IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

GENETIC VETERINARY SERVICES, INC.,	)	
Plaintiff,	)	CIVIL ACTION NO. 2:17cv108
v.	)	
LABOklin GMBH & CO. KG, et al.,	)	
Defendants.	)	

TRANSCRIPT OF PROCEEDINGS
(Jury Trial - Day 1)

Norfolk, Virginia

April 30, 2018

BEFORE: THE HONORABLE HENRY COKE MORGAN, JR.
United States District Judge, and a jury

APPEARANCES:

LOWE GRAHAM JONES
By: Mark P. Walters, Esquire
- and -
VENABLE LLP
By: Joshua Counts Cumby, Esquire
Counsel for the Plaintiff/Counter Defendant

QUARLES & BRADY LLP
By: Nikia L. Gray, Esquire
And: Michael Piery, Esquire
And: Christian G. Stahl, Esquire
And: Johanna Wilbert, Esquire
Counsel for the Defendants/Counter Plaintiffs

I N D E X

E X H I B I T S

(Proceedings commenced at 10:10 a.m.)

THE CLERK: Civil Action No. 2:17cv108; Plaintiff Genetic Veterinary Sciences, a Washington corporation, doing business as Paw Prints Genetics vs. Defendant LABOklin GmbH and Co. KG, a German company, and Defendant The University of Bern, an agency or instrumentality of Switzerland.

For the plaintiff, Mr. Cumby, Mr. Walters, are you ready to proceed?

MR. WALTERS: We are, Your Honor.

THE CLERK: For the defendants, Ms. Gray, Mr. Stahl, Ms. Wilbert, and Mr. Piery, are you ready to proceed?

MS. GRAY: We are, Your Honor.

THE COURT: All right. Counsel, I have reviewed the material submitted regarding the issue of willful damages, and I find that, in view of the stipulation of the parties, it's not possible to decide willful damages at this proceeding. And, in fact, it may be that the stipulation precludes the defendants from asserting willful damages. That issue, I'm not deciding.

But we cannot decide willful infringement at this proceeding because there's no evidence before the Court as to what the damages would be. The parties stipulated the damages and didn't take discovery on damages. They put in the stipulation that by stipulating, they weren't agreeing to the fact that that was a reasonable royalty, but they

stipulated to the amount of damages. And arguably, they made that stipulation after they had filed the counterclaim for willful damages.

So the Court can certainly infer that since they decided not to take any discovery on damages, that that's what they intended for damages. But even if the Court does not make that inference, the Court has nothing upon which to base any increase in damages even if the jury finds it's willful because there's no evidence before the Court other than the stipulation as to what the damages could be.

So even if the jury found it was willful, we'd have to have another trial on damages.

MS. WILBERT: Your Honor --

THE COURT: You've had your chance.

So the Court is not going to try damages today. If the Court finds that the patent is valid, then the Court will then decide whether the defendants are entitled to seek willful damages. If they are, then we'd have to have a trial on damages as well as willful damages because I have nothing before me at this time to increase, other than the stipulated damages, which the stipulation said are not meant to represent a reasonable royalty.

So what could I base an increase in damages on if it was found to be willful? There's nothing there. Which suggests to the Court that the parties knew what they were

doing when they stipulated damages and intended that they be the damages. That's an inference the Court could make. The Court is not making that inference at this time. But of course, if the patent is found invalid, then it's moot.

Now, as to the issue of infringement, there's no need in this case to mention infringement. The parties stipulated that infringement is present. The defendants' proposed instruction mentioned infringement repeatedly, which clearly suggests to the Court that they're mentioning infringement in the hope to distract or influence the jury away from the true issue in the case: Is the patent valid? There's no issue of infringement before the Court. There's no need for any attorney or witness to mention the word "infringement." And counsel are so advised.

The only issue before the Court is the validity of the patent. The Court finds that mentioning infringement repeatedly in the instructions would do nothing but mislead the jury. There's no infringement issue; therefore, there's no need to mention it in jury instructions, which the defendant did repeatedly.

So obviously, the defendant believes, and the Court concurs, that mixing infringement into the case would tend to influence the jury away from the real issue which it faces, which is: Is the patent valid?

So also, the last-minute edited version of the film

regarding patents submitted by the plaintiff goes into infringement. And it's also technically not -- it skips and jumps, and it's hard to follow. So I will either use the defendant's version as edited or none at all. It doesn't make any difference to me. I don't think the jury needs the film. The issue before them is very simple.

Now, why would the defendants not be entitled to the presumption of validity? You're suggesting that you submitted an alternative instruction on the basis that they wouldn't be entitled to the presumption of validity. Why aren't they entitled to the presumption of validity?

MR. WALTERS: Your Honor, we cite some cases for this, and the reasoning goes like this:

The Supreme Court, in all of their cases addressing the issue of ineligible subject matter, has not applied a presumption of validity to that particular determination. The presumption of validity has been historically applied to an examiner's or the Patent Office's determination.

THE COURT: Well, do the cases say that they're not entitled to a presumption of validity?

MR. WALTERS: It's an open issue, Your Honor. So we simply just want to preserve our objection.

THE COURT: Well, it seems to me that the Patent Office granted it. Unless you've got some case that says they're not entitled to the presumption of validity, I think

they are.

MR. WALTERS: We don't have that case, Your Honor.

THE COURT: All right. Well, then, the defendants have the presumption of validity, and the jury will be so instructed.

Now, do you want to use the defendants' edited version of the film or none at all?

MR. WALTERS: Your Honor, so the video that we submitted to you skips and is not playing well?

THE COURT: Well, I took them home this weekend, and they don't work on my video player. It has to be attached to a computer.

MR. WALTERS: Well, I do have a version of it on my laptop, and I could play it, and I've played it before, and it plays fine.

THE COURT: Well, that doesn't mean -- the question is should we use it. I don't know that it adds anything to the case, frankly. It's a simple issue.

MR. WALTERS: I tend to agree, Your Honor. So I would be in favor of not using it.

THE COURT: All right. If the defendant doesn't --

MS. GRAY: Your Honor, we would like to use the video because we do find that it provides some background into what a patent is and how a patent is obtained. We do think it is helpful for the jury to hear.

THE COURT: There's plenty of preliminary instructions that advise the jury of what a patent is. We don't need the film which goes into many others or your film which goes into infringement. As I said, infringement is not an issue. There's no need to use the word "infringement" with you or your witnesses.

MS. GRAY: Understood, Your Honor. We would be happy to use plaintiff's video as well if that was acceptable.

THE COURT: You'd do what?

MS. GRAY: We'd be happy to use the version that plaintiff submitted if that is preferable.

THE COURT: Well, the defendant is the one that submitted it, and he doesn't want to use it. So I don't think it adds anything to the case.

MS. GRAY: Thank you, Your Honor.

THE COURT: All right. Are we ready to bring the jury in?

You had objections to the witnesses, but I think two of those objections or one of the witnesses and one of the issues is contingent on willfulness being an issue for the trial, which it's not.

MR. WALTERS: That's right, Your Honor --

THE COURT: But then you moved to strike, as it ended up, one paragraph from the defendants' witness's

testimony. So I'm assuming that only that paragraph 35 is an issue. The Court will decide that when it's time for that witness to testify, whether paragraph 35 is proper or not.

I think there's some merit to the contention -- the witness seems to be saying that if you take a series of natural phenomenon and combine them somehow, that that meets the test of 101. And I'm not sure if you can take a series of things that are natural phenomenon and, by making them into a series, satisfy 101. I don't see how you can add up several zeros to equal a one. But I'm going to have to reserve ruling on that until we get to the witness's testimony.

Now, the way we're going to deal with the jury is we put 12 jurors' names in the box. I explained that to you before. Do you have any questions about it?

MR. WALTERS: No, Your Honor. Ms. Baxter was very helpful this morning in letting us know how it works.

MS. GRAY: We have no questions, Your Honor.

THE COURT: All right. Then let's bring the jury in.

You have a jury consultant?

MR. WALTERS: We do, Your Honor. This is Jason Bloom.

MR. BLOOM: Good morning.

THE COURT: So he's not going to be there once we

select the jury?

MR. WALTERS: Right.

THE COURT: Normally, the Court reads the stipulations to the jury. However, the stipulations contain information that normally you wouldn't read to a jury. For example, the stipulation on damages. It says what damages the defendant would pay, and then it says that they're not agreeing that it's a reasonable royalty.

So I don't see any sense in bringing that to the attention of the jury. In the other stipulation, there's also surplusage. So I think counsel should look at the two stipulations and eliminate the surplusage. And then, thereafter, the Court will read the stipulations to the jury.

Now, the Court is accepting the stipulations in toto. So I'm accepting the stipulations. So they're in the record. You get the difference.

(The jury panel entered the courtroom.)

THE CLERK: Civil Action No. 2:17cv108, Plaintiff Genetic Veterinary Sciences, Inc., a Washington corporation, doing business as Paw Prints Genetics vs. Defendant LABOklin GmbH and Co. KG, a German company, and Defendant the University of Bern, an agency or instrumentality of Switzerland.

Counsel for the plaintiff, are you ready to proceed?

MR. WALTERS: We are, Your Honor.

THE CLERK: Counsel for defendants, are you ready to proceed?

MS. GRAY: We are, Your Honor.

MR. PIERY: Yes.

THE CLERK: Thank you.

THE COURT: All right. Ladies and gentlemen, you are here today to serve as the jury panel. 12 of you members will be selected to serve on the jury and decide this civil case between the plaintiff and the defendant.

There are obviously many more than 12 of you here today, and the reason that we have many more than 12 here today is that both sides have the right to exercise what are called preemptory strikes, that is, to remove any person from the jury for any reason whatsoever as long as the reason is not illegal. It's up to the Court to decide whether the reason is illegal.

The Court will also be questioning you to determine if you might not be a fair and impartial juror in this case. I'm not suggesting, and the parties are not suggesting, that you're not a fair and impartial person. The question is, rather, is there anything about this case that might affect your fairness and impartiality, and if so, the Court will excuse you as a juror in the case.

You shouldn't draw any negative inference from the fact that you're excused. It's just that if your

brother-in-law is one of the attorneys or works for one of the parties, it might create the perception that you're not fair and impartial. And it's important, not only that you be fair and impartial, but also, that there's nothing about your background that suggests you would be anything other than fair and impartial.

Now, when I ask you these questions, they're limited in scope because I don't know much about you, other than what you put on your jury registration card, and that's just very basic information. So I cannot look into your minds to see if there's anything about this case that might cause you to be something other than fair and impartial. So when the questions are asked to you, you should give the questions the broadest possible interpretation in deciding whether to answer and offer information.

There may also be information about you that you think that the Court and the parties are entitled to know which does not come within the scope of the questions I ask. If that is the case, you should volunteer such information, and you should be aggressive and not passive in volunteering such information because our purpose here is to select a fair and impartial jury, but we cannot do it without your help.

At this time, the clerk will call the roll of the jurors.

THE CLERK: Jurors, when I call your name, remain

standing until the next name is called, and then you may have a seat. And also, please, answer "yes," "here," "present."

Joyce Elizabeth Almond.

JUROR 1: Here.

THE CLERK: Carleton Apelu Bitgood.

JUROR 2: Here.

THE CLERK: Jacob Christian Blythe.

JUROR 3: Here.

THE CLERK: Paula Virginia Lee Bond.

JUROR 4: Here.

THE CLERK: Stephen David Brook.

JUROR 5: Here.

THE CLERK: Perry Lieard Burritt.

JUROR 6: Here.

THE CLERK: Amber Lyn Bush.

JUROR 7: Here.

THE CLERK: Katie Catania.

JUROR 8: Here.

THE CLERK: Gary Arthur Coderre, Jr.

JUROR 9: Present.

THE CLERK: James Thomas Farrow.

JUROR 10: Here.

THE CLERK: Brian Randall Hansen.

JUROR 11: Here.

THE CLERK: Stephanie Brammer Hierstein.

JUROR 12: Here.
THE CLERK: Rosemary Stoltz Hill.
JUROR 13: Here.
THE CLERK: Maria del Carmen Huggard.
JUROR 14: Here.
THE CLERK: Brittany Ann Lery.
JUROR 15: Here.
THE CLERK: Mark Jeffrey Manthey.
JUROR 16: Here.
THE CLERK: Jesse Wade Neville.
JUROR 17: Here.
THE CLERK: Susan Thumm Paxton.
JUROR 18: Here.
THE CLERK: Amanda Marie Rhodes.
JUROR 19: Here.
THE CLERK: Michael Edward Roberson.
JUROR 20: Here.
THE CLERK: Nancy K. Ross.
JUROR 21: Here.
THE CLERK: Andrew Martin Schaubach.
JUROR 22: Here.
THE CLERK: James Edward Scott.
JUROR 23: Here.
THE CLERK: Angel Alberta Simmons.
JUROR 24: Here.

THE CLERK: Matthew Malcolm Smith.
JUROR 25: Here.
THE CLERK: Marshall Wayne Snead.
JUROR 26: Here.
THE CLERK: Deanna Michelle Sterling.
JUROR 27: Here.
THE CLERK: Mary Ellen Teaford.
JUROR 28: Here.
THE CLERK: Regina Barden Thomas.
JUROR 29: Here.
THE CLERK: Rajesh Sobhnath Upadhaya.
JUROR 30: Here.
THE CLERK: Hope Diane Veenstra.
JUROR 31: Here.
THE CLERK: And Christina White.
JUROR 32: Here.
THE CLERK: Your Honor, there are 32 jurors present.
THE COURT: All right. Do you want to administer the oath?
THE CLERK: Yes, sir. I would love to administer the oath.
Members of the jury, will you, please, stand and raise your right hand.
You shall true and perfect answer make to such questions as may be propounded to you by the Court or the

counsel so help you God?

(All having answered affirmatively, the jury panel was duly sworn.)

THE CLERK: Thank you. You may be seated.

THE COURT: All right. Ladies and gentlemen, we are now going to begin the jury selection process which starts with the voir dire examination of the jury by the Judge.

Now, before we begin this, I want to introduce everyone to you.

Seated immediately in front of me is Lori Baxter who is the courtroom deputy. It's her job to keep track of all the documents in the case, administer the oath to the jury and the witnesses, and otherwise assist the Court in the trial.

Right in front of Ms. Baxter is Carol Naughton who is the court reporter. She transcribes the proceedings. However, I want to caution you that a transcription of the testimony of all the witnesses will not be available to you during your deliberation.

It's up to you to listen to the testimony of the witnesses and to observe the exhibits as they're introduced. The exhibits will go into the jury room with you, and you'll have an opportunity to examine them during your deliberations, but you better listen carefully to what the witnesses say.

Experience has taught us that when we have 12 unbiased people deciding a case, that they will be able to collectively remember the evidence sufficiently to render a fair and impartial verdict, assuming, of course, that the jurors consult with one another because not all 12 jurors are going to remember every important fact in the case, but collectively, you will. So you'll listen to each other during your deliberations, and by that means, remember what you need to remember to render your verdict.

To my left is Kendra Johnson. She is the law clerk who assists the Court during the trial with legal issues that arise, and she also helps with the handling of the swearing in of witnesses and with documents that come before the Court.

To my right is Dale Spatz who is the court security officer. It's his job to maintain decorum in the court and also to assist with the handling of exhibits during the trial.

To his right is a judge from Japan. He's here as an observer to see how trials are conducted in the United States. He does not participate in the proceeding. He's here as an observer. And rather than mispronounce his name, I will tell you that we call him Kimi.

My name is Henry Morgan. I'm the Judge who will be presiding over the case.

Now, the purpose of the voir dire examination is to select 12 impartial jurors to decide the case. We can't assume that everybody is fair and impartial in this case without asking certain questions of you, and the purpose of the questions is to develop a knowledge of whether there's anything in your background or in your relations or personal or family that might affect your ability to be a fair and impartial juror.

If you fail to answer the questions or give an incomplete answer to the question, that may result in us seating someone who is not fair and impartial. So it's important that you answer the questions fully and fairly.

I'm going to ask questions to you collectively; that is, I direct my questions to you as a group. It's always difficult to separate yourself from a group in a situation like this and stand up and say something. We all understand that. And people have a natural reluctance to do that, but for our purposes, you've got to overcome that reluctance and give us the information if you believe that we're entitled to have it, and even if it's not responsive to a question specifically.

Now, the first two questions I ask you are rather standard, but we have to ask them in all cases. So my first question to you is:

Are each and every one of you able to read, write,

and speak the English language sufficiently to understand the testimony of the witness and the content of documents that are presented here in court? If you are able to do that, please stand at this time.

My second question is: Are you able to see and hear well enough to read the exhibits on the prompter that we have for each of you, and can you understand them sufficiently because of your command of the English language?

Now, when I ask you if you can see and hear well enough, I don't mean do you need glasses or hearing aids, because I need both myself, but can you, with the assistance of same, understand the evidence? If you believe you can do that, please sit down.

All right. Now, from now on, the questions I ask you will be answered by standing. In other words, if there's any information you believe the Court is entitled to in response to the question or otherwise related to the question, please stand, and I'll call on you one by one to explain what your particular answer is based on.

Now, I'm going to begin by having the parties introduce themselves, identify who they represent, and identify, also, their corporate representative. The reason I'm doing that is because I'm going to ask whether you have any relationship to the people or to the parties they represent.

So I'll start with the plaintiff.

MR. WALTERS: Good morning, ladies and gentlemen. My name is Mark Walters. With me is Joshua Cumby, Jason Bloom, and then our corporate representative is Dr. Lisa Shaffer.

MS. GRAY: Good morning, ladies and gentlemen. I'm Nikia Gray, and with me, I have Johanna Wilbert, Christian Stahl, and Michael Piery. And then we have our corporate representative Elisabeth Müller from LABOklin. And we also represent the University of Bern.

THE COURT: All right. I believe the clerk has identified the parties, but I'm going to ask counsel to, again, state the law firms which they're associated and the name of the party that they represent.

MR. WALTERS: So we represent a company called Genetic Veterinary Sciences, Inc. It does business under the name Paw Print Genetics, or we sometimes refer to it as PPG. And I'm with the law firm of Lowe, Graham & Jones in Seattle, and Josh is from the law firm here in D.C., Venable, and Mr. Bloom is from Bloom Strategies.

MS. GRAY: Myself and my co-counsel are from Quarles & Brady, and then Dr. Elisabeth Müller is from LABOklin, and our other client is the University of Bern.

THE COURT: Thank you.

All right. Ladies and gentlemen, are any of you

related by blood or marriage to any of the attorneys, any member of the firms with which they're associated, or any employee of the corporations they represent or to the corporate representatives who are here today?

Seeing no one standing, I assume that your answer would be negative to that question.

All right. This case arises out of a patent that relates to an in vitro method for genotyping Labrador Retrievers.

Are any of you familiar with treating Labrador Retrievers for any particular medical attention, or are you involved in the treatment of canines in any way?

All right. Do any of you own a patent or work with a patent in your work?

All right. I'm going to ask you a question which will, I'm sure, elicit some yeses for a change. I would like each member of the jury panel who has previously served on a jury -- now, you're not serving on a jury at the moment. You're just on the panel.

So my question is not directed to whether you've ever been on a panel from which a jury was selected, but rather, have you ever actually served on a jury which returned a verdict?

Whether it was in this state or another state or in federal court or state court, if you ever served on a jury

which returned a verdict before, please stand.

All right. Now, I want four items of information from you. I'm going to start with the lady on my left. First of all, whenever you answer a question, always begin by giving us your name and then tell us what court you served in and whether it was a civil or criminal case.

A criminal case, of course, is where you decided there was somebody guilty or not guilty. A civil case is one where you were asked to award some form of damages, monetary or otherwise, in favor of one party against another.

All right. I'll start with you, ma'am.

JUROR 29: My name is Regina Thomas.

THE COURT: Can you speak a little louder?

JUROR 29: My name is Regina Thomas. I served in the Virginia Beach court, and it was a civil case.

THE COURT: And did you award damages or not?

JUROR 29: Yes.

THE COURT: You did award damages?

JUROR 29: Yes.

THE COURT: Thank you. Well, let me ask you this. Is there anything about the service in that case that you think would affect your fairness and impartiality in this case?

JUROR 29: No.

THE COURT: Yes, ma'am.

JUROR 13: Rosemary Stoltz Hill. I served in New Orleans, and it was a civil case, personal injury-type civil case.

THE COURT: Did you award damages or no?

JUROR 13: Yes.

THE COURT: Was there anything about your service in that case that you think would affect your ability to be a fair and impartial juror in this case?

JUROR 13: No.

THE COURT: Thank you, ma'am.

Yes, ma'am?

JUROR 21: My name is Nancy Ross. I served in this particular court on a criminal case and City of Chesapeake in a civil case.

THE COURT: Did you say the case in this court was a criminal case?

JUROR 21: Yes. Social Security fraud.

THE COURT: Did you find the defendant guilty or not guilty?

JUROR 21: Guilty.

THE COURT: What about the civil case? Did you award damages or not?

JUROR 21: Yes, Your Honor, we did.

THE COURT: Is there anything about your service in either one of those cases that you think would affect your

ability to be a fair and impartial juror on this case?

JUROR 21: No, there's not.

THE COURT: You may have a seat.

I'm going to read a list of witnesses who will or may testify in the case. If you think that you know any of these people, as I call their names, please stand.

Dr. Lisa Shaffer.

Dr. Blake Ballif.

Dr. Elisabeth Müller.

Dr. Tosso Leeb.

Dr. Steven Friedenberg.

Anybody know any of those people?

Are there any other witnesses who I haven't identified, counsel, that will or may be called?

MS. GRAY: No, Your Honor.

MR. WALTERS: No, Your Honor.

THE COURT: All right. If you're selected to serve as a juror on this case, you must put aside any feelings of bias or prejudice or passion for or against either side based upon any reason whatsoever and decide the case solely on the basis of the evidence you hear in court and the instructions as the Court gives them to you.

The Court will decide the legal issues in the case, and you will decide the facts of the case. I will give you an introductory statement about what this case is about, and

at the conclusion of the evidence, the Court will give you written instructions which will be read to you and which you will also have the opportunity to take into the jury room during your deliberations.

You must decide the case, as I say, in accordance with the law as the Court gives it to you and the evidence as you hear it here in court. There's going to be some technical terms used in this case. You may not research, yourself, any technical term which you don't understand.

Like you, I'm going to be hearing many technical terms which I don't understand. It's up to counsel to present them in such a way that we can understand them. If you don't understand them, you can give a note to our court security officer, and he will give it to me, and we'll try to clarify anything that's not clear to you.

Now, you must remember that the evidence will be presented one question at a time, one exhibit at a time, and so the fact that you don't understand something fully after you hear a few questions of the first witness doesn't mean that you need an explanation. But at some point, if something remains unclear to you, you may need an explanation. Don't hesitate to notify the court security officer or me, the Judge, if you believe that you need further explanation, but what you may not do is conduct your own research on terms.

Unfortunately, with the growth of electronic communications and the internet, there have been instances where jurors have looked things up on the internet. That is entirely incorrect. If you do that, you are violating your oath as jurors. You must issue a verdict upon the evidence presented here in Court.

And there's a reason for that. If you research something, then you're the only one who's seen it. All the jurors must hear the evidence. Not just one. And one person who conducts some research wouldn't be reasonable to try to explain that to all the other jurors.

One of the rules that the Court has, and one of the most important rules, is that all of the jurors have to be present when evidence is presented. So by all means, don't try to research anything in any manner outside of the courtroom. You must base your verdict on what you hear inside the courtroom.

Now, is there anyone who has any information that they believe might affect their fairness and impartiality or might call into question their fairness and impartiality if it were publicly known? Because, remember, not only is it your duty and my duty to be fair and impartial, but it's also our duties not to behave in such a way that calls our fairness and impartiality into question.

Yes, sir?

JUROR 9: My name is Gary Coderre. I'm a believer in jury nullification, and if I do not believe in the right of one party over another, then I can't separate myself from that to give a judgment.

THE COURT: All right. Thank you. You may have a seat.

Anyone else?

I'll ask counsel to approach the bench.

