

1 JONATHAN BRAUN, M.D., Ph.D.
2 UNITED STATES PATENT AND TRADEMARK OFFICE
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

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5
6 GENOME AND COMPANY,
7 Petitioner

8 v.

9 THE UNIVERSITY OF CHICAGO,
10 Patent Owner

11 _____

12 Case No. PGR2019-XX

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

14 _____

15
16 DEPOSITION OF JONATHAN BRAUN, M.D., Ph.D.

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

18 Nelson Mullins Riley & Scarborough LLP

19 One Post Office Square, Boston, MA

20

21

22

23 Reported by:

24 Janet Sambataro, RMR, CRR, CLR

25 JOB NO. 172169

1 JONATHAN BRAUN, M.D., Ph.D.
 2
 3 APPEARANCES:
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 6 On Behalf of Patent Owner
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 17 New York, NY 10017
 18 BY: John Bauer, Esquire
 19
 20
 21
 22
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 24
 25

1 JONATHAN BRAUN, M.D., Ph.D.
 2 truthfully and to the best of your ability?
 3 A. Yes.
 4 Q. If you don't understand a question,
 5 tell me, and I will try to rephrase the question.
 6 Okay?
 7 A. Okay.
 8 Q. If you answer a question, it means you
 9 understood the question. Okay?
 10 A. Yes.
 11 Q. Please wait until I finish asking a
 12 question before you answer it so that the court
 13 reporter can follow us. Okay?
 14 A. Okay.
 15 Q. Counsel for petitioner may make
 16 objections, but you must still answer the
 17 question unless I withdraw the question or
 18 counsel instructs you not to answer. Understood?
 19 A. I understand.
 20 Q. You may not talk with counsel for
 21 petitioner concerning the substance of your
 22 testimony until my Cross-Examination is complete.
 23 Understood?
 24 A. I understand.
 25 Q. Please tell me if you need a break, but

1 JONATHAN BRAUN, M.D., Ph.D.
 2 P R O C E E D I N G S
 3 JONATHAN BRAUN, M.D., Ph.D.,
 4 having been duly sworn, after presenting
 5 identification in the form of a driver's license,
 6 deposes and says as follows:
 7 CROSS-EXAMINATION
 8 BY DR. KAMHOLZ:
 9 Q. Good morning, Dr. Braun.
 10 My name is Scott Kamholz. I'm representing
 11 the patent owner in this proceeding. You
 12 understand that you are here to give testimony
 13 concerning your reply declaration and post-grant
 14 review proceeding PGR2019-0002, Genome & Company
 15 versus the University of Chicago?
 16 A. I do.
 17 Q. There's no reason you cannot give
 18 truthful and complete testimony today?
 19 A. No reason.
 20 Q. No medical, health or other conditions
 21 that would prevent you from giving complete and
 22 truthful testimony today?
 23 A. No.
 24 Q. You understand that you must answer
 25 your questions truthfully -- answer my questions

1 JONATHAN BRAUN, M.D., Ph.D.
 2 not while a question is pending. Okay?
 3 A. Okay.
 4 DR. KAMHOLZ: I'm handing the witness a
 5 copy of a document previously marked Exhibit 1043
 6 in this proceeding.
 7 (Previously marked Exhibit 1043
 8 incorporated by reference.)
 9 DR. KAMHOLZ: I just noticed the copies
 10 that I have do not have an exhibit number marked
 11 on them.
 12 MR. BAUER: Can we go off the record
 13 for a second?
 14 (Discussion off the record.)
 15 BY DR. KAMHOLZ:
 16 Q. Dr. Braun, do you recognize this
 17 document as your reply declaration in this
 18 proceeding?
 19 A. I do.
 20 DR. KAMHOLZ: I'm handing the witness a
 21 copy of a document previously marked Exhibit 1002
 22 in this proceeding.
 23 (Previously marked Exhibit 1002
 24 incorporated by reference.)
 25

