UNITED STATES PATENT AND TRADEMARK OFFICE

PUBLIC HEARING ON GENETIC DIAGNOSTIC TESTING

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P R O C E E D I N G S

(9:10 a.m.)

MS. REA: Good morning, everybody, and thank you for taking the time to be with us today. This is a very important public hearing. I would also at the outset, rather, like to thank those of you on the webcast for participating and for watching, and we do hope you also consider providing written comments by March 26.

Today, we're here for a very important public hearing on genetic diagnostic testing and the accompanying study that the U.S. Patent and Trademark Office is conducting. So, we're going to be weighing the impact that independent second opinion testing has on the ability to provide the highest level of medical care to patients.

Now, as Director Kappos and the entire USPTO team work diligently towards implementing the various and many provisions of the America Invents Act, we are having a continuous, ongoing dialogue with our user community and we consider that to be vital to our mission. Not only for us to remain transparent in the process of enacting the new law, but also to ensure that your input

helps guide us and shapes how new provisions in the patent system will play out. So our user community is very important in this overall process, and that's why this study, like the other six reports that were mandated by Congress under the law, focuses intently on gathering your concerns, your experiences, and your expectations for how exclusive licensing and patents in genetic testing affects the practice of medicine.

So given the importance of our mission, I'd especially like to thank Stu Graham, my colleague on my right, Janet Gongola on my immediate right, George Elliott at the far end of the table, as well as Susan Hoffman, for their support in hosting today's hearing. And of course, we are also incredibly grateful to those who are offering their testimony today, including Congresswoman Wasserman Shultz, Tom Kowalski, Mercedes Meyer, Mary Williams, Lori Pressman, Hans Sauer, Ellen Jorgensen, Lawrence Horn, Lisa Schlager, as well as Kevin Noonan.

And for those who did not have an opportunity to pre-schedule to present

testimony, we still invite you to offer your comments after our scheduled presenters have completed. We also want to encourage a thoughtful and well- rounded discussion today.

Now, embedded in the social contract between a patent and the rest of society is a timeless acknowledgment that the American marketplace rewards hard work, innovation, and creativity, and it's the sort of acknowledgement that has allowed new technologies, discoveries, and breakthroughs to be shared with the world, and in a way that has helped us to do everything from cleaning our water to communicating faster, and of course to healing the sick. And in particular, as advances in the life sciences afford us a renewed lease on life, it is also our responsibility to evaluate how an evolving patent system is keeping pace with the evolution in patient care.

Now, admittedly, there will always be ongoing deliberations over the idea of gene sequence patenting, but that's not what today is about. Today we gather to specifically explore how we should go about balancing the interests of

accessing information about our own health consistent with the interests of patent-holders and licensees.

Now, as testimony today will certainly illuminate, making life-altering decisions about undergoing surgery or administering a medical treatment can be immensely difficult when only one test exists for identifying a specific genetic mutation. And that's why it's critical that this study today explore, first, the effect independent second opinion on diagnostic testing would have on existing patent-holders and patient care. Second, the impact that current exclusive licensing agreements have on the practice of interpreting test results and the performance of testing procedures, and third, the role that cost and insurance coverage has on the overall access to these genetic testing methods.

In the same way the America Invents Act was an explicit acknowledgment that the innovations of tomorrow cannot take root in the patent infrastructure of the past, this study today advances the U.S. Patent and Trademark Office's commitment to modernizing our IP system,

while ensuring that regulations do not establish a false dichotomy between incentives to innovate and adequate access to health care. By addressing key questions about how the status quo is affecting patient outcomes, we work towards determining how best to provide independent and confirmatory tests, and ultimately remove barriers for patient access.

Now, there's a lot at stake here, and today's conversation can provoke strong emotions. We may hear difficult stories about our loved ones, but it's a conversation that must be had. Having spent a considerable amount of my career delving into life science matters, I want to applaud the courage of my dear friend, Congresswoman Wasserman Schultz for being willing to share her story today. I also want to thank each and every single one of you for sharing your thoughts and experiences.