Ladies and gentlemen, at times during the trial, it will be necessary for the Court to ask counsel to approach the bench. And we will be up here whispering, and if you think we're doing that so that you can't hear us, you'd be correct.

But there's a reason for that. We have to take up issues outside the hearing of the jury on occasion. And one way of doing it would be to ask all of you to step out of the courtroom, which is -- takes too much time and is otherwise inconvenient to everyone. So instead of doing that, we have a conference up here at the bench.

Now, remember, don't try to listen in to what we're saying up here. And remember, also, that when you go to the jury room to deliberate and decide the case, we're not going to be listening to you. You're entitled to do that in confidence and there are times when we have to have conferences which remain in confidence.

(Sidebar conference:)

THE COURT: Any follow-up?

MR. WALTERS: Do any of them have any scientific training or experience?

THE COURT: I'm afraid of a question like that because what one person thinks is scientific training and experience, somebody else might not. I asked them if they knew anything about the patent and the trademark.

MR. WALTERS: How about if any of them are dog owners?

MS. GRAY: What about the question if any of them have any religious or strong beliefs that would prevent them from deciding this case?

THE COURT: Well, I'm not going to focus on any one thing like religion.

MS. GRAY: What about dog rescue?

THE COURT: I don't think it would serve any purpose to ask a question like that. They'll, of course, be instructed if they can consider such things, but it has to do with nationality, religion, et cetera, not just religion.

MR. WALTERS: How about any government service, if any of them have worked for the government in the past or worked for the Patent Office or anything like that?

THE COURT: Well, I can ask them if they've ever dealt with the Patent Office. I think that's fair.

MS. GRAY: Thank you, Your Honor.

(End of sidebar conference.)

THE COURT: I'm going to use the term "relatives" for those closely related to you. Have any of you or any relative who's closely related -- and by "closely related," I mean any relative who has ever lived with you or who now lives with you -- or any person to whom you're particularly close, who is a relative or even a friend, ever worked for the United States Patent and Trademark Office?

Yes, sir? Would you give us your name?

JUROR 10: My name is James Farrow. My daughter is a patent -- I guess patent agent.

THE COURT: What does she do?

JUROR 10: She reviews patents.

THE COURT: She works for the Patent Office?

JUROR 10: Yes, she works for the Patent Office. She reviews patents.

THE COURT: Do you think that would affect your ability to be a fair and impartial juror in this case?

JUROR 10: No, sir.

THE COURT: Thank you.

Now, we're about to begin the second phase of the jury selection process, ladies and gentlemen. And this is where the attorneys have the right to exercise what we call a preemptory strike. What that means is that they can strike

you for any reason they want as long as it's not an illegal reason, and the Court is the judge of whether or not it's an illegal reason.

Now, it's an imperfect science, as I can tell you, because I practiced law for many years before I became a judge, and I went through this process of exercising preemptory strikes, and it's not an exact science, and it's not intended to be a negative inference against anybody if they're not selected.

Some lawyers don't like people who wear neckties to court, men who wear neckties. Some don't like women who wear jewelry or maybe women who don't wear jewelry. I just say that because it shows you how random the selection process is.

Now, because of the number of jurors and because there was very little I heard from you today that would cause you to be disqualified, there are many more of you than will be selected. What the clerk does is pick names randomly from among you and put them in this board and passes the board to counsel, and they can remove your name from the board. That's how they would strike you.

Because of the number of jurors, many of your names will not even get in the board to start with. So the fact that you're not selected doesn't mean -- it's certainly nothing negative about you because you may never have had the

opportunity to be selected. We have to have a lot of people here in case there are a number of people who are disqualified for cause, which was not the case today.

So as I've said several times, don't draw any negative inference from the fact that you weren't selected to serve.

Now, while the attorneys are selecting their preemptory strikes, I'm going to talk to you about some basic issues which you as jurors should understand. And these are general comments that apply to all jurors, not necessarily this case specifically.

The first is that as jurors, your job is to decide the facts of the case. For example, if one witness says the light was red and another witness says the light was green, you have to decide which witness to believe.

But if the Court gave you the instruction and then said that the plaintiff has to prove the light was green by a preponderance of the evidence, then you would be the judge of whether the plaintiff has proven it as well as which witness is telling the truth.

So as I said, the Court decides the law. You decide the evidence. In deciding the evidence, you may believe or disbelieve the testimony of any witness based on the witness's behavior, the witness's interest in the case, whether you think the witness has sufficient information to

testify as to what he or she has said, and in the case of expert witnesses, whether you believe the expert witness has sufficient training and background and knowledge to give the opinion that the expert witness has given.

Ordinarily, witnesses who are not experts may not give opinions, although there may be exceptions to that rule. But an expert witness, you should judge their credibility the same way you would with any other witness; plus, you should weigh their background, education, training, and experience and also the facts upon which they base their testimony in deciding the weight to give their testimony.

You are also the judge of the weight of the evidence. Now, in this case, the issue which you have to decide, which is whether or not the patent is valid, has a different standard of proof than most cases.

In criminal cases, you probably have heard the term proof beyond a reasonable doubt. In civil cases, you may have heard the term by a preponderance of the evidence. In this case, the burden rests with the plaintiff to prove by what is called clear and convincing evidence that the patent in issue is invalid.

Clear and convincing evidence is a standard somewhere between reasonable doubt, which is a higher level of proof, and preponderance of the evidence, which is a lower level of proof. So clear and convincing is between those

two, and that's the standard you'll apply in this case. And you will make that decision on what you hear in court.

Now, as I said, you're going to hear a lot of scientific terms that will be strange to you, and it's up to the counsel in presenting this evidence to present it in a way that you and I can understand.

Let me talk about your behavior as jurors. We have a rule that you might think is sort of counterintuitive; and that is, you, as jurors, may not discuss the case with anyone, including each other, until you begin your deliberations. The reason for that is that all jurors must be present when the evidence is discussed. If you decide to go out to lunch with another juror or jurors, that's fine. If you decide to ride into court with somebody, that's fine. But you can't talk about the case because you cannot do that unless all jurors are present.

The second reason is that you're supposed to remain open-minded until you've heard all the evidence and the instructions of the Court. So that's why it's inappropriate for you to discuss the case among yourselves or let anyone discuss the case with you before you begin your deliberations because you will not have received the Court's instructions on the law applicable to the case until you begin your deliberations, and you will not have heard the closing arguments of the attorneys before you begin your

deliberations. And both of those are very important proceedings in the case.

Now, the case will begin with opening statements from each counsel. Those opening statements are not evidence, but they're very important because the attorneys will outline what they expect the evidence to be.

And since you will hear the evidence and see the exhibits one at a time, the opening statements will help you put that evidence in context so that the very first question asked, hopefully you will be able to understand why it's being asked. You may not, because evidence builds on itself and it's sometimes difficult to understand evidence until you have some background upon which to measure that evidence. And that's, of course, why you can't discuss the evidence until it's concluded.

But the opening statements are very important. They're like a roadmap which will teach you to get from point A to point B. Of course, nowadays, you don't have to read a map anymore. You just look at your iPhone or something that tells you where to turn. We don't have anything like that for you here today. So listen to the opening statements because they should be helpful to you.

But they're not evidence. So if somebody has to prove the light is green and the attorney says the light is green in the opening statement, that's not evidence. That's

just what the attorney projects the evidence will show. It's up to you to decide whether they have proven the light is green.

Now, the party with the burden of proof normally presents its evidence first. So that means the plaintiff goes first and then the defendant. On some occasions, the plaintiff is entitled to present rebuttal evidence because, again, the plaintiff has the burden of proof.

At the end of the case, when the parties make their closing arguments, the plaintiff gets to make the first argument, the defendant then argues, and then the plaintiff gets to make a rebuttal. I'm sure the defendant would like to present what we call surrebuttal, but that's not permitted in this particular case.

The reason that it's set up that way is because the plaintiff has the burden of proof. That's why they get to present their evidence first, and that's why they get to present a rebuttal argument in response to the defendant's closing.

After the opening statements, you will, for the first time, hear evidence in the case. That evidence may be in the form of questions or exhibits or physical evidence, an object. I don't know if there's any such evidence in this case.

A question is not evidence until it's answered.

Both parties have the duty to object when they believe that the other side is trying to ask a question to elicit evidence which is not proper.

Now, if you've watched trials on TV or the movies which, by the way, are designed to entertain you, not educate you, you will see sometimes that an attorney will ask a question, and the judge will glare at the attorney because the attorney knows the question being asked is improper, and the Court will say sustained, and then you'll see a shot of the attorney walking back to the counsel table with a smirk on their face as if to say, I have suggested this even though I can't answer the question.

Well, that sort of behavior is improper, and I don't expect the attorneys in this case to indulge in it. But it illustrates the point which is the question itself is not evidence until it's answered. Sometimes the answer may be yes or no. So the question places the yes and no in context, but the question is not evidence until it's answered and unless it's answered. Because if the Court sustains an objection to the question, you must act as if the question had never been asked because the question is eliciting information that's not proper evidence in this case.

Now, sometimes it's difficult to determine whether a question is proper, and sometimes the attorneys in the case may have a difference of opinion from that of the Court. So

every time an objection is sustained doesn't mean that the lawyer who asked that question should be punished for asking it. They may have believed in their own mind that the question was proper, but if they think it's improper, it's their duty to object. So you shouldn't hold it against them if they make an objection whether it's sustained or not. But you must ignore the question if the objection to it is sustained.

Occasionally, the answer will come out before I have a chance to rule. And I may have to ask you to disregard the question and the answer. It's always difficult to disregard something you've already heard. So we try to not let that happen, but despite our best efforts, it does happen on occasion. If the Court instructs you to disregard something you've heard, you have to do to it, however difficult that may be.

Now, exhibits will usually be shown to you on the screen that's in front of you. Sometimes you won't have a chance to read that exhibit as closely as you'd like or look at it for as long as you'd like. If that happens, don't worry because all the exhibits will go into the jury room with you and you'll have an opportunity to examine them at your leisure.

If during the case you're wondering what your standard should be in deciding the case, bear in mind that at

the conclusion of the evidence and the arguments of counsel, the Court will give you written instructions which you can take into the jury room with you. You may ask why am I going to read them to you if you're going to have them in writing and take them into the jury room?

Well, there are various reasons for that. One is that I read the instructions to you before the attorneys argue the case, and their arguments, to a degree, will be based on the Court's instructions. So it will help you understand the closing arguments of the attorneys better if you hear the instructions before they argue.

And hopefully, it will help you absorb the instructions by having them read to you as well as being able to read them yourself because, of course, the case must be decided in accordance with the instructions.

Now, let me say something to you about your behavior as jurors. One thing that you don't want to do is overhear anything that happens outside of court. Sometimes witnesses or attorneys may be talking about the case outside the court. So you've got to avoid inadvertently hearing what they say because if you do hear it, it might affect your thinking, and you cannot be affected by anything you hear outside the courtroom.

THE CLERK: We have a panel.

THE COURT: So it's important that you not do that.

It's fine to say good morning or good afternoon to anybody you run into or that you recognize, but don't allow yourself to get into a conversation with anybody you don't know because that person might be a witness in the case, and if one side sees you talking to the other side's witnesses, it will create a perception that perhaps you're not being fair and impartial.

All right. I think we now have a panel. So what we're going to do, since some of you are sitting in the jury box, each time a juror comes in the box, I'll ask you to come out this side if your name is not called. You might end up doing a circle, stepping out and coming back in. But we just don't have any more room.

So when each juror's name is called, I'm going to ask that juror to have a seat in the jury box, and one by one, I'll ask the jurors to step out, beginning with the jurors on the first row.

Please read the names of the jurors selected.

THE CLERK: You heard the Judge. So members of the jury: Stephen David Brook, Amber Lyn Bush, Katie Catania, Stephanie Brammer Hierstein, Rosemary Stoltz Hill, Brittany Ann Lery, Jesse Wade Neville, Susan Thumm Paxton, Amanda Marie Rhodes, Nancy K. Ross, James Edward Scott, and Christina White.

Members of the jury, I'm going to call the roll

again, and this time, please, answer "yes," "present," or "here."

Stephen Brook.

JUROR 5: Here.

THE CLERK: Amber Bush.

JUROR 7: Here.

THE CLERK: Katie Catania.

JUROR 8: Here.

THE CLERK: Stephanie Hierstein.

JUROR 12: Here.

THE CLERK: Rosemary Hill.

JUROR 13: Here.

THE CLERK: Brittany Lery.

JUROR 15: Here.

THE CLERK: Jesse Neville.

JUROR 17: Here.

THE CLERK: Susan Paxton.

JUROR 18: Here.

THE CLERK: Amanda Rhodes.

JUROR 19: Here.

THE CLERK: Nancy Ross.

JUROR 21: Here.

THE CLERK: James Scott.

JUROR 23: Here.

THE CLERK: Christina White.

JUROR 32: Here.

THE CLERK: Members of the jury, will you, please, stand and raise your right hand?

You shall well and truly try the issues joined between Genetic Veterinary Sciences, Inc., doing business as Paw Prints Genetics vs. Defendant LABOklin GmbH and Co. KG, a German company, and Defendant the University of Bern, an agency or instrumentality of Switzerland, and a true verdict give according to the evidence, so help you God?

(The jury answered in the affirmative.)

THE CLERK: Thank you.

THE COURT: All right. Ladies and gentlemen, we normally take a 15-minute recess in the middle of the morning each day of trial and another one in the middle of the afternoon. We go from 10:00 to 1:00. So we're now just about the middle of the morning. So we'll take a 15-minute recess at this time. And you may step into the jury room.

(The jury exited the courtroom.)

THE COURT: Ladies and gentlemen, I want to thank those of you who have come here today as members of the panel. For the reasons I explained to you, we have to bring many more jurors into court than end up serving, but by being here today ready, willing, and able to serve, you have done your duty, and the Court appreciates it. I don't know when your term as jurors expires, but from now until the time that

it does expire, you should keep up your regular communications with the court's jury staff as you have done up until now.

I want to thank you for being here, and you're excused with the thanks of the Court. You can stay here and watch if you want. Most people don't want to do that. Trials are open. So anybody that wants to watch has the right to do so. But those of you that want to leave may leave at this time.

(The jury panel exited the courtroom.)

THE COURT: All right. Counsel, I find that the preliminary instructions that the defendant submitted are on target, with the exception of their mention of infringement, which I'm deleting from it, but other than that, I'm going to use the preliminary instructions as submitted by the defendant to the jury in lieu of showing the film or any part thereof.

We'll take a recess and resume at 20 minutes to 12:00.

(A brief recess was taken.)

THE COURT: All right. Counsel, I have edited defendants' preliminary instructions to remove any reference to infringement. There's no reason for the term "infringement" much less "willful infringement" to be used by counsel or any witnesses during the case, and the witnesses

should be so advised. The stipulation is that we're trying this case on the issue of validity only. So it will be confined to that. There were a couple of minor edits that I made to the instructions other than infringement, but they were just -- for example, it says, "human body." I put "human or animal body." And it says, "I must decide," and I changed it to, "You must decide," which is the jury.

So with those changes, I've adopted the defendants' preliminary instructions.

MR. WALTERS: Your Honor, if I may, there were some instructions that they called preliminary, but were more in the nature of what the standard will be as given to the jury on the issue of subject matter eligibility, and so we have objections to those, and I just want to clarify, you're not going to read those yet until we have an opportunity to hear that?

THE COURT: Well, the one that says subject matter eligibility, yes. I'm intending to read that.

MR. WALTERS: Okay. Well, Your Honor, we have some objections to that. We've given them to you in a brief last night. It's not the standard for *Alice*. It's not the Supreme Court standard.

THE COURT: Well, you gave them to me last night. I haven't had a chance to look at your objections to which you gave me last night.

MR. WALTERS: Our request would be we read the preliminary instructions, just tell them what this case is about, and that we reserve the substantive instruction on the legal standard until we've had an opportunity to really consider what the proper legal standard is.

THE COURT: I'm only going to read them the introductory paragraph for their instruction. I'm not going to read the first, second, and third, because I think that does need some refining. But the introductory paragraph, I think is appropriate.

MR. PIERY: Your Honor, we think it would be helpful to have the jury instructed on subject matter eligibility and the first, second, and third steps.

THE COURT: No. Not going to do it. That's a final instruction. They don't need that as an introduction. I'm not sure I agree with the way you stated those, and they don't need that now. They need that when they have heard all the evidence.

MR. PIERY: Thank you, Your Honor.

THE COURT: All right. Now, we understand each other; we're not using the terms "infringement" and "willful infringement." We're talking validity. We're not using terms like "obvious" or whatever either. It's strictly validity under 101.

You may bring the jury in.

(The jury entered the courtroom.)

THE COURT: All right. Ladies and gentlemen -- I notice you have a book with you. Do you have a book with you?

THE JUROR: Yes, sir.

THE COURT: What is that?

THE JUROR: It's just a book, sir.

THE COURT: Just something to read during the downtime? Is that what you're saying?

THE JUROR: Well, in the break room, Your Honor. Do you want me to leave it in there?

THE COURT: Yeah. I don't think you'll have any downtime while you're in the jury box.

THE JUROR: I don't expect to have any downtime here, sir.

THE COURT: I'm going to give you some instructions that have to do with what a patent is and how it's obtained. And when I finish this, I'm going to give each of you a copy of the patent for you to keep. I'm not going to give you a copy of the patent before I read this to you because I don't want you looking at it while I'm giving you instruction, and I don't want you looking at the patent while evidence is being presented unless that evidence regards the content of the patent. In other words, I don't want you to be distracted because the evidence in the case will be

complicated.

All right. This is a patent case. It involves U.S. Patent Number 9,157,114. Patents are often referred to by their last 3 digits. I will call the patent in this case the '114 Patent.

The '114 Patent relates to an in vitro method for genotyping a Labrador Retriever. During the trial, the parties will offer testimony to familiarize you with this technology. Plaintiff contends that claims 1 through 3 of the '114 Patent are invalid. Defendant contends that claims 1 through 3 of the patent are valid. Claims 4 and 5 have no involvement in this case.

I will explain these contentions to you later. First, I will give you some background about the U.S. patent system, the parts of a patent, and how a person gets a patent. Patents are issued by the United States Patent and Trademark Office, which is part of our government. A patent is granted to the inventor for a set period of time, which in this case is 20 years from the time the application for the patent was filed.

The invention covered by a patent is described in the part of the patent that is called the patent claim or patent claims. The patent claims are found in separately numbered paragraphs at the end of the patent. When I use the word "claim" or "claims," I am referring to those numbered

paragraphs.

When an applicant for a patent files a patent application with the Patent and Trademark Office, the application is assigned to a patent examiner. The patent examiner reviews the application to determine whether or not the invention described in the patent application, as set out in the claims, meets the requirements of the patent laws for patentable invention.

The patent examiner advises the applicant of his or her findings in a paper called an Office Action. The examiner may reject the claims, that is, refuse to issue a patent containing those claims if he or she believes the claims do not meet the requirements for patentable inventions.

The applicant may respond to the rejection with arguments to support the claims by making changes or amendments to the claims or by submitting new claims. If the examiner ultimately determines that the legal requirements for a patent have all been satisfied, he or she allows the claims and the Patent and Trademark Office issues a patent.

This process, from the filing of the patent application to the issuance of the patent, is called patent prosecution. The record of papers relating to the patent prosecution is called the prosecution history or file history. The prosecution history becomes available to the

public when the patent has issued or the application is published by the PTO -- PTO means Patent and Trademark Office -- normally 18 months after filing.

A patent includes two basic parts, a written description of the invention and the patent claims. The written description, which may include drawings, is often called the specification of the patent.

You have been provided with a copy of the '114 Patent. Well, you haven't, but you will be as soon as I finish reading these instructions. Please look at the patent as I identify different sections. Well, you can't do that.

The first page of the '114 Patent provides identifying information, including the date the patent issued and the patent number along the top, as well as the inventor's name, the filing date, and a list of the prior art publications considered in the Patent Office during the time the patent was being sought.

The specification of the patent begins with a brief statement about the subject matter of the invention which is called an abstract. This is found on the first page. Next are the drawings, which appear as Figures 1 to 6 on the next six pages. The drawings depict various aspects or features of the invention. They are described in words later in this patent specification.

The written description of the invention appears

next. In this portion of the patent, each page is divided into two columns which are numbered at the top of the page. The lines on each page are also numbered. The written description of the '114 Patent begins at column 1, line 1 and continues to columns 15 and 16, lines 1 through 9. It includes a background section, a summary of the invention, and a detailed description of the invention, including some specific examples.

The written description is followed by one or more numbered paragraphs which are called the claims. The claims may be divided into a number of parts or steps which are called claim limitations or claim requirements. In the patent, the claims begin at column 15, line 11 and continue to the end of the patent at column 16, line 33.

Now, you'll have that in just a minute.

The claims of the patent define the invention covered by the patent. In other words, the claims describe what the patent does and does not cover, somewhat like the way a property deed describes the boundaries of a parcel of land. The claims are also at issue when the validity of a patent is challenged.

In reaching your determinations, you must consider each claim of the patent separately. In this case, we're concerned with claims 1 through 3 of the '114 Patent. Defendants contend that the '114 Patent is valid. Plaintiff

contends that claims 1 through 3 are invalid.

The law presumes each claim of the '114 Patent to be valid. For this reason, plaintiff has the burden of proving invalidity by clear and convincing evidence. Clear and convincing evidence has the same definition that I outlined to you.

I will now explain to you briefly the legal requirements for the ground on which plaintiff relies to contend that the patent claims are invalid. I will provide more details for the ground in my final instructions.

Certain types of claims are ineligible for patent protection. These include claims that recite natural laws, such as Einstein's E equals MC squared, claims that recite natural phenomenon, such as natural processes that occur within the human or animal body, and abstract ideas such as pure mathematical equations.

If a claim is directed to one of these ineligible categories of subject matter, then the claim may be invalid. A claim is directed to an ineligible category if it merely recites or describe the ineligible concept. A claim is not directed to an ineligible category if it recites new and useful method.

If a claim is directed to one of these ineligible categories, such a claim may still be valid if it recites enough detail and substance apart from the ineligible concept

itself to transfer the claim into an inventive concept.

You must decide whether claims 1 through 3 of the '114 Patent are developed to a natural law, natural phenomenon, or abstract idea, and if so, whether any of the claims 1 through 3 of the '114 Patent recites enough to qualify as a patent eligible application of a natural law, natural phenomenon, or abstract idea.

All right. Miss Johnson, if you'd pass out the copies of the patent to the jury.

Ladies and gentlemen, I know that you would like to have more time to look through the patent, but at this time, we're going to hear the opening statements of the attorneys. The patent will be frequently referred to during the evidence and perhaps during the opening statements, but I want you to listen to the opening statements and the testimony of the witnesses. Don't try to read the patent while they're testifying or making their statements.

If they refer to the patent, then you can look at the part of the patent to which they tell you they're referring. I mean, not to do that, but you know what I'm getting it. It's important to listen to the opening statements and the testimony of the witnesses. So don't try to read the patent while they're testifying.

Is the plaintiff ready with its opening statement?

MR. WALTERS: Plaintiff is ready, Your Honor.

THE COURT: Okay.

MR. WALTERS: Good morning, ladies and gentlemen of the jury -- actually, afternoon now, just a little bit.

My name is Mark Walters. I represent Paw Print Genetics. Paw Print Genetics is a genetic testing company. It tests dogs for genetic diseases, mutations in the DNA code, to determine whether that particular dog is susceptible to a disease or may have a gene that is known to cause a disease.

I want to start with something that is probably pretty important to understand, and that is why are we here today? We are here today because a patent issued. It covers an important test for Labrador Retrievers that not only Paw Print Genetics needs to do but other researchers need to do.

LABOklin, the defendants, threatened PPG's business with this patent. The patent is invalid. It was issued by mistake. You can see the patent number here is above 9 million. They're getting close to 10 million patents now, and mistakes do happen, and this is one of them.

