly identified, but if you assume it here, numbers are there, but which number is which?
Q. Well, if you look at the conclusion of Dr. Fleming in Dr. Simone's report, which is on page 71 of Exhibit 22, at the top of that page.
A. Page 71?
Q. Yeah.
A. On the top?
Q. Yeah. It says: "Reported concentrations of 1,3-DMAA range from 68 to 496 nanograms per gram"?

I. Khan
Do you see that?
A. Yes.
Q. Okay.
A. So we -- we cited a number, but we still aren't sure where it is coming from.
Q. What do you mean, you're not sure where it comes from?
A. No explanation is offered. Like 496 is not listed in any of the table.
Q. Okay, but --
A. Yeah, it's --
Q. -- instead --
A. Yeah, number is there, it's just --
Q. Fine.
A. -- we don't know how he came up with it.
Q. Okay. And then the next part of your rebuttal is again bringing up the fact that the Li and Fleming studies had different concentrations; correct?
A. Yes.
Q. Okay. Leaving aside the fact that they had different concentrations, you would agree with me that both of the studies report

I. Khan
finding DMAA in geranium plants; correct?
A. In one sample.
Q. Okay. And in paragraph 3 you criticize Dr. Fleming and Dr. Li's reports because they only tested a small number of samples; correct?
A. Yes.
Q. But they are the only sample -- the only studies that tested the same samples and made sure that they were testing samples from the Guangzhou -- I'm going to mispronounce that at this point in the day -- but the Guangzhou region from China; correct?
A. Guangzhou region?
Q. Yes, Guangzhou region. Thank you.
In paragraph 4, you're talking about the use of ions to assist in identification. You would agree with me that there's two parts to using an ion to detect. One is the presence of it, but the second part is also the abundance of the ion?
A. First is it present, then you look at the ratio for abundance, yes.
Q. Okay.

I. Khan
THE REPORTER: You look at the ratio for?
THE WITNESS: Abundance.
THE REPORTER: Abundance.
Q. So there's two components to using an ion for detection. It's not just 1, 2, 3; it's I have this in this percentage abundance and that percentage of abundance?
A. Linked with the retention time, yes.
Q. So depending on the circumstances, you might have two very strong transition ions and one weaker one and you may choose to only look at the two that are stronger or more abundant; correct?
A. You can choose -- so again, it all depend what is your question. If you are looking for identification, then not. But if you know that the reference and retention time is matching and you tentatively want to describe what it is, yes, you can.
Q. Okay. So when you say the use of three ions versus two ions results in a higher degree of certainty, you're not suggesting that the identification is completely flawed and

I. Khan

should be thrown out if somebody only uses two ions; correct?

A. Actually, the Li paper uses three ions.

Q. Okay. That wasn't my question. My question was, when you're talking about the use of three ions versus two ions, you're not suggesting, are you, that if you use two ions, that some means -- somehow means that your identification isn't valid and should be rejected?

A. It's not a confirmatory identification, but you can use it for the value it is.

Q. And where would I go to look for a standard that says you have to use three ions to confirm an identity?

A. No, you have to -- there is no minimum standard. In some of the analysis, people use more than three.

Q. And presumably in some analysis they use less than three; correct?

A. Less than three? Probably they can, but I'm not sure. But you have to have ratio

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of abundance. When three ions means two MRM and two MRM is looks like a normal practice where there's the Li, Fleming and other people, the Zhang paper, they all use the two MRM. And two MRM comes from three ions. Only in GC we don't have MRM, so we use three ions so actually the same thing.

Q. So Fleming did do MRMs --

A. Yes.

Q. -- correct?

Okay. And your lab used MRMs as well to confirm identity or the absence of identity?

A. Yes.

Q. Okay. Now, in paragraph 7 you talk about potential contamination from fertilizers; correct?

A. Yeah, yes.

Q. And do you have any evidence whatsoever to support the notion that the plant samples that were analyzed by Li or Fleming were contaminated by fertilizer?

A. No.

Q. And when you did your sample analysis of the fertilizer, Osmocote -- Osmocote?

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A. Yeah.

Q. You did not detect any DMAA; correct?

A. We just quickly run it just because of the curiosity. Is it fertilizer, is it organic material? We did not -- so this is what it is.