But ultimately, the dialogue we have today gives us a real opportunity to kick off a new era in how intellectual property rights interact with patent rights, and your contributing insights will not only shape a

critical public health consideration of our time, but it will also help effectuate change that reaches beyond the health and wellness of our patent system and into the health and wellness of our health care system.

Now, we can be honest and acknowledge the window of time given to us by Congress to complete this study is rather short, but that is why all levels of feedback are particularly important in aggregating a broad range of opinions in how we move forward.

Certainly, there will be many factors to consider and different perspectives to understand, but a thoughtful discussion today can assist us in doing just that. We even encourage those watching today via the micro-site to consider submitting input through written comment, as I suggested earlier, as soon as possible, or at the very least by March 26. Our final report is due to Congress in June of this year.

Now, as we dive into this study, I'd like us all to think about and comment on the fundamentals. First, are there practical

consequences of the current availability of independent second opinion genetic diagnostic tests in terms of patient health, quality of life, and longevity? Second, what entities or institutions, if any, should play an active role in ensuring that independent second opinion genetic diagnostic tests are more widely provided to our nation? And what public policies, finally, if any, should the federal government explore in order to ensure that independent second opinion genetic diagnostic tests are more widely available to those in need?

By thinking along these lines and identifying problem areas, we will be able to thoughtfully and carefully devise more mechanisms that allow innovators and health care providers to do what they've done in America for generation after generation; promote jobs, spur breakthroughs and, most importantly, heal those in need.

We have an important challenge ahead of us in guiding the implementation of the America Invents Act, and while we are making excellent headway, sharing your experiences and thoughts on

second opinion genetic testing will enable the USPTO to continue preparing a most accurate and well-informed report for Congress.

So, I encourage you to be as open as possible because I genuinely do look forward to your insights today and in the days to come. Thank you.

I would now like to direct attention to my colleague, Janet Gongola. Janet?

MS. GONGOLA: Good morning, everyone. The next item that we have on our agenda this morning is a video discussion of the issues from Congresswoman Debbie Wasserman Schultz. So, if we could have our IT people please key up the video for our viewing.

CONGRESSWOMAN WASSERMAN SCHULTZ: Good morning, and thank you to everyone at the U.S. Patent and Trademark Office for working so hard to coordinate this public hearing today. Thank you in advance to Therese Stanek Rea, Janet Gongola, Stuart Graham, and the entire USPTO legislative team for the incredible work on which you are about to embark. I am so grateful for your attention and dedication to these vital

questions of genetic testing, exclusive licensing, and how that affects patient outcomes.

For all of the advocates attending today's hearing, we are so grateful for the devotion you've given to patients undergoing genetic testing throughout your careers. Your insight and commitment have been vital to developing, nurturing, and realizing the potential of genetic tests for improving medical outcomes.

It is such a pleasure to speak with you all for the first public hearing on this important provision from the America Invents Act. I'm truly delighted that you've all dedicated yourselves to this goal, and I look forward to what the results of this study will bring.

I'm thrilled that this study is among the first wave of America Invents Act provisions to be implemented, and that process begins with you, the USPTO, and all of the advocates and organizations participating in this hearing. Over the next several months, you have the incredible opportunity to investigate this complicated aspect of patent law in need of a

thoughtful remedy.

As you know, this study is the result of a provision in the patent reform law Congress passed last summer that will help engender much-needed patient protection and choice for patients undergoing genetic diagnostic tests. My hope is that this study will illuminate ways to remove patient access barriers to second opinions on genetic testing on patented genes.