You're going to hear evidence about how that happened, you're going to hear evidence about the claims of the patent and what they cover, but we are here today because the only way to challenge the validity of this patent is to initiate this court proceeding. We can't sue the Patent Office, we can't go to the Patent Office on these grounds of

invalidity. In order to have the freedom to offer this test to customers and the ability for other researchers to do research on this particular mutation, the patent needs to be removed, and the cloud on that needs to be taken away, and you today have the power to do that.

Now, I want to tell you a little bit about Paw Print Genetics. It's based in Spokane, Washington. Spokane is a town on the eastern side of Washington, relative to Seattle, closer to the Idaho border. It's about 250,000 people. Paw Print Genetics employs three Ph.D.s, one of whom is Dr. Shaffer, who you will hear from today, two licensed veterinarians, doctors of veterinary medicine, who provide counseling to breeders, to dog owners, related to genetic and inherited disease. They employ 19 others at their facility in Spokane; mostly technicians, researchers, and clerical staff. They offer 180 different tests, and only one of those tests is at issue in this particular case, but it is an important test.

Now, PPG tests for what are called mutations, and the process of looking for whether a particular organism has a mutation is called genotyping. You're going to hear that word a lot in this case -- genotyping. It's been around for decades. It is a process that starts with taking a biological sample from any animal or plant and isolating the DNA material that exists in all of our cells.

Technology advanced quite a bit in the 1990s and 2000s. You're going to hear a little bit about that from Dr. Shaffer. It allowed us, this technology allowed us, to sequence entire genomes for organisms. It was an amazing technology. You may have heard about the Human Genome Project, the ability to actually read that genetic code and identify what that information means.

They can build genetic maps of the genome to isolate various areas in the genome that may be connected to disease. These maps allow us to look for these causes of disease. And you may have heard of some of these companies, like 23andMe or ancestry.com. What PPG does is similar to what those companies do. They use routine methods, methods that have been around for a long time, to isolate DNA and to read the genetic code in order to determine if this particular organism has a mutation in its genetic code. Those techniques are old, and they've been around for a long time.

Now, what Paw Print Genetics does as part of its business is it brings the human-quality genetic testing to the animal lab. Dr. Shaffer -- you'll hear from her -- has a background in human genetics, where it's a very highly regulated field. You can imagine people making irreversible and final decisions based on a test that they receive from a geneticist. So in the human world, you know, they might make a decision to take someone off life support or a woman who

might have the gene for breast cancer may undergo a mastectomy. Irreversible decisions, and so you need to get it right, and in the human world there are a lot of regulations to make sure that happens.

And in the animal world it's not so regulated, but what Paw Print Genetics has done is they've brought the strictest regulations into their lab in Spokane. They do a double screening method, so they'll test each sample with one method and then test it again with another method to confirm their result. And if that's still unclear, you'll hear from Dr. Shaffer that they'll even ask for another sample so that they can make sure that they give the right result.

It's very important that you guys understand today -- and you'll hear evidence about it -- that the way in which Paw Print Genetics looks for that genetic code has been around for a long time. You'll hear terms like PCR, you'll hear terms like primers. These sorts of things are ways in which scientists have been sequencing DNA for decades, and these are the same methods that Paw Print Genetics uses.

Now, another thing that Paw Print Genetics does -- sometimes I refer to them as PPG -- is they offer panels by a breed. So Labradors are known to have a certain set of diseases, and part of the evidence that you'll hear today from Dr. Shaffer is why she started Paw Print Genetics. She has a Dachshund, among other dogs, and when she sold her

company, called Signature Genomics -- it's in the human area -- she was looking to solve a problem that existed in the animal genetics testing area. She wanted to test her Dachshund, and she had to send the sample to all these different labs. So she thought, what we need to do is create a one-stop place where you can get all the tests that you need as a breeder or as a dog owner to know if your particular dog has a disease that is known to exist in the breed.

These breeds are hundreds of years old, and they've been bred in an intentional way, and so it's very important that the breeders know not to rebreed or to breed a dog that has this mutation that might cause disease. So you can carry a mutation, humans can, or dogs, or any organism can carry a mutation in their DNA code, but it may not manifest itself in a physical way.

We get half of our genes from our mom and half of our genes from our dad, and, in some cases, only when you have two copies of that mutation will you have the disease. But it's very important to know if you are a carrier so that you can avoid, if you're a breeder, to breed a dog with another carrier so that the disease doesn't exist and repeat itself in the breed.

Another thing that PPG offers are genetic counseling services. So it's one thing to have the test back, but it's

quite another to know what to do with that information. Paw Print Genetics provides that to breeders, provides it to customers, provides it on a pro bono basis. Regardless of where you get your tests, they will help you, because it's about improving the genetics for these breeds and not breeding mutations again and again inside a breed.

How it works is pretty simple. You take a swab, you swab it against the cheek of the animal, the dog, and then you send it to Paw Print Genetics, and they will have it tested. There's a website. You make an account, that sort of thing. In this sense it operates very, very similarly to some of the other human genetic testing companies you may have heard of, like ancestry.com or 23andMe.

You're going to hear today from Dr. Lisa Shaffer. You're going to hear from a lot of Ph.D.s, and she is one of them. She obtained her Ph.D. in 1990 from the Medical College of Virginia in Richmond. She is a board-certified geneticist, and she is a fellow of the American College of Genetics. She has over 300 peer-reviewed publications in genetics, she's won numerous awards, and she's worked in genetic labs since 1980.

I want to tell you a little bit about mutations. You're going to hear scientific evidence today, and I want to give you the overview of what I think you're going to hear and what's important.

DNA is a very long molecule that exists in all of our cells. It is made up of these various nucleotides that we refer to and scientists refer to as by the very first letter, A, C, T, and G. And it's like one big, long run-on sentence in your cell, and all those letters come in a different order, and they transcribe genes.

So if you look on the left, you have these three different individuals. And what this picture is meant to represent is this genetic code that each of these three individuals has. And it's all the same until you get to one area where they have a different letter in that particular area.

Now, when you have a different letter in that area what can happen is the protein can be changed. You know, our hair is made of protein, our skin is made of protein. Everything in your body that does a function is made of protein. That protein is all made based on the instructions that are in the genetic code. And so the manufacturer, if you will, that goes along the genetic code and reads it to make the protein will come to this area where there's a mutation, and it will make a protein that may not be the functional protein that will give the hair, or the skin, or whatever other tissue the right function.

Sometimes those mutations don't amount to anything, and sometimes those mutations don't amount to anything bad.

That's why we all look different, is because we have different coding in our DNA that allows us to have brown hair, be left-handed, blue eyes, and you're going to hear a lot about that. So mutations aren't universally bad, but sometimes there is a mutation that can be linked to disease, and that is what this case is about.

Now, PPG, as I mentioned, they offer 180 different tests. The way they select the tests that they're going to offer to their customers is they look at the published medical literature. The U.S. National Library of Medicine has a place called PubMed, and this is where scientists look at what other scientists are doing in other areas of the country, in other areas of the world, and it's a way for scientists to exchange information.

What PPG does is they look at this website pretty regularly, PubMed, to see if there was a new mutation discovered that is now proven to be linked to a genetic disease. This is a cite that is also put up by the National Institute of Health, and these mutations that are discovered end up being published from time to time.

Now, once a mutation is discovered, it's like finding the needle in the hay stack, and it might even be harder than that. But once that is uncovered, that information is uncovered, the actual testing to see whether you and me or our dog has that mutation is routine and

relatively easy to do. Now, what PPG does is, like other researchers, it will benefit from the information that's publicly available in the literature.

Now, PPG's test selection process involves a clinical review of the research. So once they find the research on PubMed, they don't just accept it. They will actually review it with their Ph.D.s and technicians, and they'll see if it actually makes good science, if it has really proven that there's a change in the protein that would actually cause disease. So it goes through this clinical review and a scientific review, and then they ensure that they can do the test by just the well-known, routine and conventional testing methods that are available to researchers and have been available to researchers for a long, long time.

This case is about a disease in Labrador Retrievers called hereditary nasal parakeratosis. And, for simplicity, I will refer to that as HNPK. It affects the nose of the Labrador. It's not life-threatening, but it can be very painful for the Labrador. There's a picture of it here.

Now, it's caused by a point mutation, and a point mutation is what you saw in that picture a few slides ago. It's just a single base pair change along the genetic code. I think in this particular instance there is a G-to-T substitution at position 972 of this particular gene called

SUV39H2.

Genes, again, are these sections of the DNA that make a protein. We get half of them from our mom, half of them from our dad. If one gene copy has the mutation and the other doesn't, in this particular instance there's no physical manifestation of this disease.

When it does manifest itself physically -- and, by the way, that's called a phenotype. You're going to hear that word, when it's a physical manifestation of a disease. The phenotype exists when a dog has two copies, a carrier is bred with another carrier, and then that particular dog will have the disease, will show the physical manifestation of it.

Here's a graphic to show you a little bit about how that works. On the top you have the original DNA sequence, and you can think of -- there's an enzyme that goes around, and it makes another molecule called MRNA, and the MRNA reads this particular sequence and makes protein. So the reader is going along, reading the instructions to make the protein, and it comes upon this one base pair change, and in this particular instance it causes a protein to malfunction, and that's how we get this disease.

It produces a different amino acid. Proteins are made up of these things called amino acids, all lined up together, and that is what happens when the DNA code is read. That information is translated into a string of amino acids.

You might hear the term polypeptide, and that means many peptides. These are amino acids strung together that make a protein.

So in this particular instance, the information is wrong at this particular location. That translates to a wrong amino acid, and that translates -- the wrong amino acid in this case translates to a disease.

Another disease that you may have heard of that's caused by this exact same process is sickle cell anemia. We know the location for sickle cell anemia; we can test to see if someone has that mutation. Here's another image of a dog that's afflicted with HNPK.

Now, the location of the mutation in this particular case, again, is at position 972 of this particular gene called SUV39H2. Now, everybody has -- not everybody, but every Labrador has SUV39H2. That's a naturally occurring gene. The fact that this mutation occurs in that particular gene at position 972 was certainly not something that was created by any person, it was something that nature created in the breeding process of these Labradors.

This particular location for the gene was discovered and published on PubMed in October of 2013, publicly available information. PPG did find a published patent application at that time, but it believed it would not be granted, knowing what it knows about the fact that it

believes natural laws cannot be patented.

One of the things you're going to hear about is in 2013 Dr. Shaffer was on the board of the American College of Medical Genetics, and that board participated in a lot of policy decisions that were being debated at this time in 2013. In particular, these breast cancer genes, BRCA1 and BRCA2, whether or not patents should be allowed on those particular breast cancer genes.

Now, with the Human Genome Project and with this explosion of technology that happened, allowing people to patent entire genomes of organisms, it was a race to the Patent Office to patent this and patent that. And researchers had a very valid concern at this point in time about what that was going to do to access, to research, and what that was going to do for our ability to cure disease. If one person is the only lab that is allowed to test for that particular DNA sequence, then that's not going to promote the progress, and the whole purpose of the patent system is to promote the progress.

So what happened in this particular case? You're going to hear that PPG released its test for HNPK in early 2014. You're going to hear that the patent issued October 13 of 2015, so a little bit after PPG released the test did the patent issue.

Then, about a year and change later, PPG gets a

cease and desist letter from LABOklin. LABOklin is a German-based lab. They're a lot bigger than PPG, by about ten times, and they offer about ten times as many tests annually than PPG, so this was a very serious threat to PPG's business when they got this cease and desist letter on January 24th of 2017.

Now, what did PPG do? After receiving the cease and desist letter it immediately reviewed the patent. It concluded the patent was issued by mistake, because it covers well-known, routine and conventional methods for testing for a genetic mutation. That's all PPG does. It read the claims and concluded this must have been issued by mistake, and then PPG initiated this challenge to the patent on February 22nd of 2017, less than a month after learning that it actually issued.

Now, how did this happen? You might ask yourself, there are these patent examiners at the Patent Office, how does it happen that this patent could be issued by mistake? Well, you're going to hear evidence in the prosecution history that a shortcut was used, actually, to get this patent through. It's called the streamlined eligibility analysis. It was advocated by the defendants' attorneys to be used by the patent examiner. It's a truncated or a shortened analysis, and it's not the full analysis, and we believe that's one of the reasons why this patent issued.

This is a snippet from what you heard called the prosecution history. That's the dialogue that goes back and forth between the attorneys that represent the defendants and the Patent Office, and this is a bit from the attorney's letter to the patent examiner, and it says, "Do not proceed through the full analysis." And so what you're going to hear here is that full analysis was skipped, and that's one of the reasons why this patent was allowed.

Here are the reasons that the patent examiner used, and they're kind of unclear exactly why the patent examiner allowed this patent. At first, you'll hear evidence that the examiner issued a rejection based on the grounds of invalidity, that this covers a natural phenomenon, and then what happened was the patent attorneys for the defendants wrote back and said, No, use this streamlined eligibility analysis, and then all we get are these cryptic comments from the examiner as to why it was issued. And we believe at the end of this you'll conclude that a mistake was made, that it shouldn't have been issued, when you understand what the examiner should have done, and that's the full analysis for invalidity.

Now, what should have happened here? The full analysis that we believe that you're going to do will show that this patent is invalid. You cannot get a patent on a natural phenomenon. The genetic cause of this particular

disease is a natural phenomenon. It wasn't created by any person, it was created by nature, by the universe. It wasn't created by a person. This is a discovery, it's not invention.

No person made this mutation, so you can't -- if that's all there is in this claim, then you can't get a patent on it. And if all there is at the end of the day is a way to look for this mutation, if that's what this method is, and if it covers routine and conventional methods, we submit the patent is invalid.

Now, why is it that you can't get a patent on a natural phenomenon? I mean, after all, I said it was a needle in a hay stack. It's a hard thing to find out the genetic cause of a disease, so why not give that person a patent for that? Well, here's why:

These things called natural phenomenon, they are the tools of other inventions. One of the purposes of the patent system is to advance science, advance progress. If you discover a mathematical relationship or you discover a natural phenomenon and you don't allow other people to learn from that information and to apply it, well, that doesn't advance the progress, and so that's why the law says you don't get a patent on a natural phenomenon. Because patents exclude others from using that information, so at the end of the day if all the claim is is a natural phenomenon or a way

of looking at a natural phenomenon, then it's invalid.

I thought I'd show you this to kind of have in your head what's different between discovery and invention. So discovery is when Ben Franklin flew the kite and discovered that there is this phenomenon called electricity. That was a literally shocking discovery for him, and it's something that exists in nature that he uncovered. Now, that information then can be used by an inventor to invent something, like the light bulb. You can use the concept of electricity, apply it in a way, and then you can get a license on the light bulb, but you can't get a patent on electricity, okay?

Now, Albert Einstein -- we heard a little bit about that in the opening instruction -- could he have patented E = MC squared? He discovered that relationship. No, he couldn't have patented E = MC squared.

What about Heinrich Hertz? He discovered the radio wave; that there exists this spectrum of electromagnetic radiation. Did he get a patent on the radio wave? No. Why not?

Because E = MC squared and the radio wave, these are things that exist for all scientists to use. It's the product of discovery, it's not the product of invention. Scientists research, and they make discoveries, they publish their discoveries for all to benefit from, and that's what scientists have been doing for generations. But we don't

allow patents on natural phenomenon, because it would actually hurt progress.

So there's some important questions that you're going to have to answer. You're going to have to answer, number one, are the claims in this particular patent directed to a natural phenomenon, yes or no? And then if yes, you're going to be asked, I believe, does the claim include something significantly more than that natural phenomenon, like an inventive concept? And I submit to you that that inventive concept cannot be anything that is well known, routine or conventional, like the testing methods that you'll hear are done by PPG.

Now, you have in your hand the patent. I am going to refer to a part of the patent. If you go to the very last page, that's where you're going to find the claims. So the very last page of the patent includes five claims, but only claims 1 through 3 are at issue in this case.

You're going to hear evidence from Dr. Shaffer, you're going to hear evidence from the defendants' witnesses, about what these claims cover, and at the end of the day, you're going to be asked whether these claims are invalid or not invalid, and whether they're just including a way to look at a natural phenomenon, and do they wrap up the conventional ways to do that.

Now, starting with claim 1, the very first part is

an in vitro method for genotyping a Labrador Retriever. And, again, you're going to hear this word a lot -- genotyping. No one is going to say that genotyping was invented by the defendants in this case.

Obtaining a sample from a Labrador Retriever, that's not new by itself, certainly, but that covers any way of getting a sample from a Labrador.

Genotyping this particular gene, encoding the polypeptide of a sequence ID No. 1 -- genotyping that particular gene of a particular sequence, that exists in nature, and it's not new. It's not something that was created by these inventors.

Here what you have at the very end of this claim is the natural phenomenon, detecting the presence of a replacement nucleotide T with a nucleotide G at position 972 of sequence ID No. 2.

So sequence ID No. 1 -- you're going to hear that's the amino acid sequence, so that's the protein. And so step B says, genotype the protein. Tell me what the DNA sequence is that makes that protein. Sequence ID No. 2, you'll hear, is for a region around this mutation, and it says look at position 972, and if there is a T with a G at that position, then you have a carrier of this disease. So there's nothing new in this claim, we submit at the end of the day, besides this natural phenomenon.

Same thing with claim 2 that you'll be asked to consider. It includes the method of claim 1, but then it identifies all these different ways to genotype like PCR, realtime PCR, melting point analysis, and there's a lot of other techniques in there. Now, these techniques are all techniques that you're going to hear about that have been around for decades. They teach some of these techniques, like PCR, for example, in advanced high school programs. So this is a way that you can look for the particular mutation that has been around for a long time.

Here is the third claim. Now, the third claim includes a well-known method for identifying a known sequence that uses primer pairs. Primers are -- I mean, you have to prime the pump. You might have heard of that term. It's kind of similar in that you make a section of DNA that is naturally occurring in the body, but you make a section of it so that it reads another section of the DNA, and then it amplifies that DNA in a way that can be seen by researchers so that they can determine whether the mutation exists in the sample.

This method of genotyping has been around for decades; it's not new. The only thing that's new in this claim, folks, that you'll hear about is this location of the mutation. Now, that's not something that you're able to patent because it's a natural phenomenon, and there's nothing

here besides a natural phenomenon.

And if, you know, you need any more evidence about whether it's a natural phenomenon or not, you're going to hear about that in the patent. And if you want to turn to this particular section of the patent, it's at column 4. The columns are these numbers at the very top. About line 25 -- you can see the lines are indicated in the very middle of the patent. At column 4, line 25, it has this particular section that I have highlighted on the screen. It says, "There are numerous ways to accurately determine the SUV39H2," and then it has some numbers there. That's a fancy way of saying there are numerous ways of finding this mutation at this location. And you can genotype a log. There are numerous ways to do that. And then it lists various detection techniques, including a lot of the ones you'll see in claim 2.

And then it goes on to say, "The critical information is that this variant really is the causative variant for the HNPK phenotype..." So the critical information in this patent, ladies and gentlemen, is the location of the mutation that causes this disease. There's nothing else critical or important about that patent. At the end of the day, this is a patent that covers a natural phenomenon and nothing else.

Now, here's some excuses you're going to hear from

the defendant, I think:

That the U.S. PTO granted the patent, so we should just accept that. They're going to say it was difficult to find the mutation. I think you're going to hear that they say this claim only covers Labrador Retrievers, so other breeds can be tested and that should be fine. You know, they get Labrador Retrievers, and everybody else gets the other breeds. I think you're going to hear that the claims don't cover testing the protein.

But I want to also tell you a little bit about the responses that you're going to hear from the evidence, and I want you to look out for these. We think the patent was granted by mistake and when the proper analysis is done you'll agree with that.

They will say it's difficult. It was difficult to find this natural phenomenon, but I'm sure it was difficult to discovery E = MC squared, but it doesn't mean that Einstein could patent E = MC squared.

They'll say that this disease mostly exists in Labradors or that, you know, their claims only cover Labradors. But this mutation, this particular mutation, the location of it, that only exists or mostly exists in Labradors. Maybe like Labradoodles or other breeds that are related to it, so that's not a sufficient narrowing of the claims.

And they might say, well, you can still test for the amino acid sequence, but that would be a very, very difficult test to do. You would have to biopsy the tissue, you will hear, and it's not a very commercially viable way to test for these, when you can just take a cheek swab and isolate the DNA.

So, we believe that the evidence will show that this patent is invalid. You have an opportunity, as the jury, to correct that error made by PTO. This mistake hurts consumers. If there's only one place to get the test, the price is high for the test. This mistake hurts research because whether or not you can do this test is controlled by a single party. And this mistake, at the end of the day, hurts further innovation in finding a cure for this currently uncured disease, HNPK. And, you know, it sets a precedent for other gene patents. What you guys do today could have an impact on other cases.

So, with that, I just want to thank you very much for your service today. It's a uniquely American thing here, to have a jury in a civil case, and I want to thank you all for your time and your attention.

THE COURT: All right. Is counsel for the defendants ready?

MS. GRAY: We are, Your Honor. May I proceed, Your Honor?

THE COURT: You may.

MS. GRAY: Good afternoon, ladies and gentlemen.

You just heard plaintiff's counsel talk to you about how plaintiff is going to present evidence to try to convince you that my clients have patented, essentially, a dog or a disease in a dog, if you will. Ladies and gentlemen, I'm here to tell you that this case is about patenting a dog. It's not about patenting any part of a dog. It's not about patenting a disease in a dog or a mutation in a dog. This case has nothing to do with a dog.

This case is about Dr. Tosso Leeb and his laboratory protocol that he developed. This case is about the six years of research it took him to identify the information necessary to enable his laboratory protocol. And this case is about the fact that the United States Patent Office granted Dr. Leeb a patent on his accomplishment. And, ladies and gentlemen, this case is about the fact that PPG has sued my clients alleging that Dr. Leeb's patent is invalid. This case is about the fact that PPG believes it has the right itself to determine what is patentable and what isn't.

So let's get into it. Ladies and gentlemen, my name is Nikia Gray, and I have the great pleasure of representing the defendants here today, LABOklin and the University of Bern. On behalf of both of them, I thank you for your service.

We're going to be talking here today about United States Patent 9,157,114, and I have the official copy of it right here. This patent is the patent that the United States Patent Office issued to Dr. Leeb for his laboratory protocol. And you're going to hear throughout this case that before it issued this patent, the United States Patent Office considered the exact question that plaintiff has asked you to consider. The United States Patent Office, the experts in patent law, considered this question, and they ultimately decided that Dr. Leeb's laboratory protocol was, in fact, the type of thing that could be patented.

Now, like plaintiff's counsel, I'm simply going to refer to this patent by its shorthand, the '114 Patent. This patent is owned by my client, University of Bern, and licensed to my client, LABOklin. And so I'd like to introduce you to my clients, and then I'll talk to you about the evidence that you're going to see from defendants in this matter.

The University of Bern is a university in Bern, Switzerland, that is a well-known research institution, and it can boast having many prestigious faculty members over the years, including even at one point Albert Einstein himself. We've been talking about E = MC squared. He was once a professor at the University of Bern.

One of its current very prestigious faculty members is Dr. Tosso Leeb, and he is, as I said, the inventor of the '114 Patent. And Dr. Leeb is going to be coming here from Switzerland -- he's on his way here -- and he will be speaking to you about his laboratory and about the research he does there, and particularly the research he does in the genetic causes of diseases in dogs.

And we're going to be hearing a lot in this case about Dr. Leeb and his research, and one of the things you're going to hear is that Dr. Leeb discovered the mutation that is correlated with the disease hereditary nasal parakeratosis. That's the disease that plaintiff's counsel talked to you about, and we're going to be calling it HNPK, and that's the disease that causes the dry, cracked nose on Labrador Retrievers.

But when Dr. Leeb is here, he's going to tell you that that discovery was not the only achievement that he made. He's going to tell you that during the course of his research, he also developed a laboratory protocol that was very unique and had never previously been done before. And we'll get into all of that in a minute, but I want to take a moment to also introduce you to my other client, LABOklin.

