UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENOME AND COMPANY

Petitioner,

v.

THE UNIVERSITY OF CHICAGO

Patent Owner.

Case PGR2019-XX

U.S. Patent No. 9,855,302 B2

DEPOSITION OF JONATHAN BRAUN, M.D., Ph.D.

Washington, D.C.

June 19, 2019

Job No. 162380

Reported by: Linda S. Kinkade RDR CRR RMR RPR CSR

Wednesday, June 19, 2019
9:10 a.m.

The following is the transcript of the deposition of JONATHAN BRAUN, M.D., Ph.D. held at the offices of Covington & Burling LLP, One CityCenter, 850 Tenth Street, NW, Washington, DC 20001, and reported by Linda S. Kinkade, RDR, CRR, RMR, RPR, CSR, and Notary Public within and for the District of Columbia.

APPEARANCES:

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INDEX OF EXAMINATION

J. BRAUN

PROCEEDINGS

THE REPORTER: Would counsel state their appearances for the record, please.

MR. BAUER: John Bauer for In re Genome.

MR. KIM: Kongsik Kim from Mintz Levin.

DR. KAMHOLZ: Scott Kamholz for Patent Owner, The University of Chicago.

MS. ROBBINS: Jennifer Robbins for University of Chicago.

JONATHAN BRAUN, M.D., Ph.D., having been first duly sworn, was thereafter examined and testified as follows:

EXAMINATION

BY DR. KAMHOLZ:

Q. Your name is Jonathan Braun?

A. Yes.

Q. You reside in or around Los Angeles, California?

A. Yes.

Q. You recently retired from the University of California at Los Angeles?

A. Correct.

Q. You're now affiliated with Cedars-Sinai in Los Angeles?

J. BRAUN

A. Cedars-Sinai Medical Center.

Q. You understand I'm questioning you about your expert testimony in the post-grant proceeding PGR2019-00002, Genome and Company vs. The University of Chicago?

A. Yes.

DR. KAMHOLZ: I'm handing the witness a copy of a document previously marked Exhibit 1002 in this proceeding.

(Exhibit 1002 previously marked for identification and referenced herein: Declaration of Jonathan Braun, M.D., Ph.D. in Support of Petition for Post Grant Review of U.S. Patent No. 9,855,302)

Q. This is your expert declaration in this proceeding?

A. Yes.

Q. There's no reason you can't give truthful and complete testimony today?

A. That's a double negative. Could you state that again, please?

Q. There's no reason that you could not give truthful and complete testimony today?

J. BRAUN

A. No, there's no reason that I cannot give truthful testimony.

Q. You're an inventor on one or more U.S. patents?

A. Yes.

Q. But you've never been deposed before in a patent case?

A. Correct.

Q. And you've never given testimony before in a patent case?

A. Correct.

Q. You understand that you must answer questions truthfully and to the best of your ability?

A. Yes.

Q. If you don't understand a question, tell me, and I'll try to rephrase it. Okay?

A. (Nodding head up and down.)

Q. Okay?

A. Okay.

Q. Please make sure that you speak your answers so that the court reporter can record them. Okay?

A. Okay.

Q. If you answer a question, it means you

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understood the question. Understood?

A. Understood.

Q. And you'll wait until I finish asking a question before you answer it, so the court reporter can follow us?

A. I will.

Q. Counsel for Petitioner may make objections, but you must still answer my questions unless I withdraw the question or if counsel instructs you not to answer. Understood?

A. I understand.

Q. The Patent Office rules prohibit you from having conversations about the substance of your testimony today with anyone other than me once the deposition has started, and that has already started. Do you understand?

A. I understand.

Q. You may not talk with counsel for Petitioner concerning the substance of your testimony until the deposition is entirely over at the end of the day. Understood?

A. I understand.

Q. I recommend that during breaks you go someplace else away from the rest of us until the

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deposition is over. That's the easiest way to comply.

MR. BAUER: Object to that. The witness is not going to talk to counsel during breaks. He can be with counsel during his breaks.

Q. Please tell me if you need a break but not while a question is pending. All right?

A. Okay.

Q. Finally, if a situation arises where the lawyers need to resolve an issue, I may ask you to step out of the room until the issue is resolved, and then we'll invite you back in. Understood?

A. Understood.

Q. All right.

DR. KAMHOLZ: I'm giving the witness a copy of a document previously marked Exhibit 1004 in this proceeding.

(Exhibit 1004 previously marked for identification and referenced herein: Carcinogenesis Vol. 18 Singh | Re Bifidobacterium longum)

Q. Do you recognize this as the Singh paper you cite?

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A. Yes, I do.

Q. I'll direct your attention to page 834 of this document, which corresponds to Exhibit 2 -- I'm sorry -- Exhibit page 2 out of 9. That's page 834 of Exhibit 1004. Are you there?

A. Yes, I am.

Q. Do you see in the right-hand column of that page the heading "Experimental Procedure"?

A. Yes.

Q. Now Singh fed rats Bifidobacterium longum in their diet, correct?

A. I see a statement that groups of animals were fed the modified AIN 76-A diet containing 0 (for controls) 2 percent lyophilized B. longum cultures.

Q. Singh fed rats Bifidobacterium longum in their diet.

A. I just read what I see.

Q. Dr. Braun, Singh fed rats Bifidobacterium longum in their diet, correct?

A. Yes.

Q. And later he injected them with azoxymethane, abbreviated AOM?

A. Yes.

Q. In the left-hand column of that page,

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about six lines up from the bottom, it says there Singh injected AOM to induce colon tumor genesis, correct?