With the passage of this law, Congress is primarily interested in several important questions. For example, what impact does the current lack of independent second opinion testing have on the ability to provide the highest level of medical care to patients and recipients of genetic tests, and how does this inhibit innovation for existing tests? What would be the effect of providing an independent second opinion genetic test on existing patent and license holders of an exclusive genetic test? What impact does the current exclusive licensing and patents on genetic testing have on the practice of medicine, including but not limited to the interpretation of testing results and

performance of testing procedures. And what is the role that cost and insurance coverage have on access to and provision of genetic diagnostic tests?

These vital questions must be answered because of the complicated reality that we're facing today. Tests are now available for a majority of genetic disorders, such as colon cancer, Parkinson's disease, Alzheimer's disease, stroke, and many others. But in approximately 20 percent of all cases, only one laboratory can perform the tests due to patent exclusivity for the diagnostic testing, and often the actual human gene being tested. Genetic disorders that fall into this patent exclusivity area include breast cancer, Long QT, and certain neurological diseases, such as muscular dystrophy.

I believe that the availability of a second testing procedure in these areas would have several benefits, the most important of which is that it would allow people making life-altering medical decisions based on these genetic tests to seek out an independent second

opinion. By allowing clinical laboratories to confirm the presence or absence of a gene mutation found in a diagnostic test, we can help Americans access the second opinions they truly deserve.

As you may know, I know firsthand the stress of wanting a second opinion but being unable to get it. Several years ago, just after my 41st birthday, I found a lump while doing a routine breast self-exam. It was cancer. Luckily, I found my tumor early and my treatment options initially were fairly straightforward. I was supposed to have a lumpectomy and radiation, and that would have been the end of the story, but an incredibly wise and thoughtful nurse educator asked the right questions about my family's health history that threw my story for a loop.

I never would have known that as an Ashkenazi Jewish woman, a Jew of Eastern European descent, with two paternal great-aunts who had had breast cancer, that there were some significant red flags in my genetic file. I did not know that as an Ashkenazi Jew I was five times more likely to have the BRCA1 or BRCA2 genetic mutation. I did not know that carriers of that

mutation have up to an 85 percent lifetime chance of getting breast cancer and up to a 60 percent chance of getting ovarian cancer.

My nurse suggested that I take the BRCA test, and I could not be more grateful for her knowledge and advice. This process, however, presented a new set of challenges and questions for which no woman could ever be prepared.

Now, as many of you know, there is only one test on the market for the BRCA mutations. The maker of this test not only has a patent on the gene itself, they also have an exclusive license for their laboratories to administer the tests. So, there is absolutely no way for someone who is questioning her genetic risk for breast or ovarian cancer to get a second opinion.

This is intensified by the fact that for many women, the test results are inconclusive. Imagine being faced with this decision: Your genes hold the key to your survival, having major body-altering surgery could save your life, but the test results failed to give you any answers. What would you do in that situation?

You know, you might say that I was

lucky. My tests clearly showed that I had the BRCA2 mutation, but there was absolutely nothing I could do to question these results or receive an independent confirmatory test. So, I had no choice but to make the life-altering decision to have seven major surgeries, including a double-mastectomy and an oophorectomy from a single administration of a single test.

Unfortunately, many women have to face this decision with even less reliable information than I had. No one should ever have to go through this experience without the comfort and the confidence of a second opinion. With so much at stake, it is incredibly important that we give everyone in this situation as much certainty as we possibly can.

I can assure you it was devastating to me to have to make a decision that was as life-altering as a double- mastectomy and six other major surgeries without being able to confirm the results of that genetic test. We owe that much to those whose lives hang in the balance. Many of you helped shape this legislation, and now it is your task to make sure

that your knowledge and experience can be put into practice to help save lives.

I wish you all the best of luck in this important endeavor, and I look forward to hearing all of your ideas and suggestions. Thank you so much, again, for being here today and for your dedication to the health and wellbeing of others. Thank you.

MS. GONGOLA: As Congresswoman Wasserman Schultz and Deputy Director Rea both indicated, the genetic testing study presents a unique opportunity to explore both the legal and the medical issues surrounding independent second opinion genetic diagnostic testing.