LABOklin is a German veterinary laboratory, and it is, in fact, the second-largest laboratory in Europe for veterinary services. And with us here today we have

Dr. Elisabeth Müller. She is the founder of LABOklin, and she is sitting here at counsel table with us. Dr. Müller will be speaking with you, and she's going to tell you about LABOklin and why it decided to license Dr. Leeb's patent. Dr. Müller will tell you about the fact that LABOklin uses Dr. Leeb's patented laboratory protocol in its labs to test Labrador Retrievers for the genetic mutation that is associated with HNPK.

So why are we here, ladies and gentlemen? Well, we're here because PPG has sued my clients. They've sued alleging that the patent, the '114 Patent, is invalid. And, as you heard plaintiff's counsel tell you, it's plaintiff's position that that patent is invalid because they claim that Dr. Leeb's protocol is not the type of thing that can be patented. They believe it patents a natural phenomenon, something that occurs in nature. And, of course, defendants assert that that is incorrect. We assert that the patent is, in fact, valid.

So what does this all mean? Well, it means you, as jurors, are going to get to decide did the Patent Office get it wrong? Did the Patent Office, the experts in patent law, get it wrong? And now our judge will decide the ultimate issue of whether the patent is invalid, but, as he said, he's going to ask you certain questions to help him make that decision.

One of the things you're going to be asked to consider in this case is whether the claims are directed to HNPK or the mutation that's associated with HNPK.

You're also going to be asked to determine whether the claims simply recite something that was known, routine and conventional. You'll hear those words a lot throughout the case.

Now, as this is a patent case, you guys are going to be hearing a lot about patents, Dr. Leeb's patent, and I think it's worth pointing out that Dr. Leeb's patent, like all patents, was issued as part of the patent system. The patent system is a bargain between inventors and the United States Government, where inventors are given the exclusive right to their invention for a limited time in exchange for telling the world about what they've discovered, or what they've invented, or the information they've uncovered.

And from that, us as the public, we benefit from their knowledge. And the inventor, in turn, by having the exclusive rights to their patent gets to recoup the cost of doing research, because research is very expensive. And so they get to recoup the cost of doing their research, and that, in turn, funds further innovation, because they have the money that they can spend on more research.

Now, you heard plaintiff's counsel talk to you about

the fact that patent law does prohibit certain types of inventions from being patented, and that is correct. That's not a disputed fact. Patent law does prevent certain things from being patented. These are things like, as we've said, natural phenomenon, abstract ideas. We call these things judicial exceptions.

But what patent law is concerned with when it prohibits certain things from being patented is the idea of tying up an entire industry or an entire area of study, such that nobody else can study it. So patent law doesn't want somebody to own a natural phenomenon and prevent anybody else from studying it. Because of this, defendants will present evidence to you regarding the fact that other people can still study HNPK and the mutation associated with HNPK. Dr. Tosso Leeb's patent does not prevent anybody else from studying HNPK or the mutation associated with HNPK or, for that matter, Labrador Retrievers.

Now, I think it's worth taking a moment and just thinking big picture about what we're talking about here, when we're talking about genotyping and HNPK and mutations. What we're talking about when we say genotyping, we're talking about the traits we all inherit. Every single one of us inherits one copy of our DNA from our father and one copy from our mother, and together those two copies is what makes us us. And we can pass on that DNA to our children.

Now, HNPK is a recessive disease, and what that means is that for a dog to have that dry, bumpy nose, the dog has to have received one copy of the mutation from its mother and one copy from its father. If the dog only receives one copy, say, just from its father, it doesn't receive the copy from its mother, then the dog has the mutation, but it never develops the dry, bumpy nose; it's a perfectly healthy dog. But because it has that one copy, it can pass on that copy to its puppies. And, of course, if it mated with a dog that also has the mutation, then those puppies have two copies, and those puppies will have HNPK.

So Dr. Leeb's testing protocol, as you'll learn from the evidence, allows for the detection of that mutation. It doesn't diagnose HNPK. What it does is it allows a way of detecting whether that dog, who is a healthy carrier, has one copy of the mutation.

And I should back up to specify that when a dog only has one copy of that mutation and doesn't exhibit signs but could pass on that mutation to its children, we refer to that as a healthy carrier. So Dr. Leeb's method allows you to identify dogs who have no visible sign of the illness, doesn't have the dry, cracked, bumpy nose but still has one copy of that mutation. And that's important, of course, because we don't want two dogs who don't show any signs of the disease but still have the mutation -- we don't want them

mating together and then having a litter of puppies that have that disease.

Now, we expect that plaintiff is going to present much of their evidence through their technical expert, Dr. Lisa Shaffer, and Dr. Lisa Shaffer as the evidence will show you, is a very, very skilled geneticist, there's no question about that, but the evidence is also going to show you that Dr. Shaffer is the CEO and founder of PPG. And, as the evidence will show you, PPG has an interest in this case; it is the plaintiff. And so the evidence will show that Dr. Shaffer has an interest in this case, and you get to decide whether that's a conflict of interest.

Defendants also have an expert. His name is Steven Friedenberg. And Dr. Friedenberg is an assistant professor over at the University of Minnesota, where he studies genetics; in particular, genetics in animals, genetics in dogs. And he has reviewed the arguments here, he's reviewed the '114 Patent, he's reviewed Dr. Leeb's publications, and he's prepared some opinions for you in response to Dr. Shaffer, and he'll be talking to you this week about those. And so you get to weigh all that evidence when you decide what expert can better inform you about the issues you've been asked to decide today.

Now, in terms of specifics, we believe that plaintiffs will enter evidence through Dr. Shaffer that the

claims of the '114 Patent are directed to a natural phenomenon; that is, to HNPK or the correlation between the mutation and HNPK. But the evidence you're going to see will show you, and, in fact, when plaintiff put the claims on the screen he showed you, the claims themselves don't recite HNPK. The claims themselves do not recite the correlation between the mutation and HNPK. And the evidence will further show you that when the examiner of the United States Patent Office looked at Dr. Leeb's patent application, while it was still pending, she considered this exact issue. She considered this exact issue.

I actually have -- this is the official file history for the patent. This file history is the communications going back and forth between the Patent Office and Dr. Leeb's attorneys during the prosecution of the patent, and you will see that this file history is 400 pages long.

And the evidence is going to show you that the examiner, before she allowed the claims, required certain changes to be made to them, and she required those changes specifically to ensure that the claims that issued were directed only to Dr. Leeb's laboratory protocol and not to HNPK, not to the correlation between HNPK, not to a natural phenomenon. She required changes to be made to the claims to ensure that they did not claim a natural phenomenon.

In fact, I'd like to put on the ELMO here a copy of

the notice of allowance. So I have on here a copy of the notice of allowance in this case, and the notice of allowance is the examiner's statement about what claims she's allowing and why she's doing that.

So this is a copy of the notice of allowance, and if we turn to the back of it, this is the examiner's statement of the reasons for allowance, and I'm going to read this to you. The examiner states, "The claims have been amended to be directed to a method of detecting a new and nonobvious mutation in a biological sample from a Labrador Retriever. The mutation in the SUV39H2 gene was not previously disclosed and was not found in the canine HD biochip. Furthermore, the claims no longer require a judicial exception. Thus, the claims are allowable."

That is the examiner saying she looked at this issue, and she determined that the claims were not directed to a judicial exception, the claims were not directed to a natural phenomenon, and, thus, the claims were allowable. In fact, the evidence that you will hear in this case is that PPG has not raised a single argument, not one, that the Patent Office did not already consider.

We also expect that plaintiff's counsel is going to present evidence -- or plaintiff will present evidence -- that the techniques for genotyping described in Dr. Leeb's patent were routine, conventional, well-known. You heard

those words when plaintiff's counsel was talking to you.

The evidence, though, is going to show that the claims in Dr. Tosso Leeb's patent application require the application of genotyping in a way that had never been done before. It applied to an area of a gene that had never been looked at before to detect something that nobody had known had existed at the time.

Let's say that another way. The evidence is going to show you that nobody knew that the mutation existed at the time, and the evidence will show you that because nobody knew that the mutation existed, nobody knew or had ever applied any genotyping method to the SUV39H2 gene to the area where that mutation existed, and since nobody had known that the mutation existed and nobody had ever thought to apply a genotyping method to that area of the gene, it certainly wasn't routine or conventional to do it.

So, ladies and gentlemen, in light of all this evidence, we hope that at the end, when you deliberate, you're going to come back with a verdict that the claims at issue are all valid.

Thank you for your service. We appreciate your time.

THE COURT: All right. Ladies and gentlemen, we normally take our lunch break at 1:00, and it's almost exactly 1:00, so we'll take our break now and return at 2:10.

Now, this is the first time you've taken a break since you were selected, so I want to emphasize the importance of not discussing anything about the case until you begin your deliberations. If you want to go to lunch together, fine, no problem with that, but just don't talk about the case, for the reasons that I've mentioned.

You may recess for lunch now. There's no entrance or exit to the jury room except that door, so I'm going to ask everyone in the courtroom to remain seated until the jury has exited the courtroom.

(The jury exited the courtroom.)

THE COURT: Ms. Gray, you said something in your opening statement that I have a question about. You said something about submitting questions to the jury? Are you asking that the Court submit special interrogatories to the jury?

MS. GRAY: No, Your Honor. I'm not sure what you're referring to that I said, but I did not mean that.

THE COURT: Okay. I wasn't sure. Because I don't have any special interrogatories. I assume that they're just going to answer the question is the patent valid or not valid.

MS. WILBERT: Actually, Your Honor, we have submitted a special verdict form that does have questions for the jurors to answer.

THE COURT: All right. I haven't looked at that verdict form.

MR. WALTERS: Your Honor, we have a verdict form that tracks the *Alice* Step 2 analysis, but we would also be okay with just a single-line verdict form is the patent valid or invalid.

MR. PIERY: Your Honor, we would object to a single-line verdict about whether the patent is valid or invalid, because under Section 101 the ultimate conclusion on validity is an issue of law for the Court. It's based on subsidiary factual findings for the jury, but the ultimate conclusion is an issue of the Court.

THE COURT: Obviously, we won't use anything about willful. It sounds like you just put the elements that the jury should consider as a verdict form.

MR. PIERY: Your Honor, in your opinion and order denying PPG's motion for summary judgment you identified three genuine issues of material fact that are in dispute in this case, and --

THE COURT: Well, the fact that they're in dispute doesn't mean that the jury should answer each of those questions. It doesn't mean it shouldn't, either. I'll take a look at it and decide when the time comes, but it appears that what it is is the elements that the jury should consider in arriving at whether it's valid or not valid. But I don't

know whether there's any advantage in submitting the questions to the jury, as opposed to an instruction outlining the elements.

MR. WALTERS: And, Your Honor, we take issue with whether those are the elements or not, but the Court certainly can read the cases and come to its own conclusion about what the elements are.

THE COURT: Well, right.

MS. WILBERT: Your Honor, could we also seek some guidance about your earlier ruling today? In openings plaintiff's counsel repeatedly said that our client made a threat and the threat --

THE COURT: That your client what?

MS. WILBERT: Plaintiff's attorney said in openings that my client was making a threat and that threat was of infringement. And if they're going to be allowed to argue that they've been threatened, we would like to explain that the threat was justified and that they did infringe. But, given the Court's ruling --

THE COURT: You stipulated that they infringed, Counsel. That's it. If it's stipulated, it's not part of the case.

MS. WILBERT: Are they continued to allow that we threatened?

THE COURT: Well, I don't think that that should be

part of the case. I agree with that. It shouldn't be. I mean, the letter was the letter, but I don't think you should be saying your client was threatened, any more than I believe you should be talking about the relative size of your company, as opposed to the defendant's company. I'll have to put that in the instruction now that you mentioned it.

MR. WALTERS: Okay, Your Honor. We just wanted to give the jury an idea of what --

THE COURT: What?

MR. WALTERS: We were giving background as to why the case was initiated, and they said repeatedly we sued them, and so they needed to know why, so -- it's opening statement, Your Honor.

THE COURT: All right. Well, I don't think we should be dealing with -- it doesn't make any difference who sued who in this case, it's just a question of whether it's valid.

So I think probably the plaintiff shouldn't be talking about being threatened, and the defendant shouldn't talk about being sued. The issue is, is the patent valid? That's the only issue, because of your stipulation, so there's no need to mention either way.

MS. WILBERT: We're fine with that, if it's for both parties, but if their witness is going to testify about the threat, we'd like to testify about the stipulation.

THE COURT: I don't think the use of the term "threat" is necessary. You got a letter saying quit doing it. That speaks for itself.

MR. WALTERS: Well, Your Honor --

THE COURT: Well, it's not fair for you to talk about your teeny little company being threatened by this great big company and prohibit them from talking about infringement. You were told by them to stop. That's why you sued them. That's all you have to say.

MR. WALTERS: Okay. And just that background will be what we'll introduce as to -- and our belief that the patent is invalid, basically.

THE COURT: Well, that's right. That's what the case is about.

And everybody wants to think up any bad thing they can say about the other side that will prejudice the jury against them, and that's what we're eliminating. You can't just say something bad about the other side. It doesn't make any difference how good or bad or how large or small they are. It's simply an issue of whether the patent is valid or not.

All right. I'll see you at ten minutes after 2:00.

(A luncheon recess was taken.)

MS. WILBERT: Before we bring the jury in, I believe there's a pending motion in limine that may be impacted by

this next --

THE COURT: Do you want to come forward to the podium?

MS. WILBERT: Sure. Your Honor, I believe there's a pending motion in limine that has not yet been ruled on that may influence the upcoming witness's testimony. In particular, defendants have moved to exclude reference to the *EIC* case because we believe that's relevant to the willfulness issue that's no longer a part of this case, so we'd like the Court's ruling on that motion.

We'd also like to move that the plaintiff refrain from discussing the subjective belief about the patent, because that's also relevant to willfulness, which is no longer at issue today.

THE COURT: Well, I thought that that case only had to do with willfulness.

MS. WILBERT: That's our point as well. We believe it does, but you hadn't given a final ruling on that motion, and before the next witness testified, we wanted to be clear about the scope.

THE COURT: Her subjective belief, I mean, that's a difficult target to see before she testifies.

MS. WILBERT: Well, I can make the objections as it goes. I just wanted to alert you to the issue, given the pending motion.

THE COURT: All right.

MR. WALTERS: Yeah, Your Honor, we don't intend to reference the *EIC* case. I do intend to ask her why she thinks the patent is invalid.

THE COURT: Yes, I don't know how to measure your objection, based on the subjective belief. I mean, her belief that the patent is invalid is part of the case.

Okay.

(The jury entered the courtroom.)

THE COURT: All right, ladies and gentlemen. We're now going to begin to hear the evidence in the case. As I told you previously, the opening statements were just a projection of what counsel expects the evidence to be, so we'll now hear what you may consider to be evidence.

Are you ready with your first witness, counsel?

MR. WALTERS: We are, Your Honor. The plaintiff calls Dr. Lisa Shaffer.

THE COURT: All right.

LISA G. SHAFFER, PH.D., called by the Plaintiff, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. WALTERS:

Q. Good afternoon, Dr. Shaffer. Could you state and spell your entire name for the record?

A. Yes. Lisa Shaffer, L-i-s-a S-h-a-f-f-e-r.
Q. Now, Dr. Shaffer, why did PPG initiate this lawsuit?
A. We received a cease and desist letter that included the patent. And this patent was granted, but it was clearly a mistake, and the only thing that we can do to show that the patent is invalid is through this court proceeding.
Q. Dr. Shaffer, what do you do for a living?
A. I'm a geneticist.
Q. How long have you been a geneticist?
A. Since 1990.
Q. Now, as a geneticist, why do you think this patent was issued by mistake?

MS. WILBERT: Objection, Your Honor. This is calling for opinion testimony.

THE COURT: I think that that's asking for an opinion, and you've asked her if she's a geneticist, so I think she has to be qualified as an expert witness before you can ask her that opinion.

MR. WALTERS: Okay. We'll do that, Your Honor.

BY MR. WALTERS:
Q. Dr. Shaffer, did you receive an undergraduate degree?
A. Yes, I did.
Q. From where did you receive your undergraduate degree?
A. Washington State University.
Q. Did you receive a Ph.D.?

A. Yes, I did.
Q. And from where did you receive your Ph.D.?
A. From the Medical College of Virginia, Virginia Commonwealth University, in Richmond.
Q. Are you board certified?
A. Yes, I am.
Q. For how long have you been board certified?
A. I was board certified by the American Board of Medical Genetics in 1993.
Q. Did you do a fellowship?
A. Yes, I did.
Q. Where did you do a fellowship?
A. At Baylor College of Medicine in Houston, Texas.
Q. Do you have your own patents?
A. I've had two patents granted, correct.
Q. Have you worked in laboratories over the years?
A. Yes, I've worked in laboratories.
Q. For how long have you worked in laboratories?
A. Since the mid-1980s.
Q. Now, are these genetic laboratories or other types of laboratories?
A. They are all genetic laboratories.
Q. Have you received any awards?
A. Yes, I have.
Q. What kind of awards have you received?

A. A couple years ago I received something called Women to Watch in Life Sciences. It's a -- from the State of Washington.

And then I received several regional and local business awards.

Q. Now, did you start any other companies besides PPG?

A. Yes. I had -- I have one other previous company. Called Signature Genomic Laboratories.

Q. And what was the business of Signature Genomic Laboratories, in general?

A. We did inherited disease testing or genetic disease testing on children with developmental disabilities.

Q. Now, do you have any discoveries to your own credit and name?

A. I do, many. I've published a lot, and I've identified many human conditions that are called syndromes. In fact, I have two of them that are actually named after me.

Q. Now, what syndromes did you discover?

A. So one is called the Potocki-Shaffer syndrome, and it's a syndrome that has intellectual disability for the children, and then the other one is called Lamb-Shaffer syndrome.

Q. How many peer-reviewed publications do you have?

A. More than 325.

MR. WALTERS: Your Honor, at this time we'd like to offer Dr. Shaffer as an expert under Rule 702.

THE COURT: Any voir dire on the qualifications?

MS. WILBERT: Your Honor, we don't object as to qualifications, just to the scope, because her disclosure was limited in subject matter previously and by your previous orders.

THE COURT: All right. She may proceed.

BY MR. WALTERS:

Q. All right. As a geneticist, Dr. Shaffer, why do you think this patent was issued by mistake?

MS. WILBERT: Objection. This is outside the scope of the disclosure this witness had offered. She was only offered for the purpose of laboratory techniques and not as to the ultimate issue of validity.

THE COURT: Ultimate issue of what?

MS. WILBERT: Validity.

THE COURT: Overruled.

THE WITNESS: Could you, please, restate the question?

BY MR. WALTERS:

Q. Sure. Dr. Shaffer, as a geneticist, why do you think this patent was issued by mistake?

A. Because it's only directed to naturally occurring phenomenon and then using routine methods that have been around for decades.

Q. Now, in your work as a geneticist, did you serve on any

boards?
A. Yes. I was part of the board of directors for the American College for Medical Genetics.
Q. What is the American College of Medical Genetics?
A. It's a subspecialty underneath the AMA. There's several subspecialties under the AMA, and the American College of Medical Genetics is one of those.
Q. And what is the AMA?
A. The American Medical Association.
Q. And how long did you serve on the American College of Medical Genetics board?
A. I served on the board from the year 2000 through 2008, and then I served on their foundation board from 2009 to 2015.
Q. Now, during the time that you served on the American College of Medical Genetics board, were there a lot of discoveries in the area of DNA sequencing?
A. Yes. It was a fantastic time. The Human Genome Project actually was completed in 2003, and that was the complete sequencing of the human genome.
Q. Now, were there other organisms sequenced at around this time?
A. Yes. In fact, the dog genome sequence was completed around 2005.
Q. Now, with all of these advancements in DNA technology,

was it all good?
A. Well, it was fantastic, because all of these genes were being identified, and all of these disease mutations were being identified, so it was an amazing time for gene identification and correlation with disease.
Q. Were there any down sides that you observed in your experience as part of the American College of Medical Genetics?
A. Yes. As a director of the board, we were very concerned because it seemed like all of the researchers were running to the Patent Office as fast as they could with, you know, This is the gene that I discovered, and I'm going to get a patent on it, and so we were very concerned about that.
Q. And did you participate in any policy statements that were issued by the American College of Medical Genetics during this time period?
A. Yes.
MS. WILBERT: Objection; relevance. Relevance.
THE COURT: Overruled.
A. So, yes, when I was on the board of directors for the college, we issued a statement regarding -- and this was in 2005 -- regarding the case that was pending with the patent over the breast cancer genes.
BY MR. WALTERS:
Q. And what are the breast cancer genes that were at issue

in that case?
A. So these genes are called BRCA1 and BRCA2, and the issue was that a company had patented those two genes, and the concern and the evidence was that the company -- because they had a monopoly, it was driving up the prices, so some women couldn't afford to have breast cancer testing, and especially if they weren't insured, because the price was very high for the test.

The other concern was that having one company hold a patent would limit further research on those genes and also would limit the potential to develop treatments, cures.
Q. Did the work that you did as a part of the board of American College of Medical Genetics and that breast cancer case lead to any changes in the DNA patent regime?

MS. WILBERT: Objection, again; relevance. This case is not about breast cancer, and that was a different case, with a different set of facts, and a different patent claim not at issue here.

THE COURT: I think that you can show her familiarity with the issue, but I think you're taking it a step too far at this point, so I'm going to sustain that objection.

MR. WALTERS: Thank you, Your Honor.
BY MR. WALTERS:
Q. As a part of the board, did you have the opportunity to

evaluate any other issues besides intellectual property that had to do with DNA patents?

MS. WILBERT: Objection; relevance. This case is about intellectual property.

THE COURT: Overruled.

A. So what comes along with patents and intellectual property -- you know, we were also concerned about privacy, because -- patients being able to get insurance once they've had genetic testing done, things like that.

BY MR. WALTERS:

Q. Now, as a geneticist, are you concerned about DNA patents?

A. Yes, I am.

Q. And why?

A. Well, we don't want them to limit patient access. I still have the same concerns that I had when I was on the board. We don't want to limit patient access --

MS. WILBERT: Objection, Your Honor. This case is about canine genetics, not human patient access.

THE COURT: Overruled.

A. And, so, relevant to this case would be, you know, we don't want to limit customers who have concerns about their dogs being forced to send their sample to only one laboratory.

BY MR. WALTERS:

Q. Now, do your customers make final, irreversible decisions based on your testing results?
A. Yes, they do.
Q. Can you give us an example?
A. So we have many breeders who will, once they find out that their dog is a carrier -- because breeders use us so that they can be responsible about their breeding and produce puppies that don't have genetic problems, so if they find that one of the potential parents, the mom or the dad dog, carries a genetic mutation, they may spay or neuter that dog and take that dog out of their breeding program.

We also have many examples where we've identified a dog to have an incurable disease, through our genetic testing, and the dog is, unfortunately, destined to suffer, and so those dogs have been euthanized, and this has been based on the results of the genetic testing.
Q. Can you explain in general terms what DNA is?
A. Yeah. So DNA, in the simplest terms, is the blueprint of life. It's what makes us who we are. It's, you know, why we look the way we look and the -- so many of our behaviors are genetic.

It also determines whether we're predisposed to certain diseases or whether or not we'll actually get disease or currently have disease. So that's what DNA does.
Q. And what is the DNA code?

A. So the code -- so DNA is a very interesting molecule. I like to think of it as one giant run-on sentence, and occasionally you'll have breaks in that sentence with some sort of punctuation. The sentence is written in only four letters, so A, T, C, and G, which that's the simple way of talking about those molecules that make up this long run-on sentence.

Luckily, this long run-on sentence does have a little bit of punctuation in there, and that's where the genes are. That's where these clusters of A, T, C, and G, in specific order, will code for, typically, a protein that has some function in the cell.

Q. Now, how do we get our genes?

A. So our genes are inherited from our parents, and we get half of our genes from our mom and half of our genes from our dad. And so for anything that we think about genetics, we actually have two sets. So we've got one from mom and one from dad, and this is really important, because together you need two of those.