Q. Okay. And if we look at that certificate of analysis, which is 13255, hopefully.

A. Yeah.

Q. Okay. The -- do you have it? I think it's before.

MR. DAVENPORT: 13 -- 31255?

MS. WOOLSON: Yeah.

MR. DAVENPORT: Okay.

Q. The chart -- the table says UPLC/UV, which is what? Ultra performance liquid chromatography and UV?

A. Yes.

Q. Under "Analytical Conditions" it says HPLC-TOF-MS.

A. We use both detectors, so it should be UV mass spec.

Q. So it's not -- it's not the ultra

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performance?

A. No.

Q. So this is a mistake?

A. That's a mistake. It should be mass spec.

Q. All right.

A. Because we use both detectors.

Q. Where did you source the Osmocote?

A. I think we get it from Wal-Mart.

Q. Wal-Mart. Okay.

A. Again, I'm not 100 percent sure, but --

MS. WOOLSON: All right. Let's see, why don't we go off the record for five minutes.

(Discussion held off the record.)

(Khan Exhibit No. 24 was marked for identification.)

BY MS. WOOLSON:

Q. We are talking about this one. And I will tell you that I'm only going to ask you a very few questions about the first page, but if you want to read the whole thing, you can read the whole thing.

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A. I can read it.

Yes.

Q. Dr. Khan, I'm showing you Exhibit 24, which is an email exchange of several pages long, but I really only want to ask you questions about the first page. First of all, have you seen this email exchange before?

A. Yes.

Q. Okay. And who is Mark Roman?

A. Mark Roman, sorry to inform, has passed away, but he was active member and had private lab for analysis.

Q. An active member of what?

A. AOAC.

Q. And what is that?

A. Organization of analytical chemists, AOAC.

Q. And who is Mark Blumenthal?

A. Mark Blumenthal is the CEO and founder of American Botanical Council.

Q. I think we talked about Joseph Betz and John Cardellina this morning. Who is anthony@imaginutrition.com, if you know?

A. I haven't -- I can't guess with the

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email.

Q. And John Kababick?

A. Jim Kababick has a private analytical lab called -- I think it's Flora Research.

Q. Okay. And Daniel Armstrong?

A. Daniel Armstrong?

Q. If you know. If you don't, that's okay.

A. No.

Q. And I think we also spoke about Frank Jaksch earlier. He's the person at ChromaDex?

A. That's right.

Q. And all of you are members of the AOAC; is that correct?

A. No, I don't think John Cardellina is AOAC member. I mean, he might be member, but not on the committee.

Q. And do you know -- I'm sorry. I didn't mean to cut you off. Do you know how it is that you all came to be in possession of this email which purports to be Jim Kababick's detailed comments to the Li paper?

A. Jim Kababick wrote it and probably sent it to Mark. That's what it says on the

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page. We were copied on it.

Q. And do you know why it was distributed to everyone?

A. No. I mean, this is -- DMAA is a hot topic. Everybody interested in the research, and Jim Kababick commented on this paper which was submitted to --

Q. Was this criticism ever published anywhere to your knowledge?

A. You mean as a publication?

Q. Yeah. Or a letter to the editor or anything like that?

A. No, I don't recall being published his comments.

Q. Okay.

A. Yeah.

MS. WOOLSON: That's it. I have no further questions. Thank you.

THE WITNESS: Thank you.

MR. DAVENPORT: We will read.

(Deposition adjourned at 4:51 p.m.)

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C E R T I F I C A T E

DISTRICT OF COLUMBIA:

I, MARY ANN PAYONK, shorthand reporter, do hereby certify that the witness whose deposition is hereinbefore set forth was duly sworn, and that such deposition is a true, correct, and full record of the testimony given.

I further certify that I am not related to any of the parties to this action by blood or by marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 31st day of October, 2016.

_____

MARY ANN PAYONK, Shorthand Reporter

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Index to Exhibits (Cont'd.):

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NAME OF CASE: US vs. Hi-Tech, et al.

DATE OF DEPOSITION: October 26, 2016

1. To clarify the record.
2. To conform to the facts.
3. To correct transcription error.

Page _____ Line _____ Reason _____
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IKHLAS A. KHAN, Ph.D.

SUBSCRIBED AND SWORN TO BEFORE ME
THIS _____ DAY OF _____, 2016.

_____
(Notary Public)
My Commission expires: _____

N