A. Yes.

Q. AOM is a carcinogen.

A. Correct.

Q. AOM goes through a series of chemical changes to produce the ultimate carcinogen, right?

A. Probably.

Q. AOM is converted to methylazoxymethanol, abbreviated MAM.

A. I don't recall the pharmacology of AOM.

Q. Turn to page 838 of this exhibit, 1004. That's Exhibit page 6 of 9. In the right-hand column, lines 18 to 20, AOM goes through a series of chemical changes to produce the ultimate carcinogen, correct?

A. Yes.

Q. AOM is converted to methylazoxymethanol, abbreviated MAM.

A. That's what's stated in this document.

Q. And AOM is converted ultimately to methyldiazonium ion, which is referred to as the ultimate carcinogen.

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A. That's what's stated in this article -- in this paragraph.

Q. Turn back to page 837, please. That's page 5 of 9 of this exhibit. In the right-hand column under the Discussion heading, Singh proposes that Bifidobacterium longum inhibits cecal beta-glucuronidase, correct?

A. Yes, I read that they make that statement from a prior paper that they had reported.

Q. It's known that beta-glucuronidase bioactivates MAM.

A. I don't recall that etymology.

Q. Well, you've held yourself out as an expert in this field. Do you know or do you not know that beta-glucuronidase bioactivates MAM?

MR. BAUER: Objection.

A. That's a particular biochemical detail.

Q. Dimethylhydrazine, abbreviated DMH, is a precursor of AOM, correct?

A. I don't recall.

Q. You hold yourself out as an expert in the field, but you don't know whether dimethylhydrazine is a precursor of AOM?

MR. BAUER: Objection, argumentative.

J. BRAUN

A. There are many carcinogens with sequences of their biochemistry. You're asking me a very narrow factual question. I would need to refresh myself from the literature to confidently answer that question.

Q. Do you have any reason to doubt that dimethylhydrazine is a precursor of AOM?

A. I don't know. I would have to read -- refresh myself on the literature of that pharmacology.

Q. Turn back to page 838 of Exhibit 1004. That's Exhibit page 6 of 9. In the left column, the first full paragraph, Singh says the mechanism of Bifidobacterium longum inhibition of AOM-induced colon cancer is not clear, correct?

A. Correct.

Q. Singh proposes several possible mechanisms, however, correct?

A. Correct.

Q. For example, Singh proposes pH changes that may affect resident flora.

A. That's one stated mechanism in this article.

Q. And continuing on to the right column of

that page, around line 10 or so, Singh proposes that a possible mechanism of Bifidobacterium longum inhibition of AOM-induced colon cancer is modulation of microbacterial fecal enzymes that convert the procarcinogen, right?

A. Correct.

Q. And going down a little further around line 15, Singh proposes as a possible mechanism of Bifidobacterium longum inhibition of AOM-induced colon cancer the cellular uptake of carcinogen metabolites, correct?

A. Correct.

Q. And continuing down to around line 27, Singh proposes a possible mechanism of Bifidobacterium longum inhibition of AOM-induced colon cancer being that the lactic cultures bind to MAM, thereby minimizing its reabsorption, correct?

A. Correct.

Q. And continuing down to line 33, Singh proposes as a possible mechanism of Bifidobacterium longum inhibition of AOM-induced colon cancer to be that it affects cytochrome P450 activity, correct?

A. Correct.

Q. Singh says that all these proposed

mechanisms are possible explanations of his results, right?

A. Correct.

Q. And Singh says that these antitumor mechanisms are actually anticarcinogen properties, correct?

A. Well, the end of that paragraph states that Bifido induces an antitumor effect and plays an important role as an immunomodulator in the intestines.

Q. Turn to page 833 of this exhibit, which is page 1 out of 9. In the right column, starting at about line 11, Singh explains that these lactic cultures have been shown to possess anticarcinogenic properties, among other things, correct?

A. Correct.

Q. Now going back to page 838, which is page 6 of 9 of this exhibit, you agreed that Singh identifies a number of several possible mechanisms of Bifidobacterium longum inhibition of AOM-induced colon cancer a moment ago.

A. Yes.

Q. Each of these mechanisms that we discussed that Singh proposes are not directed against the

tumor themselves, correct?

A. Correct.

Q. They're directed against the carcinogen.

A. No. At least one of them, the last one, cites an immunomodulator role.

Q. The possible mechanisms that we discussed are all directed to the carcinogen.

A. The examples that you called out before were examples that relate to metabolizing the carcinogen.

Q. And Singh does not rule out any of these possible mechanisms, these anticarcinogen properties.

A. Correct.

Q. Go back to the first page of this exhibit, please, page 1 of 9. In the abstract, the last sentence says, quote, "data suggests that oral administration of probiotic B. longum exerts strong antitumor activity," correct?

A. Yes.

Q. Singh says that the data suggests this, correct?

A. Correct.

Q. Please go to Exhibit 1002, your declaration, page 55 of 186. I'm referring to the

page numbers in the lower right-hand corner.

In paragraph 122 of your declaration you quote that sentence from Singh's abstract.

A. Correct.

Q. But you left out the words "data suggests."

A. Those are not part of the quote that I used.

Q. You left out the words "data suggests."

A. Correct.

Q. Instead you say, quote, "Singh, et al. showed," unquote, correct?

A. Correct.

Q. Singh didn't say "showed"; Singh said "suggests."

A. It's the normal understanding of readers of such articles that in the peer-review process words like "suggest" are used as a -- as a manner of speaking and not a -- and not a qualifier in the sense that you imply.

Q. Singh didn't say "show"; Singh said "suggests."

A. Correct.

Q. So the declaration deceptively misquotes

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