Q. Now, what is a mutation?

A. So a mutation can be any change in the DNA. It doesn't necessarily mean that it's bad. So it's a change in the DNA. It may change -- it may not make a change, so it's what we call benign change. It doesn't change anything in the ultimate protein, so we can't really tell that there's been a

change in the DNA.

There could be a change in the DNA that causes a different trait. So, for example, if we think about Labrador Retrievers, I think most people know that they come in three flavors; chocolate, yellow labs, and black labs. Well, they're all Labrador Retrievers, they're all dogs, but the reason why they have three different coat colors is because of a coat color mutation. So sometimes we just have a trait, like blue eyes or brown eyes, but then other times you've got a mutation that causes disease.

Q. Now, does PPG test for mutations in its lab?

A. Yes, that's what we do.

Q. Where is PPG located?

A. We're in Spokane, Washington.

Q. How many employees does PPG have?

THE COURT: That doesn't make any difference.

MR. WALTERS: Okay.

BY MR. WALTERS:

Q. Do PPG's employees have technical degrees?

A. Yes, many of them do.

Q. Okay. Like what kind of technical training do the PPG employees have?

A. So anyone who works for the laboratory has to have a Bachelor of Science in some relevant science like biology, and then we have two individuals who have Master's degrees in

genetics or cell biology. We have two veterinarians who have their Doctorate in veterinary medicine -- it's called the D.V.M. -- and then we have three Ph.D. geneticists.

Q. Are you a founder of PPG?

A. Yes, I am.

Q. And when did you start PPG?

A. In 2012.

Q. Are you a dog owner?

A. Yeah.

Q. How many dogs do you own?

A. I have five.

Q. Did any one of your five dogs play into the start of PPG?

A. What gave us the idea was that I wanted to get genetic testing done on my dog Trixie, Trixie the wiener dog, and in order to get Dachshund mutations done on her I actually had to send a sample on her to several different laboratories.

And so that was really -- that event gave me the idea of, really, why isn't there one lab that has very comprehensive testing for any dog breed? You know, I shouldn't have to send a sample all over the place to get my dog tested. And so that's sort of how I thought about starting Paw Print.

Q. In general, who are PPG's customers?

A. So the main customers are breeders, responsible breeders, who want to do genetic testing before they breed the dogs to

make sure that they're not producing puppies with problems.

We also get samples from veterinarians who have seen a dog in their clinic that have some medical problems that they think might be genetic. So they may send this dog sample to us to be tested.

And then we also get samples from concerned dog owners, who are either concerned about a genetic disease in their dog or are curious about the genetics of their dog.

Q. What sort of results do you provide to your customers after they get their dog tested?

A. So we give them a comprehensive report that can have three different outcomes. The first is that the dog -- for whatever gene or disease they've asked us to look at, the dog is normal or clear. A lot of breeders call it "clear," meaning that both copies of the gene that we've looked at have the normal dog sequence; there's no change in it.

Then the second type of result they might get is carrier, where one copy of the gene is normal and one copy of the gene has the mutation that we were looking for.

And then the third possible outcome is that the dog has -- in their two copies of the gene, both copies have the mutation, and that dog would be at risk or affected for the disease.

Q. How do your customers obtain a test result?

A. So our customers -- most of them order online through our

website, or they call us and order a kit and initiate that order through the telephone, or they may see us at a dog show.

So we go to dog shows and interact with breeders and dog owners, and if they see us at the dog show, they can order from us there, and then the final report is sent to them.

Q. How are the samples collected for testing?

A. So we -- for most of the samples -- we will collect many different kinds of samples, but the majority of people use what's called a cheek swab, where they insert a little stick with a little brush on the end between the cheek and the gum, rub gently against the inside of the cheek, and collect those cheek cells, and that's what we use to do the DNA testing.

Q. Now, do you organize your tests by breed or some other way?

A. So we do. So the -- when you go to our website, you can put in your breed, and then you'll get a list of all the diseases that have been identified in your breed.

Q. Now, how is your process at PPG different or the same as something like 23andMe or ancestry.com?

A. Well, they are similar in the respect that both use a sample. So, for example, 23andMe asks you to spit into a tube. You can't get dogs to spit into a tube, so that's why we use the cheek swabs. But ultimately, we get a sample from

the dog, and we extract DNA just like they extract DNA. And then we use routine methods to look at the various genes in the dog, and they use routine methods as well.

Q. How many tests does PPG offer?

A. About 180.

Q. And how many tests are at issue in this particular case?

A. Just one.

Q. Is this a particularly important test for PPG?

A. It's very important to us. You know, our model is comprehensive service; that you can get everything you need on your dog through us, one sample. And so it's very important to our business to be able to offer everything in -- that's available and of concern for the Labrador Retrievers.

Q. Now, let's talk a little bit about how PPG tests the samples.

What kind of techniques does PPG use to isolate the DNA, for example?

A. So we use routine DNA extraction technologies. I mean, they're so routine that even high school students do DNA extraction in their labs at high school. I mean, there are various procedures for getting DNA out of cells.

Q. Now, when it comes to extracting DNA from the cell, does PPG do anything differently from other animal laboratories?

A. I don't believe so. I mean, we actually use kits that we

purchase from companies that you just use the components in the kit and the DNA comes out. It's pretty simple.

Q. Now, we've heard a lot about this word called genotyping. What is genotyping?

A. So genotyping just refers to the process of looking up the DNA and understanding whether the individual is normal, carrier, or affected. So it's basically just looking at those base pairs of DNA, and that's simply what genotyping is. It can be done many different ways.

Q. Now, what is a phenotype?

A. So a phenotype is different. So the genotype is what does the DNA say, and the phenotype is what does the person or the dog look like. So I gave the example of chocolate, yellow, or black Labradors. That's the phenotype; that's what you see. And then the phenotype can be whether or not you have the disease. That's a phenotype as well.

Q. Now, does PPG do anything in its testing laboratory to ensure that it's delivering accurate results?

A. Yes, we do. So before Paw Print, I had a human genetic laboratory, and we did human genetic testing, and that's a highly regulated industry. I was surprised there's no regulations in animal testing, and so we implemented the standards that I had lived by for 20 years. We implemented those standards at Paw Print Genetics.

Q. Let's talk a little bit about the test that's at issue in

this case.

What is the disease state that is of concern for this particular case, as far as you understand it?

A. So it's called hereditary nasal parakeratosis, so I'll call it HNPK. It's a mouthful.

Q. Thank you.

A. And this is a condition that's found in, you know, some dog breeds, including the Labrador Retrievers, and it's where the nose gets crusty and bumpy and has fissures or cracks, and it's very painful to the dog, and those cracks can actually become infected. So it's sort of a life-long care now to take care of that nose and to make sure that it doesn't get infected.

Q. And is there any cure for HNPK?

A. Not to my knowledge.

Q. How do you understand is HNPK passed on to other generations of dogs?

A. So it's -- it's inherited, and it's what we call a recessive condition. And by recessive, that means that in order to have the condition, to be affected, you have to have the mutation in both copies of the gene. So that you had to have gotten the mutation from mom, and you also got the mutation from dad. Dogs that only got one copy of the mutation -- let's say they got the mutation just from dad and mom gave the normal copy of the gene -- are carriers, and you

look at them and they look perfectly fine. They don't have the disease.

But then when those mutations get passed on from mom and dad and now the puppy has one copy of the mutation from mom and one copy of the mutation from dad, so now they have two copies of the mutation, then they have the disease.

Q. What kind of mutation causes HNPK?

A. So it's called a point mutation or a single-base substitution.

Q. Are there any other diseases that you know about in humans that are caused by the same kind of mutation?

A. Oh, yeah, there's thousands. Things like sickle cell anemia is caused by a point mutation. There's mutations in cystic fibrosis that are point mutations.

Q. Now, you said that HNPK may exist in other breeds, but is it caused by the same mutation, as far as you know?

A. So a mutation has been found also in the Greyhound, and it's not the same mutation. It's a different kind of mutation.

Q. So Greyhounds get HNPK, but they don't get it by the same mutation at the same position. Is that right?

A. Right.

Q. What is a homozygote?

THE COURT: What?

MR. WALTERS: Homozygote.

A. It's a genetic term. So when you have two copies of the gene that are the same, whether the two copies are normal or the two copies both have the mutation, that's called being homozygous, and then the individual is called a homozygote.

If you have one copy of the mutation and one copy of the normal gene, that's called heterozygosity and you're a heterozygote.

BY MR. WALTERS:

Q. Now, how did PPG come to learn about the discovery that HNPK was linked to a particular mutation?

A. We came across the paper in an online source called PubMed.

Q. And what is PubMed?

A. So it's an online source that's curated by the National Institutes of Health. It's all publications related to medicine which get deposited in this online source, and so we occasionally look at it. You simply put in, you know, search terms like "genetic mutation" and "dog," and then you'll get, you know, a thousand papers where, you know, genetic mutations have been looked at in dogs.

Q. Now, has PPG used PubMed to develop its other tests?

A. So we use PubMed to find the publicly available publications, medical journals and publications, and then we read the papers and decide whether or not to make a test.

Q. So when did you discover a paper on PubMed that was

related to the genetic mutation that's known to cause HNPK?
A. We identified the paper in the fall of 2013.
MR. WALTERS: Your Honor, may I approach the witness with an exhibit?
THE COURT: You can give it to Mr. Spatz. This is your exhibit book you're going to now?
MR. WALTERS: That's right, Your Honor.
BY MR. WALTERS:
Q. Dr. Shaffer, could you please turn to what we've marked as Exhibit 26.
Can you identify Exhibit 26 for the record?
A. Yes. This is the manuscript that we found on PubMed that describes the HNPK mutation.
MR. WALTERS: Now, Your Honor, I'd like to move the entrance of Exhibit 26 into evidence.
THE COURT: All right.
(Joint Exhibit No. 26 received in evidence.)
THE COURT: I want to advise counsel that because an exhibit is in the book or agreed upon doesn't mean it's admitted, because what usually happens is that not all the exhibits are used. So you have to ask for the exhibit to be admitted, which you've asked, and it will be admitted.
MR. WALTERS: Thank you, Your Honor.
BY MR. WALTERS:
Q. So can you tell the jury what you found in this

publication in the fall of 2013?
A. So this publication describes this condition that had been previously described about ten years before, but this -- which is typical of scientific publications. It talks about what is the disease, and then it identifies the mutation that appears to cause the HNPK, and then the mutation was found in a gene called SUV39H2.
Q. You reviewed this publication. Is that right?
A. I read it, correct.
Q. And after reading it, was there anything else in that publication new, besides the location of where the mutation is that is linked to HNPK?
A. No, there wasn't anything new.
Q. For example, what about the methods used for genotyping that were identified in this particular publication? Were any of those new?
A. No. They used standard techniques, like PCR and sequencing.
Q. Can you explain to the jury what PCR is, in general?
A. Yes. So PCR is an acronym that stands for polymerase chain reaction. The polymerase chain reaction, which I'll refer to as PCR, what this does is allow researchers and diagnosticians like myself to look at just the gene or region of interest.
So the dog genome has roughly 3 billion base pairs

of DNA, so A, C, T, and G, the long run-on sentence. And it's really difficult to sift through 3 billion base pairs of DNA, so in the 1980s this technique was developed that allows you to amplify just the region of the genome that you're interested in, away from all that other noise. And so you can amplify it almost like a Xerox machine, you copy the DNA over and over and over again, so you essentially are amplifying it -- is how we refer to it -- you're amplifying it away from the noise so that you can just look at that one region.

Q. Now, after reviewing this publication and learning about the location of the mutation that's linked to HNPK, did PPG develop a test for HNPK?

A. Yes, we did.

Q. And what sort of methods did HNPK -- or did PPG select for its HNPK test?

A. So the method that we used for HNPK are the same methods that we used for the majority of the tests in our lab. So everything starts with a PCR; we amplify. So if a customer were to order HNPK, we amplify that region using PCR, and then we'll apply some other genotyping method. Because PCR on its own can be used for genotyping, but usually you use a secondary method. And so in this case we used a method that specifically amplifies just the normal or just the mutant copy of the gene, and then we use another method called mass

spec.
Q. Now, when did PPG release its test for HNPK?
A. April of 2014.
Q. Did you look for a patent at that time, before you released the test?
A. So we didn't release just this test. So in the spring of 2014 we had developed many tests, like 40 tests, and so this is just one of those. And prior to releasing those tests, we did do a patent search for all of those tests, including HNPK.
Q. And did you find anything in connection with HNPK?
A. We found an application that had been submitted, yeah.
Q. Did you review the application at that time?
A. We did look at it.
Q. Why did you release a test, if you found an application that was pending?
A. Because it's just an application. Lots of applications never make it through the whole granting process.
Q. And did you see anything new in that application besides conventional methods?
A. No, we didn't see anything novel.
Q. So when did you first learn that a patent had been granted on -- that was related to HNPK?
A. So we didn't -- we were unaware that a patent had been granted on this until we received the cease and desist

letter, and attached to that cease and desist letter was the patent.

Q. And what did you think when you received that notice of that patent?

A. I was shocked. I was shocked that in -- well, I was notified in 2017. So I was like, oh, my gosh, 2017, and, you know, we don't patent DNA anymore. What is going on?

Q. What did you do in response to that information, learning that the patent was issued, in fact?

A. Well, so we submitted, you know, what is called a motion for summary judgment within a month to have a court, you know, review the patent to determine its validity.

Q. And that's what we're here for, as far as you know?

A. Yes.

Q. That's why we're here, as far as you know?

A. Yes.

Q. Okay. Now, I want to direct your attention to the claims of the patent.

Claim 1 says, "an in vitro method for genotyping a Labrador Retriever comprising" -- do you see that?

A. Yes.

THE COURT: You are looking at claim 2?

MR. WALTERS: Claim 1.

THE COURT: Claim 1, and that's on what page of the patent?

MR. WALTERS: That is on the last page of the patent.

THE COURT: The top of the left-hand column, right?

MR. WALTERS: That's correct.

THE COURT: Can you find that, ladies and gentlemen? It's on the last page.

MR. WALTERS: Your Honor, I believe this is already in evidence. If it's not, we'll officially move that it be in evidence.

THE COURT: Well, does it have a number?

MR. WALTERS: Number 1, Your Honor.

THE COURT: All right. Exhibit 1, the patent, will be admitted in evidence.

(Joint Exhibit No. 1 received in evidence.)

BY MR. WALTERS:

Q. Dr. Shaffer, do you see where it says, "an in vitro method for genotyping a Labrador Retriever comprising..."?

A. Yes, I do.

Q. What does "in vitro" mean?

A. So in vitro means outside of the main organism, so this means that the method is being practiced, you know, in a petri dish or in a test tube.

Q. And again remind the jury, if you could, what genotyping is.

A. Again, genotyping is looking at the DNA of interest and

determining whether or not the mutation is present.
Q. So this is saying it's a method of determining the DNA in a laboratory? Is that a fair translation?
A. Yes. So, basically, looking at the strand of DNA taken from a Labrador in a laboratory.
Q. Okay. Now, what about 1(a)? It says, "obtaining a biological sample from the Labrador Retriever."
Do you see that?
A. Yes, I do.
Q. Is that limited in any way to a particular method of obtaining the biological sample?
A. No.
Q. So this would cover the cheek swab method that PPG uses?
A. Sure, or blood, or any other kinds of tissues that we receive in the lab, correct.
Q. And, as far as you know, were scientists collecting samples in that manner prior to the filing date for this patent, which was May of 2012?
A. Decades before.
Q. Okay. Now, the second part says, "genotyping a SUV39H2 gene encoding the polypeptide of sequence ID No. 1."
Do you see that?
A. Yes.
Q. What is sequence ID No. 1?
A. So sequence ID No. 1, as shown in the patent, is the

amino acid sequence of the protein or the polypeptide, and it's because proteins are made up of these building blocks called amino acid. So this is just basically the string of amino acids that make up that polypeptide.

Q. And so this says, "genotyping SUV39H2 gene encoding the polypeptide." As far as you know, is that a naturally occurring gene?

A. It is. It is. It's in -- as far as I know, it's in all mammals. In fact, I think it's been found outside of mammals. It's been found in Drosophila, which is the fruit fly, and it actually was found first in mice, in the year 2000.

Q. Now, when it says, "genotyping an SUV39H2 gene encoding the polypeptide" of this sequence, what does that mean?

A. It means, looking at this gene and this -- and it's the gene that codes for this protein.

Q. So looking at the naturally occurring sequence?

A. Correct, looking at the naturally occurring gene that encodes that protein.

Q. Okay. Let's move on to part (c). It says, "detecting the presence of a replacement of a nucleotide T with a nucleotide G at position 972 of sequence ID No. 2."

Do you see that?

A. Yes.

Q. What is sequence ID No. 2?

A. So that's a reference to the sequence that was put into the patent. That sequence is about 1,000 base pairs around this particular mutation that they're describing.
Q. And was this particular mutation, the T with the nucleotide G at position 972, something that was created by nature?
A. Yes, naturally occurring. It wasn't created in the lab or a laboratory, I should say.
Q. Okay. And part (c) says, "detecting the presence of a replacement of a nucleotide T with a nucleotide G at position 972 of sequence ID No. 2." What is that saying, in regular English?
A. It's saying, basically, in some manner you're looking to see whether that sequence has the T or the G.
Q. Now, in your opinion, is there anything else a part of this claim besides a method for looking for this mutation in a laboratory from a sample that's obtained from a Labrador Retriever?
A. There's nothing other -- no, there's no invention here. It's just taking a sample and looking at the naturally occurring DNA and finding whether or not it has an alteration or mutation in the DNA.
Q. Now let's move on to claim 2.
Do you see where it says, "The method according to claim 1, wherein the genotyping is achieved by PCR..." and it

has some other things in there? Do you see that?
A. Yes, I do.
Q. So, first, before we move on to the other part of the claim, when it says, "the method according to claim 1," what does that mean?
A. It means that that claim 1, which is what we've just gone over, getting a sample from the Labrador, and then looking at the gene sequence, and then looking to see if it has a T or a G -- it's referring to that.
Q. And then what are all these other methods that it talks about; PCR, realtime PCR, melting point analysis of double-stranded DNA? What are those?
A. So these are all routine methods that have been around for decades. Most of them are being used today. Some of them actually are not used very often anymore, but they're all routine. They've been around forever. We have, actually, more methods than this in order to do genotyping.
Q. So does claim 2 --
THE COURT: How long is "forever"?
A. Decades, so at least 20 years, 30 years for some of these.
BY MR. WALTERS:
Q. So claim 2 says look for this mutation, but you can do it by any number of these ways. Is that fair?
A. Correct.

Q. Now, let's go through just each of these ways, and I want to get your personal experience, if you have any, with each of these.
A. Okay.
Q. Now, the first we've already talked about, PCR, but I'm going to ask you a different question about that.
Have you ever used PCR yourself?
A. Yes, I have.
Q. When did you first use PCR?
A. In the mid-1980s.
Q. How about realtime PCR? Is that something that you've had personal experience with?
A. Yes.
Q. And when did you have personal experience with realtime PCR?
A. In the early 2000s we published a paper in which we used realtime PCR.
Q. And you used it for genotyping?
A. Yes.
Q. How about melting point analysis of double-stranded DNA? Is that a new genotyping technique, as far as you know?
A. No, that's been around for decades, as well.
Q. How about -- did I already go over melting --
A. Yes.
Q. Mass spectroscopy. How about mass spectroscopy? Is that

a new genotyping technique, as far as you understand?
A. No, it's not new.
Q. Do you have any personal experience with mass spectroscopy?
A. Yes. When I was at Baylor College of Medicine, that technology was used to identify mutations with other -- I mean, other people in the department were using that, and then we're currently using it, actually, in our laboratory.
Q. Now, mass spectroscopy, you used it at Baylor College, you said?
A. Others were using it at Baylor, but I was there at the same time.
Q. Okay. So you observed this with your own eyes?
A. Yes.
Q. And have you read about this in the literature, mass spectroscopy?
A. Yes.
Q. It wasn't something that was invented in this patent, as far as you know?
A. Oh, no. It's been around for, again, 20 or 30 years.
Q. How about direct DNA sequencing? What is that referring to?
A. So that's using methods to -- exactly what it says; directly sequencing pieces of DNA, and that's been around since the late 1970s, or mid-1970s.

Q. And how do you know that?
A. Well, I learned that in school, and it's something that, you know, if you go to PubMed and you put it in, you're going to get thousands of papers.
Q. How about restriction fragment length polymorphism, or RFLP? Was that a genotyping technique that was in use routinely prior to May of 2012?
A. Yes. I actually used that in my dissertation when I got my Ph.D.
Q. And, again, when did you get your Ph.D.?
A. In 1990, so I used it in the late 1980s.
Q. How about single-strand conformation polymorphism, or SSCP? What is that?
A. So that's where you can tell the difference between whether a strand has the mutation or doesn't have the mutation by the way that the DNA behaves. And, again, that's been around for, you know, 20 or 30 years.
Q. Would you consider that a well-known technique prior to this patent?
A. Oh, yeah.
Q. And, again, it's a technique for genotyping. Is that right?
A. It is, yes.
Q. How about high-performance liquid chromatography, or HPLC? What is that?

A. So, again, that's looking at the differences the way that DNA will behave based on whether or not a mutation is present. So, you know, all of these are various ways of looking at DNA.
Q. And has this HPLC method been in conventional, routine use since before this patent was filed?
A. Yes.
Q. How long before?
A. Again, the early 1990s is my recollection when it was used for -- in human diagnostics.
Q. Okay. Now, how about single-base primer extension? What is that?
A. So this is a way to identify -- again, it's a genotyping method. It's a way to identify the differences between a normal sequence and a sequence that has a mutation.
Q. And was this a method that was in use routinely by scientists prior to the filing date of this patent, in May of 2012?
A. Yes, it was.
Q. And how do you know that?
A. Again, it was being used when I was in the department at Baylor College of Medicine. It was being used to look at human sequences, as well as on a quick PubMed search I found, you know, papers back to the early 1990s.
Q. Now, we've gone over claims 1 and 2. Looking at claims 1

and 2, in your opinion, do they include anything significantly more than the location of where this mutation is on the dog genome?

A. No.

THE COURT: Well, you didn't specifically cover the last one.

MR. WALTERS: Oh, we're going to get to that one, Your Honor.

BY MR. WALTERS:

Q. So let's look at claim 3.

Do you see, Dr. Shaffer, where it says, "The method of claim 1, wherein the genotyping utilizes a primer pair comprising a first primer and a second primer..."? Do you see that?

A. Yes.

Q. What are primers?

A. So a primer is a small piece of DNA that you can make, but you make it based off the naturally occurring sequence that you found in the genome. So it's -- we talked about PCR and how to amplify DNA. Well, how you do that is -- I always have to use my hands. How you do that is you make these primers, and these primers have to be sufficiently long so that they're unique, and you put them in with DNA under conditions that allow them to find their perfect match in the genome.

And those primers will sit down on the DNA, they'll find their perfect match, and you've made that because you copied it from the perfect match, so now those primers sit down where they're meant to be in the genome, and then you use those to amplify across that sequence.

Q. Is this a way of using PCR?

A. It is. It is PCR.

Q. Now, were scientists using primers in this manner before this patent was filed, in May 2012?

A. Yes.

Q. Would you consider it a routine use by scientists at that time?

A. Yeah, it became very routine in the mid-1980s, after it was first developed.

Q. Now, is there anything new about using a contiguous span of at least 14 nucleotides? Do you see that?

A. Yes, I see that.

Q. Is there anything new about using 14 nucleotides for the primers, prior to May of 2012?

A. No. Anybody who's experienced in molecular biology knows that you have to use a primer that is sufficiently long so that it's unique, and primers are typically 14 to 20 base pairs in length, is what you need to achieve in order for it to find only its unique place in the genome so that it doesn't sit down, you know, in the wrong place, it only sits

down in the right place.
Q. So did you personally use primers in PCR in this manner prior to May 2012?
A. Yes.
Q. Was that a routine thing that you did in your research at that time?
A. It's very routine.
Q. Okay. And it's -- is this claim asking to do it for the sequence ID No. 2?
A. Yes.
Q. And again, remind the jury what sequence ID No. 2 is.
A. So sequence ID No. 2, again, as it's shown in the patent, is about a thousand base pairs surrounding the mutation that was described in that manuscript.
Q. And is that a naturally occurring sequence?
A. Yes, it is.
Q. Okay. What is part 3(a)? Here it says, "said first primer hybridizes to a first DNA strand of the SUV39H2 gene." What is that talking about?
A. So in order for PCR to work, the primer has to sit down in its specific unique location, and that's called hybridizing.
Q. And so is this saying for the primer to hybridize on this is first strand of the gene?
A. I'm sorry? What was the question?