I echo the enthusiasm that Congresswoman Wasserman Schultz has expressed for the prospect of this study in advancing the debate concerning genetic diagnostic testing and patient health care options. I also greatly admire the courage, honesty, and strength of Congresswoman Wasserman Schultz in sharing her personal experience with genetic diagnostic testing and the profound impact it has had on her life and her medical choices. Her commitment on

the subject matter of this study humanizes it in a powerful and inspiring way.

Now, as the first step in conducting the genetic diagnostic testing study, the agency published a notice in the Federal Register on January 25 of this year announcing hearings and soliciting written comments about ways that a second opinion genetic test might be made available in situations where there is a gene patent and that patent is licensed to a particular company that offers a primary diagnostic test. I am delighted that 10 witnesses are scheduled to give testimony today on that topic.

For those of you who did not pre-schedule to give testimony, we will open the floor to you to express your views after the pre-scheduled testimony is complete. Additionally, the agency will hold a second hearing on March 9 at the University of San Diego at the Joan B. Croc Institute for Peace and Justice. To date, we have five witnesses scheduled to give testimony at that hearing.

Finally, we encourage patients, medical professionals, insurance providers, and

the IP community, all members of the relevant public, to share views on the subject matter of this study via written comments. Written comments can be submitted to the agency via e-mail at a special e-mail address created, genetest@USPTO.gov. Written comments are due by March 26 of this year.

From the written comments that we collect as well as the testimony given today and at our second hearing, we will prepare our report for Congress. It is our intention to make fact-findings and, where appropriate, offer recommendations for solutions. Our report is due to Congress by June 16 of this year.

I now want to turn and discuss the protocol that we are going to follow for today's hearing. I will invite each of our pre-scheduled witnesses to come to the podium and give testimony. Each witness will be given the time allotted on the agenda to deliver their testimony. After each witness's testimony is complete, I will open the floor for questions from the panel.

In light of the number of witnesses and

the desire to stay relatively on schedule today, audience questions and commentary will be held until the end after all witnesses have given testimony. If you as a member of our audience, our web audience as well as our live audience, would like to ask a question or make a comment, please come to the microphone in the center aisles, state your name, followed by an organization that you may represent, if any. Our hearing is being transcribed today, so please speak clearly into the microphone as you provide your testimony, ask a question, or give any commentary.

With that, I introduce Dr. Stu Graham, the chief economist and head of the genetic testing study. Dr. Graham will provide more details for you about the scope of the study.

MR. GRAHAM: Thank you, Janet. I am Stuart Graham, a chief economist here at the USPTO, and my office has been given the responsibility to lead this study, and I'm happy to be here along with my colleagues from the USPTO to take testimony today.

In our quest for information posted in

the Federal Register on January 25 and in this hearing today and in San Diego on Friday, March 9, we are seeking comments and information on how to best address a specific set of questions related to genetic diagnostic testing.

Our interest is in collecting evidence to enable us to best answer the questions posed in the legislation, and to provide Director Capos with the best evidence possible in order that he may consider what recommendations, if any, are appropriate to make in the final report.

As we enter the six decades since the publication of Watson and Crick's findings, medical knowledge has fundamentally changed. There are no fewer than 2,400 genetic diseases for which diagnostic tests have been developed, with hundreds of laboratories providing tests for these diseases. From these many sources, there are differing organizational forms used to provide both primary and secondary tests, many licenses and business models, and significant variation in the way that testing results are ultimately made available to both patients and caregivers.

While there have been several important studies and reports covering issues related to genetic diagnostic testing in recent years, the set of questions posed in the America Invents Act Section 27 have generally been given too little attention or left unaddressed entirely. That is not to suggest that these questions are unimportant. In fact, having adequate evidence with which to formulate reliable answers to these questions would meaningfully inform the current debate about how genetic diagnostic testing is made available to patients by physicians and insurers, and the role if any that patenting is playing in the availability and reliability of these tests.