1 JONATHAN BRAUN, M.D., Ph.D.
 2 Q. Do you recognize this document as your
 3 opening declaration in this proceeding?
 4 A. I do.
 5 Q. Please take your reply declaration,
 6 Exhibit 1043, and turn to Page 1.
 7 (Witness complies.)
 8 Q. And look at Paragraph 2.
 9 Do you see there you refer to your
 10 "educational background, career history, and
 11 other qualifications" as provided in your opening
 12 declaration?
 13 A. I see it.
 14 Q. And turn to Page 3, please.
 15 (Witness complies.)
 16 Q. The heading on this page is "Extensive
 17 Human Oncology Clinical Experience."
 18 Do you see that?
 19 A. Yes.
 20 Q. You don't describe in your opening
 21 declaration or in your reply declaration being
 22 board-certified in internal medicine; correct?
 23 A. Correct.
 24 Q. And, in fact, you're not
 25 board-certified in internal medicine; right?

1 JONATHAN BRAUN, M.D., Ph.D.
 2 is in the manner of pathology consultations;
 3 correct?
 4 A. Correct.
 5 Q. You don't describe in your opening
 6 declaration or in your reply declaration having
 7 ever prescribed a therapeutic agent to a cancer
 8 patient; correct?
 9 A. Correct.
 10 Q. You don't describe in your opening
 11 declaration or in your reply declaration having
 12 ever prescribed a checkpoint inhibitor to a
 13 cancer patient; correct?
 14 A. These questions misperceive the role of
 15 pathologists in the planning of care to oncology
 16 patients.
 17 Q. You don't describe in your opening
 18 declaration or in your reply declaration having
 19 ever prescribed a checkpoint inhibitor to a
 20 cancer patient; correct?
 21 A. The role of myself and the pathologists
 22 on my team in tumor boards play a direct role in
 23 the decision about the choice of therapies.
 24 Q. You don't describe in your opening
 25 declaration or in your reply declaration having

1 JONATHAN BRAUN, M.D., Ph.D.
 2 A. Correct.
 3 Q. You don't describe in your opening
 4 declaration or your reply declaration being
 5 board-certified in oncology; correct?
 6 A. Correct.
 7 Q. And, in fact, you are not
 8 board-certified in oncology; correct?
 9 A. Correct.
 10 Q. You don't describe in your opening
 11 declaration or in your reply declaration having
 12 ever provided medical care to a patient; correct?
 13 A. Could you repeat your statement?
 14 Q. You don't describe in your opening
 15 declaration or in your reply declaration having
 16 ever provided medical care directly to a patient;
 17 correct?
 18 A. No. That is not correct.
 19 Q. You don't describe in your opening
 20 declaration or in your reply declaration having
 21 ever provided medical care directly to a cancer
 22 patient; is that correct?
 23 A. No. That is not correct.
 24 Q. The medical care that you describe
 25 providing to cancer patients is in the matter --

1 JONATHAN BRAUN, M.D., Ph.D.
 2 ever prescribed a checkpoint inhibitor to a
 3 cancer patient; correct?
 4 A. I have answered my -- to the best of my
 5 ability your question.
 6 Q. You have never prescribed a checkpoint
 7 inhibitor to a cancer patient; correct?
 8 A. Correct.
 9 Q. You don't describe in your opening
 10 declaration or in your reply declaration having
 11 ever been principal investigator on a clinical
 12 trial; correct?
 13 A. Correct.
 14 Q. You have never been a principal
 15 investigator on a clinical trial; correct?
 16 A. Correct.
 17 Q. You don't describe in your opening
 18 declaration or in your reply declaration having
 19 ever referred a patient to a checkpoint inhibitor
 20 clinical trial; correct?
 21 A. As a pathologist, my clinic activities
 22 play a direct role in making the ascertainment
 23 about whether a patient is suitable to be
 24 referred for a clinical trial.
 25 Q. But you have never referred a patient