Q. Is this saying the first primer hybridizes to a first part of the gene, first strand of the gene?
A. Correct. I mean, the way that it works -- I mean, the typical, routine PCR -- where there's lots of fancy, different ways now that you can use these things, but this is very typical, where you'll have one primer sits down on the DNA, and then I'm suspecting you're going to ask me about part (b), which is the second primer, so it's done between two primers, typically.
Q. Okay. So part (b) is the second primer?
A. Correct.
Q. There are two parts of DNA, right? There are two sides?
A. Well, DNA is a double helix, and in order to do this method we -- so we talked about hybridization, which is where it sits down on the DNA in the right place. Well, you also can take that double helix and break it apart and make it into single strands, and so the primer sits on one of the strands -- one primer sits on one strand, and one sits on the other strand.
Q. And, again, is this all part of that same technique that was in use prior to May 2012?
A. Correct.
Q. And it's a technique that you used yourself; is that right?
A. Yes.

Q. How about this part (c)? It says, "the 3' ends of said first and second primers are located on regions flanking the position 972 of sequence ID No. 2, or of nucleotide positions complimentary thereto." What does that mean?
A. So, basically, it's saying, again, we're using -- or they're describing PCR to amplify the sequence, and they're saying basically these primers -- in order to amplify the sequence that contains the mutation, you want to put the primers so that they flank on either side the mutation. I mean, if the mutation is here and you put your primers out here on this huge, long run-on sentence, you're not going to amplify the right region.

So they're just saying what we all do, is you want to put your primers down that flank the mutation, because that's the whole purpose of this, is to amplify that region.
Q. So now having gone over all of the parts of claim 3, does claim 3 contain anything significantly more than the location of the mutation that's known to cause HNPK?
A. No.

MR. WALTERS: No further questions, Your Honor.

CROSS-EXAMINATION

BY MS. WILBERT:
Q. Hi. My name is Johanna Wilbert, and I have a few questions for you.

You testified that PPG offers a variety of tests for

dogs to see if they have a genetic mutation, correct?
A. Uh-huh.
Q. And to develop those tests, PPG reviews medical literature, correct?
A. Correct.
Q. And PPG looks for articles that identify mutations associated with diseases, correct?
A. Correct -- well, yes.
Q. And PPG offers testing for Labrador Retrievers, correct?
A. Yes, we do.
Q. And PPG offers to test labs for the mutation associated with HNPK?
A. Correct.
Q. And PPG did not independently research HNPK to determine its cause?
A. No, we did not.
Q. And PPG did not discover the genetic mutation that was associated with HNPK?
A. No, we did not.
Q. And you personally learned about HNPK when you read a journal article, correct?
A. Correct.
Q. And the article identified the mutation that caused HNPK, correct?
A. Correct.

Q. Could you look at Exhibit 26? Exhibit 26 is the article in which you learned about HNPK, correct?
A. Yes.
Q. And I believe we have an enlargement of a version of it. Let me just get that pulled up.
Exhibit 35 also has the same article that was submitted as Exhibit 26. So the heading would be wrong, but the blow-up should be the same, if you could look at the screen and see if that's actually the same article.
A. Yes, it is.
THE WITNESS: So just for the sake of having the blow-up, could we show the blow-up of the article?
THE COURT: Yes. We'll admit Exhibit 35, since that's the one you're showing that you say that that's identical to Exhibit 26.
MS. WILBERT: Exhibit 35 has an e-mail attached, so it's slightly different, but the article I'd like to ask the witness about is the same.
THE COURT: Okay. We'll admit Exhibit 35.
(Joint Exhibit No. 35 received in evidence.)
BY MS. WILBERT:
Q. And this article is titled "A Mutation In The SUV39H2 Gene In Labrador Retrievers With Hereditary Nasal Parakeratosis," and it gives some information about the disease; is that correct?

A. Yes.
Q. And the last named inventor in this article is Tosso Leeb; is that correct?
A. That's the last author on this paper, correct.
Q. And Dr. Leeb is the inventor of the patent at issue in this case?
A. Correct.
Q. The article identifies the mutation that is associated with HNPK, correct?
A. Correct.
Q. And before you saw this article that identified the HNPK mutation, you were not aware of any tests for the HNPK mutation, were you?
A. No, I was not.
Q. And before you saw this article, PPG as a company did not offer tests for the mutation associated with HNPK?
A. Correct.
Q. And before this article, PPG never tested for the mutation associated with HNPK, correct?
A. Correct.
Q. And it was the article that is shown in Exhibit 35 and Exhibit 26 that gave PPG the information needed to develop PPG's test, correct?
A. Correct.
Q. I'd like to look at the language of claim 1.

Claim 1 does not specifically refer to any of the techniques that you were describing in your direct testimony earlier, does it?
A. No, it does not.
Q. Now, PPG sells tests for specific dog breeds, correct?
A. Correct.
Q. And a Labrador is just one of the dogs that PPG sells tests for, correct?
A. Correct.
Q. And PPG would sell different tests for a Greyhound, correct?
A. Some are different, but -- so correct, and some might be the same.
Q. Looking at claim 1, claim 1 states that the invention claimed is an in vitro method, and the term "in vitro" means in glass or in lab, correct?
A. Correct.
Q. So that means that this procedure takes place in a lab, correct?
A. A laboratory, correct.
Q. You offered the opinion that the patent is invalid, correct?
A. Correct.
Q. You discussed these beliefs, but you do not have a law degree?

A. No.
Q. And you've never worked as a patent agent, have you?
A. No, I have not.
Q. And you've never worked as a patent examiner with the Patent Office, have you?
A. No, I have not.
Q. And you are not admitted to the Patent Bar, are you?
A. No, I'm not.
Q. You are aware that the U.S. Patent Office has patent examiners, correct?
A. Yes.
Q. And examiners review the patent applications, correct?
A. Yes.
Q. And examiners consider whether the applications meet the requirements of the patent, correct?
A. Yes.
Q. And examiners have technical backgrounds, like yourself, to assist them in reviewing the technology assigned to them, correct?
A. Actually, I don't know what the requirements are to be a patent examiner.
Q. Did you consider that when you were evaluating whether the Patent Office made a mistake?
A. What the examiner's background was?
Q. Yes.

A. No.

MS. WILBERT: Your Honor, I'd like to offer Exhibit 2 into evidence.

MR. WALTERS: No objection, Your Honor.

THE COURT: There are too many exhibits in this one binder.

Exhibit 2 is -- I don't know how many pages it is. It doesn't have page numbers on some of it. Are you introducing the entire exhibit?

MS. WILBERT: Yes, Your Honor.

THE COURT: Was there any part of the exhibit you want us to read?

MS. WILBERT: Yes, Your Honor.

THE COURT: Surely you don't expect us to read the whole thing.

MS. WILBERT: Your Honor, under law we can admit the certified file history of the patent that's at issue, and I believe in this case there are going to be different pages throughout the case that will be relevant, so we'd like to just admit the entire exhibit at this time. And I'd be happy to draw attention to particular portions of the exhibit.

THE COURT: Well, you can admit the entire exhibit, but that doesn't mean it's wise to do so. But if you want to admit the entire thing, I'll admit it.

(Joint Exhibit No. 2 received in evidence.)

MS. WILBERT: Thank you, Your Honor.

THE COURT: But I would like for you to tell us where your focus is.

MS. WILBERT: Absolutely.

BY MS. WILBERT:

Q. Have you reviewed the file history in forming your opinions about the validity of the patent?

A. No, I have not.

Q. So you formed your opinion that the Patent Office got it wrong without reading what the Patent Office did?

A. Correct.

Q. I'd like to draw your attention to the certified file history. It is in your binder as Exhibit 2. And this is 414 pages long. If you could, turn to roughly page 395. If it's helpful, I'm happy to display it on the screen.

A. Yeah. Because this is a blank page. I don't know what 395 is. They're not numbered.

THE COURT: Page what?

MS. WILBERT: It's 395, but if we want to look at the screen, we have it up as the notice of allowance.

A. Can you make it bigger? I can't read that.

BY MS. WILBERT:

Q. We can skip to the next page.

THE COURT: Where does it say 395?

MS. WILBERT: It gives you a sense of how far back

it is. I'm sorry, but the Patent Office official copy doesn't have numbers, and that is what the Patent Office gave us. The entire document is 414 pages long, so if you start at the back --

THE COURT: Do we have Bates numbers on this exhibit?

MS. WILBERT: No, Your Honor. This exhibit came from the United States Patent Office. It wasn't produced by either party.

THE COURT: Well, that has nothing to do with whether it has Bates numbers on it. How can we find it?

MS. WILBERT: I'm happy to show you on the document camera, if that's easier.

So it's a page that looks like this, titled "Notice of Allowability."

THE COURT: I don't know how we can find it without taking the jury's time to leaf through it, so I'll look at the copy.

BY MS. WILBERT:

Q. And is the notice of allowability what the Patent Office issues when an examiner is granting a patent? And I'd like to ask you to look at page 2 of the notice of allowability. And it may, at this point, be easier if we can look at the blow-up that we prepared.

Here it's discussing what the examiner did. Were

you aware that the examiner had a telephone interview with the attorneys for the inventor?
A. No, I wasn't aware.
Q. So you did not consider the steps that the examiner took in analyzing this issue in forming your opinions about the validity of the patent?
A. No, I just looked at the claims.
Q. And did you know that the claims were amended in the prosecution history?
A. I assumed so, because it looked very different than the application. The final patent looked different than the original application.
Q. And here the file history shows that the claims have been amended to be directed to a method of detecting a new and nonobvious mutation in a biological sample of a Labrador Retriever.

Did you consider that the Patent Office believed that the claims had been amended to be a method of detecting new and nonobvious mutation?

MR. WALTERS: Objection; lacks foundation.

MS. WILBERT: Your Honor, she's been certified as an expert, and if she's going to be giving opinions about validity, the basis of her opinions can be challenged with file history documents. The foundation is that she's an expert and hasn't offered an opinion on this topic.

MR. WALTERS: Your Honor, she hasn't offered an opinion on the Patent Office, what they believe.

THE COURT: The objection is overruled. The only problem is I can't find where it is in the exhibit, and I don't know what the page before this or the page after it says.

MS. WILBERT: Would it be helpful to give you just a photocopy separately? We can mark it as a different exhibit.

THE COURT: It wouldn't be helpful. What would be helpful is if you would put Bates numbers on it between now and tomorrow.

MS. WILBERT: Okay, we can arrange that.

THE COURT: All right.

BY MS. WILBERT:

Q. In forming your opinion that the Patent Office made a mistake, did you consider the next sentence that said, "the mutation SUV39H2" -- and let's pause there. We've used a lot of abbreviations.

The SUV39H2 gene is the gene that's associated with HNPK, correct?

A. Correct.

Q. Did you consider the fact that the examiner determined that it was not previously disclosed on the canine HD biochip?

A. I can consider it now, if you'd like.

Q. Did you consider that when you formed your opinion before testifying today?
A. No, because this is the first time I've seen this, and I don't know where to find it in context in the book. This is pulled out of --
Q. Sure --
THE COURT: Don't interrupt the witness's answer, Counsel.
Go ahead.
A. So in looking at this today, the first sentence is that it's simply a method directed to a mutation in a biological sample in a Labrador, so there's nothing invented there. You asked for my opinion.
And the second sentence is that she found it interesting and patentable because it was not found on the canine HD biochip. There's a lot of genes not found on the canine HD biochip, because that's not the purpose of this chip.
BY MS. WILBERT:
Q. But it's one of the facts that the patent examiner considered in doing her job, correct?
A. It appears so, yes.
Q. And it's not one of the factors that you considered in forming your opinion before testifying today about whether the patent was valid, correct?

A. No, but it supports my opinion that it's not valid.
Q. The fact that the mutation was not previously disclosed?
A. No, and the fact that it was not found on the canine HD biochip. It's irrelevant. There's lots of genes not on that chip.
Q. You are aware that the Patent Office found it relevant, correct?
MR. WALTERS: Objection, Your Honor; foundation.
A. They must have.
THE COURT: The objection is overruled.
BY MS. WILBERT:
Q. And after reaching these conclusions, the patent examiner stated that the claims no longer require a judicial exception. Do you see that?
A. I do see that.
Q. And the Patent Office ultimately issued the '114 Patent, correct?
A. That's why we're here.
Q. And in openings, your attorney mentioned the streamline eligibility analysis. Did that influence your opinion about whether the patent was valid?
A. No, I just recently learned about that. I didn't even know that it had been pushed through like --
THE COURT: You didn't know what?
THE WITNESS: I didn't know that this patent had

been pushed through that way, with that exception. I didn't know that before preparing for this trial. I just learned about it the other day.

That didn't -- that didn't influence my conclusions that this patent is not valid.

BY MS. WILBERT:

Q. And are you aware that the Patent Office actually did not use the streamline eligibility analysis?

A. I'm not aware -- I mean, I'm only aware of what I've heard in this courtroom, because I wasn't aware about this judicial exception.

Q. So your attorney's testimony about the patent being invalid, that wasn't the basis for your opinion?

MR. WALTERS: Objection to the reference to opening statements as testimony, Your Honor.

THE COURT: I'm afraid that question -- I didn't understand your question.

MS. WILBERT: That's fair.

THE COURT: Well, I want to hear your question again.

MS. WILBERT: Sure. I had understood that there was a reference to something I thought the witness had relied upon in forming her opinion --

BY MS. WILBERT:

Q. And it sounds like you did not rely upon that, so --

A. No, it was just simply my knowledge as a scientist and knowing that DNA was not created in a laboratory and this mutation was not invented. It wasn't created, it's naturally occurring. That's what I based my decision on.

Q. And you also testified that you were concerned when the patent issued because it would only be offered by one lab; is that correct?

A. Right. Not knowing anything about how the patent holder was going to enforce or monopolize the information, that was my concern; that our customers could no longer get that test from us, and we would no longer be able to offer them a comprehensive Labrador Retriever panel.

Q. And my client has actually offered to partner with you twice and offer a license to you for this technology, correct?

MR. WALTERS: Objection, Your Honor; irrelevant.

THE COURT: Ladies and gentlemen, as I told you at the beginning of the case, there will sometimes be a question that was answered that shouldn't have been asked, and that's what just happened.

That question is totally irrelevant to the issue before you, which is: Is the patent valid? Any negotiations that might have taken place between the parties before this litigation was instituted is totally irrelevant and is not permitted to be introduced in evidence, so you will disregard

the question and the answer.

MS. WILBERT: Your Honor --

THE COURT: Don't talk to her anything about negotiations between these parties, Counsel. I'm sure you know that that's not admissible.

MS. WILBERT: Your Honor, I believe it goes to bias.

THE COURT: If you have something to say, come up here and say it, don't say it in front of the jury.

MS. WILBERT: Okay.

(Sidebar conference:)

MS. WILBERT: There's been reference to a number of factors that are factually incorrect. For example, she testified that she's concerned that this is going to prevent other people from using it, and there's, to my knowledge, one lab, but the parties have had significant negotiation between them that those --

THE COURT: Their negotiations are not admissible, Counsel.

MS. WILBERT: It goes to bias for her invalidity --

THE COURT: No. The negotiations -- look at the Federal Rules. Negotiations are not admissible.

MS. WILBERT: This wasn't for settlement, Your Honor. She's saying that she --

THE COURT: It wasn't? Then what would the negotiations for a license be if it wasn't for settlement,

and if you agreed on a royalty as a resolution of damages? Now, what you're talking about is negotiations. Don't do it again.

MS. WILBERT: Okay.

THE COURT: Don't. The objection was sustained. I told the jury to disregard it. Don't do it again.

(End of sidebar conference.)

BY MS. WILBERT:

Q. You are the CEO and founder of PPG, correct?

A. That's correct.

Q. And you have an ownership interest in PPG, correct?

A. Yes, I do.

Q. And PPG profits by selling tests such as the HNPK test, correct?

A. Correct.

Q. And it would be in PPG's interest to have this patent found invalid, correct?

A. Correct, and our customers' interests as well, correct.

MS. WILBERT: No further questions.

MR. WALTERS: Your Honor, I have a brief redirect.

REDIRECT EXAMINATION

BY MR. WALTERS:

Q. Dr. Shaffer, I believe you mentioned that you have your own patents.

A. Correct.

Q. Now, in getting those patents, were there any other companies involved in the back-and-forth with your company and the Patent Office besides your company and the Patent Office?
A. No, it was just -- this was my previous company and the Patent Office.
Q. Now, does the fact that the file history is 400 pages long tell you anything about how this patent was reviewed at the Patent Office?
A. Well, just, in my lay opinion, it looks like there was a lot of going back and forth. It's really big, so --
THE COURT: I don't think that's a proper question. The jury will disregard that. The witness hasn't testified as to any expertise in the operation of the Patent Office, and the length of the patent history is of no concern to the Court, except that I can't find it because of the lack of page numbering. But the fact that it's long doesn't make any difference. And this witness is not entitled to comment on it, so you will disregard any comments the witness made about the length of the patent history. There's no evidence that that means anything.
MR. WALTERS: Your Honor, I have no further questions.
THE COURT: All right. You may step down.
Ladies and gentlemen, this would be a good time to

take an afternoon break. So we'll take a 15-minute recess.

(The jury left the courtroom.)

THE COURT: Counsel and ladies and gentlemen, you're not required to stand when the jury enters and exits the courtroom.

The problem with your question about negotiations is because you asked about negotiations. If you had asked about is there another method of sharing the patent vis-à-vis licensing, that would have been fine. But you related it to the negotiation, and that's the reason it was inadmissible.

We'll take our recess.

(A brief recess was taken.)

MR. PIERY: Your Honor, before the jury comes in, we want to -- we anticipate that plaintiff is resting his case after this last witness, and we want to let you know we have a motion for a directed verdict, if you want to hear that before he brings out the jury.

THE COURT: Is that right?

MR. WALTERS: Yeah. We have Dr. Shaffer as our witness, and we'll rest our case now.

THE COURT: All right. Well, tell the jury that something has come up, and we'll take a little longer before we resume.

Is this Exhibit 2 supposed to be the entire patent history?

MS. WILBERT: Your Honor, this is the original. It came from the Patent Office, and it's certified, and it is the entire history.

THE COURT: That's the original, and you say it's 444 pages?

MS. WILBERT: 414.

THE COURT: 414. Because I was looking through here, and I saw a page 595 or something.

MS. WILBERT: Some of the references that were submitted either as prior art -- this is a combination of multiple individual documents that's have been certified --

THE COURT: It's a combination of what?

MS. WILBERT: Because the file history is a combination of multiple documents that were passed and submitted back and forth between the patent examiner and the inventor, it is a compilation of multiple documents, but the Patent Office, when it gives these certified copies, gives it in a bound form, so it's a single document that we received from the Patent Office as the official copy.

THE COURT: So that's in the same form that you received it from the Patent Office?

MS. WILBERT: You're right, Your Honor.

THE COURT: You asked them for the patent history, and this is what they sent you?

MS. WILBERT: Correct.

THE COURT: Because you look, and one portion of it begins on page 559 and goes through 575.

MS. WILBERT: I believe that may be some of the reference material that had been submitted that was an excerpt. I don't believe that there's a dispute between the parties that this is the official copy.

THE COURT: If you tell me what you asked for and that's what they gave you --

MR. WALTERS: This appears to be what we got from the Patent Office.

THE COURT: -- that's acceptable. I didn't understand why they should be numbered the way they were or weren't.

Okay. Do you want to make your motion?

MR. PIERY: Yes, sir. Your Honor, defendants move for a judgment as a matter of law that no reasonable juror could find that claims 1 through 3 of the '114 Patent are invalid.

As you know, the *Alice* test is a two-step test, and based on Dr. Shaffer's testimony, no reasonable juror can conclude that the claims fail either of the two steps of the test.

THE COURT: Well, the Court believes that if it found that Dr. Shaffer's testimony was accurate that it would grant summary judgment to the plaintiff based on the *Alice*

case, so unless -- I'm certainly not going to grant summary judgment against the plaintiff. If the Court believes her testimony, then, as I say, I think the plaintiff would be entitled to summary judgment. It appears that all this is is a compilation of known techniques to a naturally occurring event.

MR. PIERY: Your Honor, we disagree. So under the first step of the *Alice* test the claims must be directed to a natural phenomenon, and here, as Dr. Shaffer testified, the claims are an in vitro -- meaning in laboratory -- method, and the Federal Circuit has said that method claims are generally eligible.

The claim here does not start and end with the natural phenomenon. We're not claiming HNPK, the claims are not --

THE COURT: I don't know what they are, and I don't think the in vitro makes any difference whatsoever, but what they are is a natural phenomenon that was tested, according to Dr. Shaffer, with known testing methods that had been used for decades. You can't patent a discovery.

MR. PIERY: Correct, Your Honor, and the claims are not attempting to patent the discovery, they're patenting the laboratory method that involves the discovery. It is not the discovery itself.

THE COURT: The methods, according to the evidence

are all well-known and preexisting, so adding methods to a natural phenomenon, when all the methods are preexisting, doesn't get you there.

MR. PIERY: Your Honor, under Step 1 the inquiry is not whether the method was preexisting, the inquiry is whether the claims are directed to the natural phenomenon. And that's like the *CellsDirect* case, where the Court found that it satisfied both steps of the *Alice* test, even though every step in the claim was a well-known step. The Court found that when you analyze the claim as a whole -- and this is the Federal Circuit that found this. When you analyze the claim as a whole, it was not directed to this -- the discovery that these liver cells could survive multiple freeze cycles, which was unknown, nor was it directed to the actual freezing, which were routine and conventional. When the claim was viewed as a whole, it was not directed to this process that it was new and improved.

Further, under Step 2 --

THE COURT: There's no new method of testing here. Your motion is overruled.

MR. PIERY: Your Honor, could I comment on Step 2 quickly?

So under Step 2, we think the analysis performed by plaintiff --

THE COURT: If you don't pass Step 1, you don't get

to step 2, but go ahead.

MR. PIERY: Your Honor, under the *Alice* test, if the claims satisfy either steps, the claims are eligible. Under Step 2, plaintiff has performed an incorrect analysis by dissecting the claims and looking at each limitation of the claims individually to determine whether that limitation was well-known and routine.

The proper analysis under step 2 is to view the claim as a whole, and that's a direct quote from the *CellsDirect* case. You cannot dissect the claim into its individual parts and ask whether those are routine and conventional, the claim must be viewed as a whole. And here, when the claim is viewed as a whole, there's no testimony in the record that any of those techniques were used to genotype this portion of this gene, and that, when viewed as a whole, is what is unconventional and not routine about --

THE COURT: This gene is a natural occurring phenomenon, and all of these methods are just methods of detecting a naturally occurring phenomenon, according to the plaintiff's evidence. That is not sufficient, and the Court denies your motion.

MR. PIERY: Thank you, Your Honor.

THE COURT: All right. You can bring the jury in.

(The jury enters the courtroom.)

THE COURT: Does the plaintiff have more evidence

that it wishes to present at this time?

MR. WALTERS: No, Your Honor, the plaintiff rests.

THE COURT: All right. Is the defendant ready with its evidence?

MS. GRAY: Yes, Your Honor. Defendants would like to call their first witness, Dr. Elisabeth Müller.

THE COURT: Dr. Who?

MS. GRAY: Elisabeth Müller.

ELISABETH MULLER, Ph.D., called by the Defendant, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. GRAY:

Q. Good afternoon. Please introduce yourself for the jury.

A. Good afternoon. Good afternoon, ladies and gentlemen. My name is Elisabeth Müller.

Q. Dr. Müller, where do you live?

A. I live in Germany. I live in Bad Kissingen.

THE COURT: I'm sorry. It's not necessarily your fault, but I'll have to ask you to talk slower and into the microphone, because I can't understand you.