To assist with the completion of this study, the USPTO is seeking public comments and conducting public hearings on the circumstances under which independent second opinion genetic diagnostic testing is currently available or not available to physicians and their patients, and about the impact of such availability on the quality of medical care and the practice of medicine; the effect of independent second

opinion genetic diagnostic testing on relevant patent and license holders; and the impact on medical costs and of insurance coverage.

We are, therefore, pleased to have an excellent set of speakers today to help us learn more about these issues, and I encourage our speakers to provide robust evidence on these questions. Since these questions have been largely unaddressed in previous reports and studies, it is incumbent upon us, so the USPTO may provide the most meaningful response to the Congressional mandate, to collect a robust set of data and the best evidence available to help inform this report. So, I encourage you to point us to reliable evidence upon which we can identify generalizable findings, if possible.

In our Federal Register notice, we provided a detailed set of questions that directly relate to the issues raised in the legislation. We encourage those here today and anyone listening through our live stream to consider responding and offering information at the e-mail address provided by Janet and also in the Federal Register notice.

In the meantime, let us turn the program over to live comments from several members of the public and representatives of organizations who have expressed an interest in these issues and a willingness to give testimony. For that, I hand the program back to Janet Gongola.

MS. GONGOLA: Thank you, Stu. It is time now for our first witness testimony, so I invite Mr. Tom Kowalski, a shareholder at Vedder Price, to please come to the podium and offer your testimony.

MR. KOWALSKI: Good morning. Thank you for having me.

My name is Tom Kowalski, I am appearing here today at the United States Patent and Trademark Office, or the Patent Office or USPTO, pursuant to Section 27 of the America Invents Act, calling for a study on genetic testing and the January 25, 2012, Notice of Public Hearing in the Federal Register, which I shall refer to as the Federal Register notice.

I thank the Patent Office for having these hearings and for scheduling my appearance. I am the Tom Kowalski who gave testimony

concerning prior user rights on October 25, 2011. I'm a shareholder in the New York office of Vedder Price in the Intellectual Property Group. I am also an adjunct professor at New York University's Brooklyn campus, the Polytechnic Institute of New York University, teaching intellectual property law. I am also on certain editorial boards, as well as an editorial advisor to Nature Biotechnology. I also speak at conferences.

I represent and have represented many clients in ex parte and inter-parties proceedings, including before the U.S. Patent Office, U.S. Courts, and foreign patent offices and courts, primarily in biotech and chemical matters, including having presented numerous -- excuse me -- prosecuted numerous patents involving nucleic acid molecules or isolated DNA or, more broadly, genetics that I understand have been and are of significant commercial interest.

For convenience, I have posted on my LinkedIn profile a sample of the hundreds of patents that I have prosecuted. My client base

includes universities and not-for- profits, such as the International AIDS Vaccine Initiative, or IAVI; and Health Research Incorporated, or HRI; the tech transfer entity of the New York State Department of Health, including its Wadsworth laboratory and the Roswell Park Cancer Institute. However, today my statements reflect my personal views based upon my education, training, and experience. I am not standing here on behalf of my clients or for my firm, or New York University, or any of the publications or conference organizers with whom I am or have been affiliated. No person or entity has asked that I appear before you.

In more than 25 years of practice, I have participated either via papers or in person in patent proceedings throughout the world, including prosecuting numerous isolated nucleic acid molecule patents. I have studied the ongoing case of the *Association of Molecular Pathology versus the USPTO*, also known as *the Myriad case*, and issues in that case including having reviewed publicly available documents and interfacing with players pertaining to that case.

Further, I have personal experience that I believe dispels assumptions of Section 27 of the AIA. Accordingly, I respectfully submit based upon my education, training, and experience I am well qualified to present this testimony.

