JONATHAN BRAUN, M.D., Ph.D.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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GENOME AND COMPANY,

Petitioner

v.

THE UNIVERSITY OF CHICAGO,

Patent Owner

_____

Case No. PGR2019-XX

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

_____

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

Thursday, November 21, 2019 10:05 a.m.

Nelson Mullins Riley & Scarborough LLP

One Post Office Square, Boston, MA

Reported by:

Janet Sambataro, RMR, CRR, CLR

JOB NO. 172169

JONATHAN BRAUN, M.D., Ph.D.

APPEARANCES:

COVINGTON & BURLING
On Behalf of Patent Owner
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JONATHAN BRAUN, M.D., Ph.D.

P R O C E E D I N G S

JONATHAN BRAUN, M.D., Ph.D.,
having been duly sworn, after presenting identification in the form of a driver's license, deposes and says as follows:

CROSS-EXAMINATION

BY DR. KAMHOLZ:

Q. Good morning, Dr. Braun.

My name is Scott Kamholz. I'm representing the patent owner in this proceeding. You understand that you are here to give testimony concerning your reply declaration and post-grant review proceeding PGR2019-0002, Genome & Company versus the University of Chicago?

A. I do.

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

A. No reason.

Q. No medical, health or other conditions that would prevent you from giving complete and truthful testimony today?

A. No.

Q. You understand that you must answer your questions truthfully -- answer my questions



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truthfully and to the best of your ability?

A. Yes.

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

A. Okay.

Q. If you answer a question, it means you understood the question. Okay?

A. Yes.

Q. Please wait until I finish asking a question before you answer it so that the court reporter can follow us. Okay?

A. Okay.

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

A. I understand.

Q. You may not talk with counsel for petitioner concerning the substance of your testimony until my Cross-Examination is complete. Understood?

A. I understand.

Q. Please tell me if you need a break, but



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not while a question is pending. Okay?

A. Okay.

DR. KAMHOLZ: I'm handing the witness a copy of a document previously marked Exhibit 1043 in this proceeding.

(Previously marked Exhibit 1043 incorporated by reference.)

DR. KAMHOLZ: I just noticed the copies that I have do not have an exhibit number marked on them.

MR. BAUER: Can we go off the record for a second?

(Discussion off the record.)

BY DR. KAMHOLZ:

Q. Dr. Braun, do you recognize this document as your reply declaration in this proceeding?

A. I do.

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

(Previously marked Exhibit 1002 incorporated by reference.)

Q. Do you recognize this document as your opening declaration in this proceeding?
A. I do.
Q. Please take your reply declaration, Exhibit 1043, and turn to Page 1.
(Witness complies.)
Q. And look at Paragraph 2.
Do you see there you refer to your "educational background, career history, and other qualifications" as provided in your opening declaration?
A. I see it.
Q. And turn to Page 3, please.
(Witness complies.)
Q. The heading on this page is "Extensive Human Oncology Clinical Experience."
Do you see that?
A. Yes.
Q. You don't describe in your opening declaration or in your reply declaration being board-certified in internal medicine; correct?
A. Correct.
Q. And, in fact, you're not board-certified in internal medicine; right?





A. Correct.
Q. You don't describe in your opening declaration or your reply declaration being board-certified in oncology; correct?
A. Correct.
Q. And, in fact, you are not board-certified in oncology; correct?
A. Correct.
Q. You don't describe in your opening declaration or in your reply declaration having ever provided medical care to a patient; correct?
A. Could you repeat your statement?
Q. You don't describe in your opening declaration or in your reply declaration having ever provided medical care directly to a patient; correct?
A. No. That is not correct.
Q. You don't describe in your opening declaration or in your reply declaration having ever provided medical care directly to a cancer patient; is that correct?
A. No. That is not correct.
Q. The medical care that you describe providing to cancer patients is in the matter --





is in the manner of pathology consultations; correct?
A. Correct.
Q. You don't describe in your opening declaration or in your reply declaration having ever prescribed a therapeutic agent to a cancer patient; correct?
A. Correct.
Q. You don't describe in your opening declaration or in your reply declaration having ever prescribed a checkpoint inhibitor to a cancer patient; correct?
A. These questions misperceive the role of pathologists in the planning of care to oncology patients.
Q. You don't describe in your opening declaration or in your reply declaration having ever prescribed a checkpoint inhibitor to a cancer patient; correct?
A. The role of myself and the pathologists on my team in tumor boards play a direct role in the decision about the choice of therapies.
Q. You don't describe in your opening declaration or in your reply declaration having





ever prescribed a checkpoint inhibitor to a cancer patient; correct?
A. I have answered my -- to the best of my ability your question.
Q. You have never prescribed a checkpoint inhibitor to a cancer patient; correct?
A. Correct.
Q. You don't describe in your opening declaration or in your reply declaration having ever been principal investigator on a clinical trial; correct?
A. Correct.
Q. You have never been a principal investigator on a clinical trial; correct?
A. Correct.
Q. You don't describe in your opening declaration or in your reply declaration having ever referred a patient to a checkpoint inhibitor clinical trial; correct?
A. As a pathologist, my clinic activities play a direct role in making the ascertainment about whether a patient is suitable to be referred for a clinical trial.
Q. But you have never referred a patient

to a clinical trial for a checkpoint inhibitor, have you?

A. Correct.

Q. You don't describe in your opening declaration or in your reply declaration having ever administered a checkpoint inhibitor to treat cancer in a human subject; correct?