A. I'm sorry.

THE COURT: It's not your fault.

A. Is that better this way?

THE COURT: Yes.

A. Yes. My name is Elisabeth Müller. I'm living in Germany. I live in a small town in the northern part of Bavaria. So if you look at the map in Germany, that's kind of in the center.

BY MS. GRAY:

Q. What do you do for a living?

A. I'm trained as a veterinarian, but I founded a veterinary laboratory almost 30 years ago, and so I work as a veterinarian in a veterinary laboratory.

Q. You mentioned you founded a laboratory. Is that LABOklin?

A. That is LABOklin, yes.

Q. Are you the owner of LABOklin, too?

A. I'm the owner. We started with three, and the other ones were two other veterinarians who wanted to retire some years ago.

THE COURT: I'm sorry. I didn't understand what you just said. You were the owner of --

A. I'm the owner of LABOklin, yes, that is right.

THE COURT: And what did you say before that?

A. We started with three people, and then my two -- the two co-owners, sorry -- they decided that they wanted to retire, and then I took over their part, so it's completely my laboratory now.

THE COURT: Okay.

BY MS. GRAY:
Q. Please tell us what your responsibilities are as owner and founder of LABOklin.
A. Okay. The laboratory is what we would call a small/medium sized enterprise. So it's not terribly big, and that is why I have a variety of responsibilities.
So I'm responsible for the finances, I'm responsible for the organization of the lab work, and I'm responsible for finding out how we want to change our portfolio constantly in order to make it an attractive portfolio for the clients that we have.
THE COURT: Make it attractive to who?
A. For the clients, for our customers that we have.
BY MS. GRAY:
Q. Will you please tell the jury briefly why you're here today?
A. I am here because I am the license holder of a patent that belongs to the University of Bern, and within the contract, I'm -- my duty is to defend the patent in every way I can.
Q. Let's discuss LABOklin. Where is it based?
A. It's based in a small town, 22,000 inhabitants, in the northern part of Bavaria, and we started with 13 people. I was number 13. I am still number 13. We grew through the years, and now we are one of the larger employers in the

town.
Q. Generally speaking, what does LABOklin do?
A. Okay. The big headline is animal health, really. So we concentrate on companion animals -- that is, dogs, cats, horses -- and then we continue with smaller animals. And the headline for that is animal health, so we support in detecting diseases, in monitoring diseases, and in preventing diseases.
Q. Does LABOklin offer veterinary diagnostic services?
A. It's all about veterinary diagnosing work, yes. That's the laboratory work behind what is maybe the veterinarian and practice needs in order to find a proper diagnosis, in order to find the best possible therapy, for instance.
Q. Why are veterinary diagnostic services important?
A. I think every one of us gets sick every once in a while, and we expect the medical doctor to find out what our disease is in order to pick the appropriate tool, the appropriate medicine or diagnostic work in order to get us better. And throughout the years, I think all of us who have animals know that our expectation is we want the same thing for our dogs and cats, of the animals that live close with us. We want the best possible diagnosis in order to get the best treatment and to have happy and healthy animals.
And that's what we try to do, and that's where we change our portfolio. When there's new methods coming up

that are better than the old ones, when there are tests coming up to detect a disease, then we will change accordingly.

Q. What veterinary services did LABOklin offer when you founded it in 1989?

THE COURT: In when?

MS. GRAY: 1989.

THE COURT: 1989.

A. 1989, almost 30 years ago, we started with our lab, and at that time we did what everybody associates with laboratory medicine. We did hematology work, like anemia, yes or no, or infection, yes or no. We did clinical chemistry, like liver parameters, kidney parameters. And we did microbiology, a lot of microbiology; that is, the bacteria that cause cystitis, in order to find out which is the best treatment.

BY MS. GRAY:

Q. How has the services that LABOklin offers changed over time?

A. Frankly speaking, when we started with 13 people, I knew we had to grow, although not so surprising, actually. And it was fun, really, to introduce new tests to whatever the veterinarian needed, so we added on more parameters that might be of use; some hormone detections or antibody detections or different kinds of tests.

And then by and by we started looking at different

fields of interests. So we did not have pathology, for instance, when we started, and more and more I think pet owners want to know when there's lumps and bumps that grow and they are cut out with surgery is that something malignant or is it benign? Does it come back, or is it treatable, or is it something that we don't have to look after? So pathology would be a whole area that we started working on as well, and there's several specialists working in that field now.

And then we started going into genetics, looking into genetically based identification of animals. So is this dog the dog that's supposed to be? Who are the parents? Can I identify the parents? Do they belong to the breed they're supposed to belong to? And do they carry hereditary diseases like HNPK, so do they carry diseases that are genetically based?

Q. Who are LABOklin's customers?

A. When I told you about our service we offer, our customers mainly are veterinarians, veterinarians who work. So almost 80 percent of our customers will be veterinary surgeons who ask for help to have a successful surgery.

Q. Does LABOklin have any other types of customers?

A. Okay. With the genetics field coming up, we have more and more breeders, dog owners, breeders, and kennel clubs coming into the range of our customers. Currently we have

several kennel clubs as customers, as well, because quite often it's not just the pet owners' interest whether or not a dog carries a disease, kind of silently carries it; from the outside being healthy but carrying a disease. Quite often it's in the interest of the breeder club or the kennel club as well. The kennel club wants the entity of these animals that belong to a breed to be a healthy entity.

Q. You mentioned that LABOklin has a laboratory in Bavaria. Is that in Germany?

A. Bavaria is in Germany, yes. It's, by area, one of the largest countries in Germany, and that's where the home of the laboratory is based. And when we started to grow, we realized that it might be interesting for other customers, other veterinarians within Europe, to take part in that service, so we started with satellite laboratories in several countries within Europe. And so we have a lab in Austria and Switzerland and Poland and Spain and Britain and the Netherlands, and we have representatives in other countries, people that are local in their countries, speak their language, know what are the special needs in these countries and make it possible to meet the demand.

Q. Does LABOklin have any laboratories in the United States?

A. No. See, we have our main laboratory in Germany, and I think you saw a picture that was -- I had two things that I never wanted to do. I never wanted to be an entrepreneur, I

thought it was risky, and I never wanted to build a house. And I did build a house, and that is where the lab is in. And the small satellites just run basic laboratory service, and we carry the samples that are not worked on in the satellite labs. We carry them to the main lab with an overnight courier, and that's the way we can serve with lots and lots of exotic tests very quickly and for a very fair price.

That's the concept. And I couldn't run that concept with the United States, so I don't run any laboratory in the United States, and I don't intend to do that.

Q. I'd like the jury to understand a little bit about your educational background, so let me ask you, where did you go to school?

A. Okay. I guess you have to forgive if I don't phrase correctly in the English language all the time, because I'm born and raised in Germany, graduated from high school in Greenville, Ohio. At that time I felt that was a great time to start studying there as well. My parents thought it was a great time to go back to Germany, finish school there, so I ended up studying veterinary medicine in Hanover vet school. Graduated from Hanover vet school, and then I did my doctors degree in microbiology and worked in practice at the same time.

After that, I stayed at the university for some more

years, because having left practice, I thought that was the thing for veterinarians, to work in a practice, and you deal with sick animals, getting them healthy, and I realized that these subjects around healing, like the power clinics, like microbiology, for instance, are extremely interesting, so I did a specialization in microbiology. So that would be an equivalent -- it's a specialization. It's a four-year course with special exams.

And currently I'm -- the laboratory is a teaching place for microbiology, to get the specialization for different other specializations as well, so I'm entitled to take final exams for microbiologists in that field. It's quite nice.

Q. For our jury, could you explain what microbiology is, in generally terms?

A. Microbiology is everything about all these bugs that get us sometimes sick, sometimes not, so it would be bacteria like E. coli. Everybody knows E. Coli or staphylococci. It would be fungi, like dermatophytes, and it would be viruses. All that belongs to microbiology.

Q. So let me ask you, Dr. Müller, do you consider yourself an expert in genetics?

A. By no means. I'm a specialist in microbiology. In saying that, I work a lot in the office now running the business, so I'm not really taking actively part in the

microbiology that much anymore.

I probably know a little bit more about genetics than somebody on the street, because I run a genetic department, and I know my basics in order to judge what kind of tests we want to run and how much that costs in terms of investment, for instance.

Q. What was your goal when you founded LABOklin?

A. Actually, the goal was we wanted to serve with best possible lab service for the veterinarian. And, saying that, that changes throughout the years, of course, because the demand changes. The expectations and the pet owners change, but the demand changes as well, so we do a lot of introducing new methods or new tests in order to be on the top level.

Q. What does LABOklin do to try to offer the best possible veterinary services?

A. My -- I'm the lucky person who can decide how to spend the money, so I can spend a considerable amount of money that we have in order to do research. Some of the research we do on our own. Sometimes that may be smaller projects, like find out if there is a test suitable that is on the market, sometimes our bigger projects, and then we work together with universities or other institutions. Sometimes they are kind of really big projects, like European-funded projects that we participate in. And all that is usually done because we want to be kind of at the edge, and we do that by having quite a

lot of students in our laboratory at the same time. So there will be mass spectroscopy students, veterinary thesis students, and all that.

Q. You mentioned research. Does LABOklin conduct its own research?

A. I think so, to a certain extent, yes. And quite often, because we are, of course, not a research institution like that, we use collaborations with universities in order to find answers to our questions. And most of that we -- that leads into publications or conferences where we take active part in, so part of our employees work at the university, have university contracts at the same time, give talks, educate students.

Q. You mentioned universities. What universities has LABOklin collaborated with?

A. Quite a lot, actually. That depends on what kind of subject we're on, because then it depends on -- we look for the scientific group that matches our demand in that field. So there's a long ongoing collaboration with Berlin University, with Eaton, with Munich University, the German ones. We've known University of Bern for a long time and work with them together. We've been working together with Texas A & M University. With University of Philadelphia we have doctorate students together, and we are just in the process of recruiting new ones because I've got this idea

that I really want to follow. Michigan. University of California-Davis is a university we work together with quite often.

Q. So is it fair to say that you collaborate with a lot of universities?

A. I think so.

Q. How long has LABOklin had these collaborations?

A. Well, the first years when we started we were too small, and we didn't really have the resources to do that, but it's getting more throughout the years, and I think more than 15 years that we've collaborated with universities.

Q. Does LABOklin collaborate with universities specifically in the area of researching gene mutations?

A. We have collaborations in all sorts of fields. So it may be some disease like infectious disease, it may be a genetic problem, and we do research in genetic areas as well, yes.

Q. Does anyone at LABOklin review scientific publications about new gene mutations that might have been identified?

A. Well, yes, of course. I mean, if we want to be -- with the genetic portfolio that we offer, if we want to be kind of on top of what people have as interests, then of course we will go file the literature, the current literature of what is going on.

Quite often we don't even need to do that because we try to be -- well, we have these collaborations going, and we

go to the conferences that are going on. And if you're in the veterinary genetics field, there is one big conference, world conference, going on every second year, and that takes place alternatively in the States and Europe, and if you go there then you know which group is working on which kind of project.

And genetics normally is -- research is not something that is done within a snip, it takes some time. So you know the groups are working on what kind of idea, you know what they need. Sometimes they approach us for samples for definite animals, sometimes we collaborate in a different manner, and that is why, yes, we look at literature, but we know a lot by our -- yeah, by the involvement in the scientific group as well.

Q. If, from one of these publications or the conferences you were talking about, you learn about a new gene mutation that you would like to offer a test on, what do you do then?

A. Normally, we would approach the group that's actively working on that and ask them if we can offer the test. It's very nice, because then we get some control material and we discuss the relevance. If there's a publication, normally we look for a patent, is there a patent filed, because then we want to watch the patent. That's pretty easy. You just go to the internet and search for patents that are filed. Then you know it takes a year, or one-and-a-half, roughly, in

order for the process to go through. And then it's either denied, or normally what happens is there is a notice in the files "Will be validated soon," and then you know you've got to get going with your decision what to do, because then it's going to be filed, and it will be validated within some weeks.

Q. So if you learn that a patent is going to be validated on a test that you want to offer, what do you do?

A. Well, we did that several times. We approached the work group where we knew the test was going to be patented or was in the process, we approached the work group and asked for a license. We asked them if there is a possibility to work together.

So the normal process would be you make a memorandum of understanding with the parties involved that you will get the possibility to test, and then you're involved in the patenting or you get a contract, and you pay for the samples that you test, and you pay back to the university that way.

Q. What do you do if you are unable to get a license to the patent?

A. Well, my personal belief is that when a patent is valid, it's valid and that's it, really. It's like a red light down the street. And then I stop testing, even if there is -- even if it's a very interesting test.

So if I don't get a license, I will negotiate is

there a different way of collaboration, for instance. And we did that. It's like there's a very interesting mutation that affects the eyes. It's an eye disease in lots of breeds, dog breeds. That's a progressive retina atrophy, so they get blind throughout the years, these animals, and that's a patent that's held in the United States. And it's owned by OptiGen.

We approached OptiGen. OptiGen told us that, no, they didn't want to give us a license. And then we asked them is there a different way we can collaborate, and so we are -- now we are an office, kind of a trader's office for them, so the German dog breeders can send their samples to us, we can handle the export of the samples. There's some legal stuff involved in that. You can't just send animal samples back and forth across the borders, and OptiGen will carry out the test and give the results back.

So there's a lot of different ways that all of the people in the genetic field are proceeding.

Q. Are breeders still able to get that test for the eye that you mentioned, even though LABOklin did not get a license for it?

A. Oh, yes, of course. I mean, there are different agents, really, within Europe, for instance, that handle that, even though OptiGen refused every German -- or every European genetic lab. They refused to be a testing body, and there

are several labs that act as an agent then, in that case. And I don't think that there is any harm for the breeders. It's pretty quick. It's pretty easy-going.

Q. I'd like to talk about the University of Bern for a second, which is a co-defendant with LABOklin in this case.

Did you mention that the University of Bern is one of the universities that LABOklin collaborates with?

A. Yes, that is true. We collaborate for some time, really, in that case basically in the genetic field. I got to know Dr. Tosso Leeb years ago, and he is an expert. He's not a veterinarian, but he's an extremely straightforward working veterinary geneticist.

As I said, we are in the veterinary field, not only in the genetic field but in the disease field as well, so quite often animal owners approach us because of some other tests that they run, other diagnostics, and they say, Well, do you know anybody who works on that method? Could you get involved in that? Because we need -- or we are looking for a solution to a genetic problem. And that's how we work together with the University of Bern.

Q. How long have you been collaborating with the University of Bern?

A. I guess it must be ten years, at least.

Q. You mentioned Dr. Tosso Leeb. Are you aware that Dr. Tosso Leeb is the inventor of the patent that we're

discussing in this case?
A. Oh, yes, certainly. I mean, we kind of followed his work with the HNPK. That was a big issue with the Labrador breeders, and they were really looking for a solution. Because, as was mentioned before, it's kind of a nasty disease for the dogs. They don't die, but they need extra care and handling, and when you breed with an animal that looks healthy and that is a carrier and you breed it with another carrier, then 25 percent of the offspring will fall as diseased animals, and that's a problem, of course, for a breeder, who does not want to be part in having puppies that are diseased in the end.
Q. And you mentioned earlier that LABOklin is a licensee of the '114 Patent.
A. Yes. Actually, the University of Bern decided, because of that what I think is extraordinary work that happened, that was probably patentable, so they approached the -- first thing, they approached the European Patent Office with a patent, and then, actually, in that case they came to us and asked us, Would you like to have a license? Because I think the nature of most of the scientists in universities is they want to solve problems. They want to find out if they can do it, sort of, and when they solve a problem, then they want to move on to something else. And they don't want to bring their energy into doing routine laboratory work, and normally

that's not their -- it's not only not their favorite, it's not their specialty. The system is not set up for that. So what they like to do is move on to the next question and find somebody else who carries out the test.

And in that specific case, with the patent being filed and later on invalidated, the idea was the work group moves on to the next test. The patent is there, there's a license coming back, and the license money is kind of feeding the next research work.

Q. Why did LABOklin decide to license the '114 Patent from the University of Bern?

A. As I said, we were asked. Of course, I could have said no, but the Labrador is quite a common dog breed. It's been stated to be the most common breed and most popular breed in the United States for six years in a row, and it's quite common in Europe as well. So we have a rather large dog population, and the disease was so interesting to the dog breeders that we thought we would get kind of a return on investing for the patenting and keeping up the patent for more years. You have to pay every year, and it gets more expensive every year. So it's not just a one-time investment.

Q. Why did LABOklin -- let me back up.

I believe you mentioned that you licensed the European patent.

A. That is true, actually -- well, what I said is the University of Bern was actively looking for somebody to carry out the test, after having done the research, and they approached us, and the deal was you either get a contract or you don't. If you get a contract, you have to look after the patent in whole.

And the concept of the University of Bern was get a European patent, file a patent in the United States, which was then validated, and file a patent in Canada as well, and it's validated in the meantime in Canada, as well.

Q. So LABOklin holds the patent in Europe, the United States, and Canada; is that correct?

A. That is true. And, having said that, our concept is we look after the people around the corner, so to say, and we don't have a lab in the United States, we never wanted to have one, and then we did sort of the same thing that the University of Bern did, we actively approached our partners who we knew were active in the genetic field in the United States and said, Well, are you interested in running the tests? There is a patent coming up or later on there is a -- I think we asked them first thing, when the patent was validated already, there is a patent. Are you interested in running the test, because we don't want to do that?

And then we approached, for instance, the University of Davis in California, and they said that they're interested

in that. We approached VetGen, they were interested in that, and since there were nonexclusive licenses, we would have taken anybody else on board as well. That's not a matter of having one or two labs. That's not the problem.

And the license money that comes back to us, that is kind of passed through. Most of that is passed through to the University of Bern.

Q. How many licensees do you currently have in the United States for the '114 Patent?

A. Right now we have two.

Q. Is that UC-Davis and VetGen?

A. That's true.

Q. Did you offer to share the technology with PPG?

A. Indeed, we did.

THE COURT: Counsel --

MR. WALTERS: Objection.

MS. GRAY: Your Honor, may we approach?

(Sidebar conference:)

MS. GRAY: This is per your instructions earlier that we could ask if they shared the technology if we don't go into anything about licensing.

THE COURT: You just asked if you were offered a license.

MS. GRAY: Excuse me, Your Honor. I asked if they offered to share the technology. I didn't say anything about

a license.

MR. WALTERS: Your Honor, that's two different --

THE COURT: What was the question? Please repeat the question.

(Record read as follows: Did you offer to share the technology with PPG?)

MR. WALTERS: Your Honor, sharing is licensing.

THE COURT: It's the same thing.

MS. GRAY: Thank you.

(End of sidebar conference.)

THE COURT: The jury will disregard that question. I don't think it was answered, but the jury will disregard the question.

BY MS. GRAY:

Q. I'd like to talk a little bit about why LABOklin is involved in this case.

A. Uh-huh.

Q. Are you familiar with the company PPG?

A. Yes, I am.

Q. How did you first learn of PPG?

A. Unfortunately, I did not know of PPG before 2016, so most people in the --

THE COURT: Where are you going with this, Counsel? Let me see you at the bench.

(Sidebar conference:)

MS. GRAY: I'm asking is the patent on the genetic cause for HNPK because --

THE COURT: Is the patent what?

MS. GRAY: On the genetic cause for HNPK because Mr. Walters represented to her that the claim was for HNPK. The claim is not.

THE COURT: You asked does the claim relate to the cause of the disease. Is that what you're asking?

MS. GRAY: Yes. I'm asking her because Mr. Walters specifically asked her that question.

MR. WALTERS: My objection is based on the fact that the Court ruled that it's an expert matter whether these claims are directed to a natural phenomenon and whether the methods are routine. She did get into what her laboratory does, and I asked her about that.

THE COURT: I don't see what -- it's obvious to everybody that the test has nothing to do with determining the cause other than you can say it takes two parents to cause it, but the patent doesn't have anything to do with that. I don't understand.

MS. GRAY: I was responding to a statement that Mr. Walters asked her because he asked her -- I don't have the specific question represented, but he represented to her that the patent was on the genetic cause for HNPK. So I'm just going to have her confirm that that is not what the

claim is.

MR. WALTERS: Well, Your Honor, the patent includes the mutation that is causing -- did I leave out the word mutation? Is that what counsel's objection is?

THE COURT: I don't know. It seems like we're dancing on the head of a pin.

MR. WALTERS: Right.

THE COURT: I think we can agree that the patent does not deal with what causes it, causes the mutation, except to the extent that some combination that animals with the mutation may cause it in their offspring.

MS. GRAY: Mr. Walters also asked her if the -- if Dr. Leeb had invented the -- had invented the cause of HNPK, the mutation.

MR. WALTERS: I think I said the genetic cause.

MS. GRAY: Yes. The patent, though, is not on the genetic cause. So I was just wanting to tell the jury that the patent --

THE COURT: I think all this does is confuse the patent more than ever.

MR. WALTERS: I think my question was did he invent the mutation, and of course, he didn't.

MS. GRAY: The patent is not on the mutation. It's on the method. It is a method claim.

MR. WALTERS: Well, it's the mutation in the method

we're looking for is basically what the patent is.

MS. GRAY: That's a big difference, though.

MR. WALTERS: We have a legal dispute, really.

THE COURT: Yeah. I don't think this witness is qualified to testify on that. She's not a genetic expert.

MS. GRAY: Your Honor, but Mr. Walters was allowed to ask that question to her.

THE COURT: I don't remember exactly what his question was.

MR. WALTERS: I think I asked did Dr. Leeb invent the mutation, something like that.

THE COURT: Well, he obviously didn't invent the mutation.

MS. GRAY: May I ask her what did Dr. Leeb invent?

THE COURT: Well, I think that would require testimony from an expert geneticist. I think I can just say to the jury that there's no contention that Dr. Leeb invented the mutation.

MR. WALTERS: Right.

THE COURT: Nor need there be. It's just he discovered the mutation.

MS. GRAY: Your Honor, it's important that the jury understand that that's not what the patent's on. The patent is on a method for detecting --

MR. WALTERS: She'll have her expert tomorrow that

can talk about that. I don't know if we'll get on today. But I mean, they can get somebody up there who is qualified to talk about that.

THE COURT: I don't think -- I thought his question was did he invent the mutation, did he invent the cause. But the mutation -- and he didn't.

MS. GRAY: Right.

THE COURT: All right. Well, let's just tell the jury that he obviously didn't invent the mutation, but you can't ask her questions as an expert in genetics because she testified she isn't.

MS. GRAY: She is a licensee of the patent. So she should have personal knowledge as to what the patent actually claims.

THE COURT: I think that's a legal issue, what it actually claims.

MS. GRAY: Thank you, Your Honor.

(End of sidebar conference.)

BY MS. GRAY:

Q. I have only two more questions for you, Dr. Müller.

If the '114 Patent is found to be valid, would it be bad for pet owners?

THE COURT: What did you say? If it's found to be valid, what?

MS. GRAY: Would it be bad for pet owners?

MR. WALTERS: I'll just object to the lack of foundation.

A. Okay --

THE COURT: I don't think that's a proper question; although, it was asked to Dr. Shaffer, so I'll permit you to ask your witness the same thing.

A. Okay. Then maybe I can say I think, in contrast to Dr. Shaffer, I don't really believe that it would be bad for pet owners. And you might say, well, I'm involved in earning money with it, but the thing is that there is not very limited access to the test, even if the patent is valid. There's different institutions --

THE COURT: I think you've gone far enough with that. Let's move on to the next question.

BY MS. GRAY:

Q. If the '114 Patent is found to be valid, would pet owners only have a single laboratory to test for the mutation?

THE COURT: No.

MS. GRAY: Then I have no further questions for this witness, but we will likely ask some redirect.

So opposing counsel is going to ask you some questions, and then I may come back.