1 JONATHAN BRAUN, M.D., Ph.D.
 2 to a clinical trial for a checkpoint inhibitor,
 3 have you?
 4 A. Correct.
 5 Q. You don't describe in your opening
 6 declaration or in your reply declaration having
 7 ever administered a checkpoint inhibitor to treat
 8 cancer in a human subject; correct?
 9 A. My role as a pathologist directly
 10 involves me in the choice to administer such an
 11 agent, and my work as a pathologist provides
 12 critical information in monitoring the patient
 13 undergoing such therapy.
 14 Q. But you have never administered to a
 15 human subject a checkpoint inhibitor to treat
 16 cancer in that human subject; correct?
 17 A. Correct.
 18 Q. You don't describe in your opening
 19 declaration or in your reply declaration having
 20 ever administered to a human subject anything to
 21 treat cancer in that human subject; correct?
 22 A. Your questions misperceive the role of
 23 a pathologist in the planning and execution of
 24 therapeutic interventions for patients. A
 25 pathologist plays critical roles together with

1 JONATHAN BRAUN, M.D., Ph.D.
 2 the oncologist and other members of the team on
 3 deciding what therapies to administer, how to
 4 monitor adverse reactions, and to assess the
 5 response to treatment. It also is critical to
 6 decide if that therapy should be maintained or
 7 changed to another therapy.
 8 So I've been regularly involved in all
 9 phases of the management of cancer patients.
 10 Q. But you don't describe in your opening
 11 declaration or in your reply declaration having
 12 ever administered to a human subject anything to
 13 treat cancer in that human subject?
 14 A. I've given you my best answer to your
 15 question.
 16 Q. And you, in fact, have never
 17 administered to a human subject anything to treat
 18 cancer in that human subject; correct?
 19 A. In my years of medicine, there's been
 20 times when I have directly prescribed and
 21 administered therapies to patients.
 22 Q. To treat cancer?
 23 A. Yes.
 24 Q. Turn to Page 3 of your reply
 25 declaration.

1 JONATHAN BRAUN, M.D., Ph.D.
 2 (Witness complies.)
 3 Q. In Paragraph 12, you refer to the role
 4 of pathology consultations to "provide critical
 5 information for diagnosis or management of cancer
 6 patients."
 7 Do you see that?
 8 A. Yes, I do.
 9 Q. That critical information includes the
 10 type of cancer; correct?
 11 A. Yes. It also includes many other types
 12 of information that I use to make the decision
 13 about what treatments to use and how to monitor
 14 the response to treatment.
 15 Q. In Paragraph 12, you refer to "surgical
 16 pathology cases."
 17 Do you see that?
 18 A. Yes.
 19 Q. In the typical surgical pathology case,
 20 the pathologist receives a tissue specimen from
 21 the patient; right?
 22 A. Correct. Sometimes it's received.
 23 Sometimes the pathologist does the intervention
 24 to collect the specimen.
 25 Q. The pathologist analyzes the tissue

1 JONATHAN BRAUN, M.D., Ph.D.
 2 specimen to confirm the presence or absence of
 3 cancer in the tissue specimen if it's a cancer
 4 case; right?
 5 A. That's one of the activities that the
 6 pathologist -- the pathologist also produces
 7 other information to determine the biologic
 8 features of the tumor that can be used to predict
 9 or make the best choice for therapies that would
 10 be most beneficial to the patient and also to
 11 decide on biomarkers that can be used to monitor
 12 care.
 13 Q. Your role as a pathologist in a
 14 surgical pathology case involves analyzing a
 15 tissue specimen received from a patient; right?
 16 A. Correct.
 17 Q. And the treatment is determined based,
 18 at least in part, on the information the
 19 pathologist provides, including the type of
 20 cancer and the other things you mentioned?
 21 A. Correct. In addition, the pathologist
 22 participates in the treatment planning conference
 23 with the oncologist and other members of the team
 24 to discuss and together come to a consensus about
 25 the treatment plan, the management and monitoring