A. My role as a pathologist directly involves me in the choice to administer such an agent, and my work as a pathologist provides critical information in monitoring the patient undergoing such therapy.

Q. But you have never administered to a human subject a checkpoint inhibitor to treat cancer in that human subject; correct?

A. Correct.

Q. You don't describe in your opening declaration or in your reply declaration having ever administered to a human subject anything to treat cancer in that human subject; correct?

A. Your questions misperceive the role of a pathologist in the planning and execution of therapeutic interventions for patients. A pathologist plays critical roles together with





the oncologist and other members of the team on deciding what therapies to administer, how to monitor adverse reactions, and to assess the response to treatment. It also is critical to decide if that therapy should be maintained or changed to another therapy.

So I've been regularly involved in all phases of the management of cancer patients.

Q. But you don't describe in your opening declaration or in your reply declaration having ever administered to a human subject anything to treat cancer in that human subject?

A. I've given you my best answer to your question.

Q. And you, in fact, have never administered to a human subject anything to treat cancer in that human subject; correct?

A. In my years of medicine, there's been times when I have directly prescribed and administered therapies to patients.

Q. To treat cancer?

A. Yes.

Q. Turn to Page 3 of your reply declaration.





(Witness complies.)

Q. In Paragraph 12, you refer to the role of pathology consultations to "provide critical information for diagnosis or management of cancer patients."

Do you see that?

A. Yes, I do.

Q. That critical information includes the type of cancer; correct?

A. Yes. It also includes many other types of information that I use to make the decision about what treatments to use and how to monitor the response to treatment.

Q. In Paragraph 12, you refer to "surgical pathology cases."

Do you see that?

A. Yes.

Q. In the typical surgical pathology case, the pathologist receives a tissue specimen from the patient; right?

A. Correct. Sometimes it's received. Sometimes the pathologist does the intervention to collect the specimen.

Q. The pathologist analyzes the tissue





specimen to confirm the presence or absence of cancer in the tissue specimen if it's a cancer case; right?

A. That's one of the activities that the pathologist -- the pathologist also produces other information to determine the biologic features of the tumor that can be used to predict or make the best choice for therapies that would be most beneficial to the patient and also to decide on biomarkers that can be used to monitor care.

Q. Your role as a pathologist in a surgical pathology case involves analyzing a tissue specimen received from a patient; right?

A. Correct.

Q. And the treatment is determined based, at least in part, on the information the pathologist provides, including the type of cancer and the other things you mentioned?

A. Correct. In addition, the pathologist participates in the treatment planning conference with the oncologist and other members of the team to discuss and together come to a consensus about the treatment plan, the management and monitoring

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plan.

Q. And those treatments, if successful, will stop progression of the cancer; right?

A. That's one possible outcome.

DR. KAMHOLZ: I'm giving the witness a copy of a document previously marked Exhibit 1045 in this proceeding.

(Previously marked Exhibit 1045 incorporated by reference.)

Q. Do you recognize this as the Ridaura article you cited in your reply declaration?

A. I do.

Q. You see that Ridaura reports on experiments using germ-free rodents?

A. That's one part of the design of the research. There are other parts to the design as well.

Q. But no part of this research involves the use of specific pathogen-free rodents?

A. When the mice were recolonized, that would be considered a specific pathogen-free animal.

Q. Ridaura does not identify any animals in this case as specific pathogen-free; correct?



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A. A person with ordinary skill in the art would understand that the reconstituted animal would fall into the category of specific pathogen-free.

Q. Ridaura reports on experiments using gnotobiotic rodents; correct?

A. Correct.

Q. Gnotobiotic refers to a facility in which the microorganisms are either known or excluded; right?

A. Ridaura describes mice that start as germ-free, meaning by a set of definitions that the Washington University facility defines that they lack identifiable microorganisms. The work mainly describes those mice after they were recolonized with microbiota from different human sources.

Q. Ridaura investigated transplantation of microorganisms by gavage of germ-free rodents; right?

A. Correct.

Q. Ridaura also investigated transfer of microorganisms between co-housed rodents; right?

A. Correct.



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Q. Ridaura does not discuss breeding; correct?

A. Ridaura describes a well-established process of establishing a microbial community in a mouse and the dynamics in which it sustained that mouse over time.

Q. But Ridaura does not describe or discuss breeding.

A. Well, a person with ordinary experience would understand that this article teaches how a microbial community is established in a mouse or in a colony.

Q. But Ridaura does not discuss breeding; correct?

A. A person of ordinary skill would understand that organisms are vertically transferred from mothers to babies by co-housing. This provides documentation of the details about how that transfer occurs.

Q. But Ridaura does not discuss breeding?

A. I've given you my best answer to your question.

Q. Ridaura termed transfer of microorganisms between co-housed rodents as



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"invasion"; correct?

A. On Page 1, the term "invasion" is used to describe the dynamic of a genus of bacteria when encountered by co-housing between two mice.

Q. Turn to Page 5, please.

(Witness complies.)

Q. Do you see at the top of Page 5, in the middle column, Ridaura says, "The most successful LNch invaders of the OBch microbiota were members of the Bacteroidetes"?

A. I see that statement.

Q. And continuing on to Page 6, left-hand column at the top, do you see Ridaura reported that "In contrast, co-housing did not result in significant invasion of LNch intestines with members of the OBch microbiota"?

A. I see that.

Q. Ridaura found that some microbiota invaded the intestines of co-housed rodents readily, but others did not; right?

A. That misunderstands the ecology here. Ridaura is describing the dynamics of the ecology between mice with two different ecologies, a distinct one in the obese mouse; another one in

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