CROSS-EXAMINATION

BY MR. WALTERS:

Q. Good afternoon, Dr. Müller. Is it Müller?

A. Müller.
Q. My name is Mark Walters. I represent PPG.
We have not met before today; is that correct?
A. That's correct.
Q. Now, is it accurate that LABOklin is the exclusive licensee for the '114 Patent from University of Bern?
A. Well, what the University of Bern did was they looked for one party to take over, because they wanted to move on with their interest of research, and they wanted to have one party to look after the patent and then the licenses.
Q. And I believe you said that the university asked you guys to take over the test because they don't want to do the routine work. Did I hear that right?
A. The University of Bern, they do research quite a lot in the genetic field, and they come up regularly with interesting results. Sometimes they feel it's not worthwhile patenting, because maybe there is not enough animals that might be tested, and then the costs explode in comparison to the relatively small amount of money that is created by genetic tests in the veterinary field.
The veterinary field works different than human medicine. In human medicine, with the genetics there's lots and lots of money spent for one test, and that's different in the veterinary field. There you talk about $30, $40 the most, normally. So, in that case, the university quite often

goes the way that they say, Well, we produced something, we want to move our interests to something else, but we are not a routine commercial lab.

Q. And that was my main question, is you can detect this mutation, can you not, using routine methods that have been around for a long time?

A. You see, in this case I think we're not talking about a method, as such, but we are -- like a PCR. That is a method. We are talking about the special invention by Tosso Leeb, and I guess the jury decides or the Court decides in the end is that worthwhile an invention to be patented, yes or no.

Q. Well, you know, my question to you, though, is you testified that the university passed on the testing for this to you because they're not interested in the routine laboratory work, and my question to you is that isn't it true that routine laboratory work is all you need to find out if a biological sample has that mutation, yes or no?

A. Well, if you know all of the stories behind it, and if you know how to do that, then you can use a relatively routine technique to carry it out. But, see, that is like, let's say, cooking a soup. You need the stuff, you need pots, but by that you're not a cook. You need the ingredients.

And PCR, for instance, as we heard before, is on the market for lots of years. It deserved a -- on the market for

loads of years. At the same time, if you don't know which exactly area to look at, what kind of ingredients, what kind of buffers and whatsoever you need, what kind of process you want to run this, then you can work for ages and you don't get the right result.

Q. But isn't the key piece of information where to look, not how to look?

A. Both. Both, but saying that -- see, as I stated, I'm not a microbiologist. I have genetic specialists in my lab. They are good for doing their own research, they are good for communicating with research groups, and they are good for transferring technology whatsoever from one place to a different -- in that case, to mine. But that's me personally, and I don't think that I should answer that.

Q. Now, between LABOklin and the University of Bern, they control who gets to test for this, based on the patents. Is that right?

A. Well, patents -- the inventor was the University of Bern, and the University of Bern negotiated the contract with us, "with us" being LABOklin, and the University of Bern cites in that contract some specific things, like they want to know how many tests are run, because they want to know how much money they got in return for their research, but otherwise we have relatively free hands.

Q. But they have to get your permission or the university's;

is that right?
A. The -- well, if you look at a license contract, where money has to go back according to the number of tests are run, there is a certain -- there's some dollars that go back to the university. Of course, the university has -- the University of Bern has the right to know who is performing the test, and they have -- of course, it's in their interest to make sure that it's done in a proper way, and they get regularly files on what's going on where.
Q. Now, Dr. Leeb didn't invent the actual mutation, did he?
A. I'm not a genetic specialized person, right? Dr. Leeb cannot invent a gene. Well, he could, technically speaking, but that was a gene existing in the laboratory.

What his scientific work was that took several years was to find a correlation then between a mutation and a disease that was a mutation that was on a site that was completely unexpected. And so that was not just working for some days in order to get your little star for having worked a lot. And quite often, really, this genetic work on diseases will even fail, even after several years of work, even though these people are specialists, and even though they have succeeded in some work.

So currently brown is -- the fourth gene for the brown color in dogs is something that he probably doesn't like to talk that much because he still fails to find the

genetic cause.
Q. So Dr. Leeb found the genetic cause for HNPK, but then he and the university passed over the testing job to you because they don't want to do the routine methods? Did I understand that correctly from you?
A. Dr. Leeb's group, his being the leading one, did what was bound up as an invention in order to correctly identify the genetic disposition for the HNPK. He passed that on to us, knowing that we are working in the genetic field for quite some time. We have quite some expertise in that as well. We are members of the International Society of Animal Genetics for --
THE COURT: Ms. Müller --
A. I'm sorry.
THE COURT: I'd like to focus on the answer to the question, rather than making a presentation.
A. Okay, sorry.
THE COURT: Let's just answer the question.
A. I'm sorry.
MR. WALTERS: Your Honor, may the court reporter read it back, please?
(The record was read as follows: Question: "So Dr. Leeb found the genetic cause for HNPK, but then he and the university passed over the testing job to you because they don't want to do the routine methods? Did I understand

that correctly from you?")
BY MR. WALTERS:
Q. Just "yes" or "no."
A. I wouldn't phrase it that way.
Q. How would you phrase it?
A. Am I allowed to phrase it.
THE COURT: Yes, but please do that, and don't get into lots of other areas.
A. Okay, right.
So once the scientific work was bound up, then there was the possibility to pass the knowledge on in a way that a well-working genetic laboratory could carry out the test.
BY MR. WALTERS:
Q. And do you have any reason to believe that PPG isn't a well-working genetic laboratory that is capable of finding this in a sample using routine methods?
A. Well, actually, I've never been there, but knowing Dr. Shaffer's CV, I'm absolutely impressed, and I'm absolutely sure that she will be able to carry out the test. And that's what she obviously does, because -- and obviously she doesn't get any complaints, so that's working well, but I think that was not the question. I never questioned --
Q. No, that answers my question, and I have no further questions, but I do thank you for coming over to testify.
A. You're welcome.

REDIRECT EXAMINATION

BY MS. GRAY:

Q. Just a couple more questions for you, Dr. Müller.

You mentioned, and opposing counsel was asking you about, saying that the University of Bern did not want to do the routine work to commercialize the test. What did you mean by that?

A. Well, University of Bern likes research. University of Bern does not like service for the pet owner. They don't like to do what PPG is doing, what we are doing. We create results, and then we are on the phone. We write e-mails explaining the results, giving advice on how to deal with a case. They don't like to do that, and they're not good in that. They're not good in being as quick as possible. They are good in concentrating on research. That's where they're focused on, and that's why they want to divide that.

Q. Are you familiar with what the '114 Patent claims?

A. More or less, yes.

Q. Does the '114 Patent claim the genetic cause for HNPK?

MR. WALTERS: I'll just object, Your Honor. I think it's a matter of expert testimony. She hasn't been qualified as an expert.

MS. GRAY: Your Honor, if I may respond.

(Sidebar discussion.)

THE COURT: Ladies and gentlemen, the patent in

issue discovered or uncovered the mutation. That does not mean that the inventor of the patent somehow caused the mutation, nor need the patent cause the mutation. The inventor doesn't have to invent the cause of the mutation in order for the patent to be valid. We're not talking about the cause of the mutation, we're talking about its discovery and the method for its discovery.

Let's move on.

BY MS. GRAY:

Q. Dr. Müller, you were asked about a paper published by Dr. Tosso Leeb.

A. That's right.

Q. Are you familiar with that paper?

A. Roughly. As I said, I'm a microbiologist, so the reading of genetic papers I leave to my genetic people in the office, and then I will -- I can read the abstract, I feel that's interesting, yes or no, and then we decide together if we want to pursue that case.

Q. Do you know if that paper is different than the '114 Patent?

A. I couldn't tell you. It's like everything concerning patents I use the advice of a patent attorney, and I approach the Patent Office, and I rely on the expert. So that's -- actually, by the way, I do have two patents in genetic cases, and that's what we did. We filed the case, and then we hoped

that it was worthwhile patenting, because in that case it was not even something where we would get a considerable amount of samples, but we just wanted to know was our work good enough for being patented.

MS. GRAY: Thank you. I have no further questions for the witness.

THE COURT: All right. Okay, Dr. Müller. You may step down.

A. Sorry for not being loud enough in the beginning.

THE COURT: Well, you know what the problem was. I kept saying it wasn't your fault. Do you know why I couldn't hear you? Because the battery in my hearing aid went out.

A. I was not --

THE COURT: As soon as I put it back in, I didn't have any more problem. It was not your fault.

A. I thought I was not close enough to the microphone.

THE COURT: No, it was not your fault.

All right. I think we've gotten to the end of the day, ladies and gentlemen. It's almost 5:00. We don't ring a bell at 5:00, but neither do we start a new witness at 5:00. So I'm going to ask you to please return directly to the jury room at 10:00 tomorrow morning.

And I'll caution you. When you go home tonight, your family and friends are going to want to know what you've been doing all day, since it's not what you usually do. And

it's normal for your family and friends to be curious, but don't tell them anything more than the fact that you have been selected to serve on a jury in the federal court. And you can blame it on me and say, The Judge instructed me that I couldn't say any more than that.

Now, when the case is over, you can say whatever you want to whomever you want, but you can't do it until after your verdict. So the best way to avoid something maybe subliminally affecting your thinking about the case is just not to give anybody an opening to ask you any question.

So please return to the jury room exactly as you leave it today. It's not your job to go home tonight and try to learn something about the case, it's your job to come back tomorrow morning without having any involvement with the case until you start hearing tomorrow's evidence.

Okay. You are excused for the day. I know you have to stop in the jury room. Please leave your notebooks in the jury room.

And I'll ask everybody to remain seated until the jury has had an opportunity to retrieve whatever they left in the jury room and exit the court.

(The jury exits the courtroom.)

THE COURT: Is there anything that you would like to take up before we adjourn?

MR. WALTERS: Not from the plaintiff's side, Your

Honor.

MS. GRAY: Not from defendants' side, Your Honor.

THE COURT: How many witnesses do you anticipate calling tomorrow?

MS. GRAY: Tomorrow we have Dr. Friedenberg, who is our expert witness.

We also have Dr. Leeb coming from -- tomorrow we have Dr. Friedenberg, who is our expert witness, and then we also have Dr. Tosso Leeb, the inventor, coming over from Switzerland. He won't be here until tomorrow evening. We talked about this at the pretrial conference, that he will testify on Wednesday.

THE COURT: So you only have two witnesses?

MS. GRAY: We have two more. Tomorrow we have one. It would be Dr. Friedenberg. And Wednesday it would be Dr. Leeb.

THE COURT: All right. Well, what we'll have to do is take up instructions tomorrow, then.

MS. GRAY: Thank you, Your Honor.

THE COURT: But before we hear from Dr. Friedman --

MS. GRAY: Friedenberg.

THE COURT: -- Friedenberg, we have to decide the paragraph 37 issue.

MR. WALTERS: 35, Your Honor.

THE COURT: 35. And any other testimony based on

what he said in paragraph 35. And that's going to be a problem for the Court, because when I look at that paragraph it looks like to me that what he's saying is that, as I said before, that if you add zero and zero and zero up you get one, which doesn't seem right to me. And you can't take a group of well-known methods of testing and combine them or put them in some particular order and thereby create an inventive method. So you're going to have to persuade me that he can testify as to what he outlined in paragraph 35 or testify otherwise as to what he put in paragraph 35.

Now, I think that the rest of his testimony, insofar as it was discussed previously, is not objectionable. I haven't heard anything in the evidence that leads me to believe that it is objectionable.

Now, I know the purpose of Dr. Friedenberg's testimony. Do we have -- I haven't read the outline of Dr. Leeb's testimony. Where is that?

MR. WALTERS: I don't think -- he's not testifying as an expert --

THE COURT: He's not testifying as an expert.

MR. WALTERS: Dr. Leeb is not. He just happens to be a doctor.

THE COURT: Well, that's the same problem I had with Dr. Shaffer, who you claim was going to testify as a lay witness, and I don't think that her testimony could be

presented as a lay witness. The fact that Dr. Leeb is a -- was not listed as an expert may cause us problems, because if he was the inventor, he is an expert.

So what is he going to attempt to testify to?

MS. WILBERT: Your Honor, in patent cases it's common to have the inventor speak about the inventive process --

THE COURT: Don't tell me what is common.

MS. WILBERT: We'd like him to --

THE COURT: Come up to the podium. Tell me what he's going to testify to.

MS. WILBERT: He was going to testify about the steps and the method that he invented.

THE COURT: Well, how is he going to do that as a layperson?

MS. WILBERT: Sir, I'm not --

THE COURT: I've already said that the plaintiff's doctor couldn't do that as a layperson, and she didn't. I sustained your objection to her testifying as a layperson. Now it seems to me that you're trying to use somebody who obviously is an expert as a lay witness. Now, how are you going to do that?

MS. WILBERT: We were going to ask him factual questions about what he did and the challenges that he faced in carrying out those factual steps, so it would be

historical discussion of what he did and what happened when he did those things, which would not be opinions forward-looking.

THE COURT: The concern is you can't ask him his opinion, because he is an expert. So you can't ask him his opinion as a layperson, because he's not a layperson, he's an expert. That doesn't mean an expert can't testify as a factual witness, but anything that comes close to being an opinion is not going to be admissible. So you're going to have to handle it very carefully.

MS. WILBERT: I'm sorry. Yes, we were planning to have him speak about what happened and the steps that he took from a factual perspective. That's what he's disclosed for.

THE COURT: Okay. Well, you remember we went through the same thing with Dr. Shaffer, who you objected to testifying without being qualified.

MS. WILBERT: We maintain that objection. We understand.

THE COURT: Well, she was qualified. There were no challenges to her qualifications.

MS. WILBERT: No, the issue is one of disclosure.

THE COURT: Well, the first thing she said was that, in her opinion, this was a tried-and-true method. She definitely said that. So I don't know -- you objected to her testifying as to her conclusion that it was a tried-and-true

method. That's the first thing she said, but -- in her written disclosure.

But, I mean, you're telling me all about things that usually happen in a patent case, and there are not many things that usually happen in a patent case that have happened in this case. This has not been the usual patent case.

So all I can say is it's going to be very difficult to have the inventor, who is an expert, testify as a layperson. You may tell me that that's done all the time in patent cases. It's not done all the time in the patent cases I've tried. So, I mean, it's possible, but it's going to take, as I say, some careful handling.

What I'll do is I'll try to get a draft of the instructions ready so we can go over instructions tomorrow. Now, there's always the possibility that something will arise subsequently in the case that might change those instructions, so we'll just have to do the best we can tomorrow. But we'll have to use that time tomorrow to try to get the instructions straight, because I don't want us to just waste that time. I didn't really -- I didn't anticipate that we would have -- I mean, five witnesses is one thing, but we're only going to have four.

MS. GRAY: Correct, two more.

THE COURT: Right. Is Dr. Friedenberg going to

testify as to the patent history? Is that in his testimony?

MS. WILBERT: Yes, Your Honor, that was disclosed in his report.

MR. WALTERS: That's the paragraph 35 issue, Your Honor. He's not qualified to testify on behalf of what the Patent Office does, and no qualifications were disclosed with respect to that.

MS. WILBERT: And, Your Honor, we have questions for him related to the technology referenced by the examiner. We'd like him to be able to explain some of the technical terms to the jury in connection with the examiner's statement and confirm that it reflects his understanding of those terms and what technically happened. So we see this as a scientific explanation for a lay jury that doesn't have the technical understanding of some of the terms.

THE COURT: Well, the reason I ask the question is you've got this 414-page exhibit, and we've only looked at two pages of it. Now, there's a certain reason for having the entire exhibit introduced, because otherwise somebody may say you've hidden something, there's something else in there that you've hidden in the mass of documents here, but, on the other hand, we could have a summary exhibit which just includes the portions of the record that you deal with and have that introduced as a summary exhibit and have the rest of it just there as back-up, in case your opponent claims

your summary is invalid for some reason or misleading. Because the jury is not going to read 414 pages. Neither is anyone else.

So it might be better to try to get those exhibits, those portions of that exhibit and if there are other similar exhibits, as a summary exhibit. There's no need for counsel -- I don't know that you'd do it; you'll find somebody else to do it. There's no reason to have somebody go through and number it if that's not necessary, but unless you do something of that nature, it may be necessary.

We can talk about the verdict form tomorrow, too. So you can be prepared to discuss the verdict form, whether it should be just a general verdict or a special interrogatory. It can't be both, it's got to be one or the other.

Let me make sure I've got everything I need here. I've got the defendants' jury instructions and the plaintiff's jury instructions, and we put the objections in there, didn't we, Kendra?

THE LAW CLERK: Yes, we did. We put them in this morning.

THE COURT: All right. And we've got the proposed verdict form from the defendant. I don't have one from the plaintiff. You may have sent one in; it's not in my file. Is it just a general verdict form?

MR. CUMBY: No, Your Honor, it's a special verdict form which we submitted to chambers and served on opposing counsel last Monday.

THE COURT: Well, we probably got it. I just --

MR. CUMBY: And then we also filed it this afternoon, just to be sure.

THE COURT: Okay. Well, yours is somewhat like the defendants', except you have different criteria.

MR. WALTERS: Yeah. It's different in that ours follows the *Alice* test, Your Honor.

MR. PIERY: Your Honor, as we explained earlier, ours addresses the factual disputes that you identified in your order on summary judgment, which will lead you to make the ultimate conclusion on invalidity, which the Federal Circuit has recently reconfirmed. They also make the conclusion that invalidity is an issue for the Court. The jury decides the underlying factual disputes.

MR. WALTERS: I mean, *Alice* is a pretty simple test. It's, number one, is this claim directed to a natural phenomenon, yes or no? Number 2 is, does this claim include something significantly more, like an inventive concept, other than the natural phenomenon? That's the test.

And then there are other cases we have from the Federal Circuit that will help the jury answer those two questions.

THE COURT: Well, most of the cases dealing with that issue are computer program cases.

MR. WALTERS: You know, there are some other cases that are not computer program that we can direct the Court's attention to. They are in our brief, and in the citations that we set forth --

THE COURT: Well, let's put it this way: I'm used to dealing with that test as it relates to computer programs. This, while similar, is not exactly the same as a computer program.

MR. WALTERS: The law says to use that same test, and it was the same test that's used by the Federal Circuit in the *Ariosa* case, which is that cell-free DNA case that we cited. That's probably the closest that we have from the Federal Circuit, after *Alice*, that applies the *Alice* test in the context of a DNA testing type case.

MR. PIERY: To be clear, Your Honor, the Federal Circuit has not said that those two questions need to go to the jury. The Federal Circuit has ruled that the ultimate conclusion on invalidity is a legal issue but that the jury may resolve the underlying factual disputes, such as the three genuine issues of material fact that you identified in your order.

So our concern with the plaintiff's two questions is that they don't resolve the three issues of material fact

that you identified in your order.

THE COURT: Well, the fact that I identified three issues of material fact as preventing the Court from granting summary judgment does not mean that they're the only three issues. That just means that the Court identified those as three issues where it found that there was a material issue of material fact. That doesn't mean that they're the only three issues that the jury should answer.

MR. PIERY: That's correct, Your Honor, but we think that by the two questions that plaintiff has posed it doesn't even address all of the facts that you've identified, let alone the additional ones.

MR. WALTERS: Your Honor, this is a jury instruction, and I think if we get into a bunch of questions about the particular facts that underlie the actual question that the jury has to resolve, you know -- I mean, they need to be instructed about the ultimate question that they need to resolve, and that is, is this claim directed to a natural phenomenon, *Alice* Step 2, and then -- or that's *Alice* Step 1, and then they need to be asked, under *Alice* Step 2 -- if they answered that question yes, then they need to be asked, under *Alice* Step 2, does the patent claim include anything significantly more than the natural phenomenon, and it can't be well-known, routine and conventional methods. And so that's the ultimate question, and the cases from the Federal

Circuit, the recent ones, do say that that is something that the jury would have to consider.

MR. PIERY: Your Honor, they say that the Step 2 question is something the jury would have to consider, which is one of our questions. They do not say that the only two questions the jury can consider are Step 1 and Step 2.

MR. WALTERS: Well, I mean if you just give them Step 2 -- I mean, you have to answer Step 1 to get to Step 2.

THE COURT: That's the way I understand it. Counsel told me they were independent.

MR. PIERY: Well, they are independent in that the patentee only needs to satisfy one step for the claims to be valid under the law. It doesn't need to satisfy both Step 1 and Step 2.

MR. WALTERS: Well, it wouldn't make any sense to give them Step 2 unless they answer Step 1 "Yes."

THE COURT: That's the way I understood it to be; that there was no reason for them to consider Step 2 unless their answer to Step 1 was "Yes."

I would like a two-page informal, whatever you want to call it. That is, a normal typed page. I've had people try small type and narrow margins. Just a normal two-page statement regarding paragraph 35 of --

MR. WALTERS: Dr. Friedenberg?

THE COURT: -- Dr. Friedenberg's report. I think

that may actually impact the instructions, too. Anyway, I'm going to try to get the instructions ready for tomorrow morning. I want that two-page submission in my office by 9:30 tomorrow morning.

MR. WALTERS: And should we file it contemporaneously with giving you a working copy?

THE COURT: What is that?

MR. WALTERS: Should we file it contemporaneously with giving you a working copy?

THE COURT: You may, if you wish. I want a working copy, but if you want to file it, you certainly may do that.

MS. WILBERT: Your Honor, to clarify, the paragraph 35 that you're referring to is the reference to the Patent Office file history; is that correct?

THE COURT: I'm sorry?

MS. WILBERT: You asked for briefing about paragraph 35 with respect to whether Dr. Friedenberg can speak about the file history of the patent. Is that correct?

THE COURT: I think there's more to it than that. The question is can he testify as to what is in paragraph 35. I don't mean necessarily -- it's not necessarily limited to what he states in paragraph 35, but may he base an opinion upon what he states in paragraph 35.

All right. I've told the jury to be here at 10:00, so we have to resolve that -- the contents of paragraph 35

before 10:00. Now, I may resolve it based on what you give me in writing, or I may not, so you should be available from 9:30 on, in case I have questions for you about that issue.

Now, what, if anything, have you done about trying to put the stipulations in language appropriate to go to the jury? I don't know that there's anything necessarily appropriate in the second stipulation that's not in the first one, because we're not going to send the jury anything that has to do with damages.

MR. WALTERS: Your Honor, I don't see why the jury would need to learn about those stipulations. We gave a list of stipulated facts in our draft pretrial order, which I believe those are the ones we intended would go to the jury. They are --

THE COURT: Well, if you agree on that, that's fine. Usually, as I say, I read stipulations to the jury, but I don't think those stipulations were drafted with the idea that they were going to the jury, and I don't think it would be appropriate for either one of them to go to the jury without editing.

So if you want to just say -- I mean, both stipulations are part of the case. They're fine in the case, and the Court will consider them in arriving at its verdict, but that doesn't mean that they are proper exhibits for the jury. So if counsel can agree that the only thing you're

stipulating to, as far as the jury is to hear, is what's in the final pretrial order, then so be it.

That's fine with me.

MS. GRAY: Your Honor, defendants would agree with that; that we use the final pretrial order.

THE COURT: Well, plaintiffs apparently agree with it, too.

MR. WALTERS: Yeah, Your Honor. There are 12 stipulated facts, and a lot of them are background about the companies, they've already heard it, and it is not something that is in dispute.

THE COURT: Well, I customarily read the stipulations to the jury when requested to do so by counsel, but I read them myself. So whenever you ask me to read them, I'll read them, and we'll consider that the two stipulations were for the Court's consideration, not the jury's.

MR. WALTERS: I think that's right, Your Honor. And as far as the mechanics of reading this, I think it would make sense to read it when the jury is charged with their instructions.

THE COURT: All right. Well, whenever counsel requests, either counsel requests the stipulations to be read, I'll read them. Is there anything further?

MR. WALTERS: Not from the plaintiff, Your Honor.

MS. GRAY: Not from defendant, Your Honor.

THE COURT: All right.

(Off the record at 5:35 p.m.)

CERTIFICATION

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/s

Carol L. Naughton

May 18, 2018