1 JONATHAN BRAUN, M.D., Ph.D.
 2 plan.
 3 Q. And those treatments, if successful,
 4 will stop progression of the cancer; right?
 5 A. That's one possible outcome.
 6 DR. KAMHOLZ: I'm giving the witness a
 7 copy of a document previously marked Exhibit 1045
 8 in this proceeding.
 9 (Previously marked Exhibit 1045
 10 incorporated by reference.)
 11 Q. Do you recognize this as the Ridaura
 12 article you cited in your reply declaration?
 13 A. I do.
 14 Q. You see that Ridaura reports on
 15 experiments using germ-free rodents?
 16 A. That's one part of the design of the
 17 research. There are other parts to the design as
 18 well.
 19 Q. But no part of this research involves
 20 the use of specific pathogen-free rodents?
 21 A. When the mice were recolonized, that
 22 would be considered a specific pathogen-free
 23 animal.
 24 Q. Ridaura does not identify any animals
 25 in this case as specific pathogen-free; correct?

1 JONATHAN BRAUN, M.D., Ph.D.
 2 Q. Ridaura does not discuss breeding;
 3 correct?
 4 A. Ridaura describes a well-established
 5 process of establishing a microbial community in
 6 a mouse and the dynamics in which it sustained
 7 that mouse over time.
 8 Q. But Ridaura does not describe or
 9 discuss breeding.
 10 A. Well, a person with ordinary experience
 11 would understand that this article teaches how a
 12 microbial community is established in a mouse or
 13 in a colony.
 14 Q. But Ridaura does not discuss breeding;
 15 correct?
 16 A. A person of ordinary skill would
 17 understand that organisms are vertically
 18 transferred from mothers to babies by co-housing.
 19 This provides documentation of the details about
 20 how that transfer occurs.
 21 Q. But Ridaura does not discuss breeding?
 22 A. I've given you my best answer to your
 23 question.
 24 Q. Ridaura termed transfer of
 25 microorganisms between co-housed rodents as

1 JONATHAN BRAUN, M.D., Ph.D.
 2 A. A person with ordinary skill in the art
 3 would understand that the reconstituted animal
 4 would fall into the category of specific
 5 pathogen-free.
 6 Q. Ridaura reports on experiments using
 7 gnotobiotic rodents; correct?
 8 A. Correct.
 9 Q. Gnotobiotic refers to a facility in
 10 which the microorganisms are either known or
 11 excluded; right?
 12 A. Ridaura describes mice that start as
 13 germ-free, meaning by a set of definitions that
 14 the Washington University facility defines that
 15 they lack identifiable microorganisms. The work
 16 mainly describes those mice after they were
 17 recolonized with microbiota from different human
 18 sources.
 19 Q. Ridaura investigated transplantation of
 20 microorganisms by gavage of germ-free rodents;
 21 right?
 22 A. Correct.
 23 Q. Ridaura also investigated transfer of
 24 microorganisms between co-housed rodents; right?
 25 A. Correct.

1 JONATHAN BRAUN, M.D., Ph.D.
 2 "invasion"; correct?
 3 A. On Page 1, the term "invasion" is used
 4 to describe the dynamic of a genus of bacteria
 5 when encountered by co-housing between two mice.
 6 Q. Turn to Page 5, please.
 7 (Witness complies.)
 8 Q. Do you see at the top of Page 5, in the
 9 middle column, Ridaura says, "The most successful
 10 LNch invaders of the OBch microbiota were members
 11 of the Bacteroidetes"?
 12 A. I see that statement.
 13 Q. And continuing on to Page 6, left-hand
 14 column at the top, do you see Ridaura reported
 15 that "In contrast, co-housing did not result in
 16 significant invasion of LNch intestines with
 17 members of the OBch microbiota"?
 18 A. I see that.
 19 Q. Ridaura found that some microbiota
 20 invaded the intestines of co-housed rodents
 21 readily, but others did not; right?
 22 A. That misunderstands the ecology here.
 23 Ridaura is describing the dynamics of the ecology
 24 between mice with two different ecologies, a
 25 distinct one in the obese mouse; another one in

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