According to the AIA, the Director is to report to the Committees on the Judiciary of the Senate and House on a number of topics. My comments will primarily focus on Section 27(b)(2) and (3) of the AIA as well as issues in the Federal Register notice. I am providing comments on issues relevant to the scope of the study.

With that, let me start with something a little bit perhaps humorous. In the 2005 film “Thank You For Smoking”, the following dialogue occurs between lead character Nick Naylor and character Joey Naylor, Nick Naylor's grade school son.

Joey, "Dad, why is the American government the best government?"

Nick, "Because of our endless appeals system. Joe, you're not writing that down."

Joey, "Mm-hm."

Nick, "Joey, stop for a second. What

is the subject of your essay?"

Joey, "Why is the American government the best government in the world?"

Nick, "Your teacher crafted that question?"

Joey, "Yeah, why?"

Nick, "Well, I'll look past the obvious problems in syntax for a moment and I'll focus more on the core of the question."

Well, today unlike Nick Naylor, with respect to Section 27 of the AIA and the Federal Register notice, I will focus on both the obvious problems in the questions and in the core of the questions.

Turning to what I see are the obvious problems in the questions of Section 27 and the Federal Register notice, please allow me to introduce the concept of “Do-Over.” Do-Over is an informal phrase, meaning to do something again. In American English it is defined as to do something again from the beginning, especially because you did it badly the first time.

Section 27 of the AIA, to me, epitomizes the initial cynical answer that the character

Nick Naylor gives to his son. It is to me an example of America's endless system of appeals, an attempt to "Do-Over" the Federal Circuit's decision in *the Myriad case*. However, do-over is not necessary as to the Federal Circuit's decision in *the Myriad case*. The Federal Circuit did not do badly in *the Myriad case*, but rather in my view Federal Circuit correctly decided the issues. Specifically, in the face of calls by the plaintiffs therein to gut the U.S. patent system by making a carve-out from patent eligible subject matter as to isolated DNA, in *the Myriad case* the Federal Circuit correctly held that claims to isolated DNA are patent-eligible subject matter and that method claims directed to only comparing or analyzing DNA are patent ineligible subject matter.

The holding of the Federal Circuit in *the Myriad case*, in my experience, is consistent with foreign patent laws, for example, the directive of the European Parliament and of the Council of July 6, 1998, also known as the Biotech Directive of Europe. Hence, the Federal Circuit's holding in *the Myriad case* needs no

Do-Over as it is consistent with the goals of the AIA to harmonize U.S. patent laws with foreign patent laws.

Other obvious problems with Section 27 include assumptions of a number of facts that have not been demonstrated. Namely for example, that there are, indeed, "a current lack of independent second opinion testing," or that the "effective ways to provide independent confirming genetic diagnostic test activity" are somehow needed "where gene patents and exclusive licensing for primary genetic diagnostic tests exist." Also, problems include no definitions for "genetic diagnostic tests," or a "gene patent."

On the lack of definitions, is a gene patent supposed to be those patents that claim isolated nucleic acid molecules or only isolated DNA? That is, for example what about claims to RNA? The Manual of Patent Examining Procedure, MPEP, is a guide for examiners. In Section 2163, the MPEP states that a gene comprising SEQ ID No. 1 requires a determination of what the claim covers as a whole, and a conclusion that specific structures such as a promoter, a coding region,

or other elements are included. In other words, the term "gene" contains more than merely sequences that encode a protein.

For example, a gene can contain a promoter region, a region of DNA that facilitates transcription of a coding region. There are patent claims to promoters. Are these gene patents? Also, there is DNA encoding what is known as a leader sequence or a signal sequence that is an extension of a protein that facilitates transport of a protein out of a cell and is cleaved from the protein. There are patent claims to signal sequences or leader sequences. Are these gene patents?

The term "gene patents," to me, is unclear as when a patent applicant uses the term "gene in a patent claim." Similarly, the term "genetic diagnostic test" is unclear. Are these the types of tests only in *the Myriad case*? Are they only the diagnostic methods that involve the use of an isolated nucleic acid molecule or isolated DNA?

What about a method calling for isolating a virus from a patient, amplifying DNA

from the virus, detecting whether that DNA codes for a particular protein, wherein if it codes for one protein versus another it is indicative of the type of virus? Is that method a genetic diagnostic test? I don't know. The term "genetic diagnostic test," to me, is thus vague.

I will further address the problems with the assumptions in Section 27 of the AIA. The greatest problem, to me, with Section 27 of the AIA and the Federal Register notice is that, to me, they are beyond the remit of the USPTO. The Patent Office exists pursuant to Article 1, Section 8, Clause 8 of the U.S. Constitution. To me, under that Clause, the Patent Office exists to promote the useful arts and sciences. Accordingly, I submit that many considerations of Section 27 of the AIA and of the Federal Register notice such as “the … level of medical care”, “the interpretation of test results”, “the performance of testing procedures”, “the cost and insurance coverage … of genetic diagnostic tests”, and “quality of care” are beyond the Constitutional remit of the Patent Office. Such matters, to me, are not proper considerations of

the Patent Office, but rather are proper considerations of the Department of Health and Human Services and the Food and Drug Administration, and to me such considerations are not patent law issues. They are health care or health reform issues.

Moreover, to me collectively the issues of Section 27 of the AIA and the Federal Register notice are matters that should be addressed by the Department of Health and Human Services, the Food and Drug Administration, the Federal Trade Commission, and the Patent Office, collectively, for example, through an interagency committee that includes both personnel of those agencies and practitioners who practice before them.

My understanding is that Section 27 of the AIA arose from Representative Wasserman Schultz proposing a Section 27 that would have exempted from infringement a genetic diagnostic tester's performance of a confirming genetic diagnostic test activity that would have constituted infringement under Section 271(a) or (b) of Title 35, then withdrawing that proposed amendment to the AIA and introducing a

stand-alone bill that became the present Section 27 of the AIA and called for a study by the Patent Office on effective ways to provide confirming genetic diagnostic test activity where gene patents and exclusive licensing exists.

Thus, with all due respect, in my opinion these hearings are part of ongoing Congressional activity to attempt to create a poorly defined class of patents as to which, especially for those that have issued or will issue from patent applications already pending, there will be an uncompensated taking in violation of the Fifth Amendment to the U.S. Constitution, fueled by one instance of what appears to be, in my opinion, an unsympathetic patentee and a failure by the U.S. Government as patent assignee to act responsibly, and a straw man, the BRCA gene issue, advanced in the context of *the Myriad case* that has been propped up by those who, in my opinion, have and have had a broader agenda of eliminating patents pertaining to DNA.

In *Continental Paper Bag Co. v. Eastern Paper Bag Company*, the Supreme Court recognized

that the ability to exclude is the very essence of the right conferred by a patent. Further, patent rights are property rights. If the proposed provision of independent second opinion genetic diagnostic testing is enacted, the government would be requiring the owners of already issued patents and patents to issue from pending applications to suffer a permanent invasion of their property. In *Loretto v. Teleprompter Manhattan CATV Corp*. and *Kaiser Aetna v. United States,* the Supreme Court held that where the government requires an owner to suffer a permanent invasion of property, however minor, it must provide just compensation.

Also, I note that when the United States went from a 17-year from issue date patent term to a 20-year from filing date patent term, Congress changed the term of patents prospectively, not retroactively, presumably to avoid a violation of the Fifth Amendment. Thus, with regard to Section 27(b)(2) of the AIA, I therefore submit that one effect on existing patent and license-holders of providing independent second opinion genetic diagnostic

testing would be an uncompensated taking in violation of the Fifth Amendment to the U.S. Constitution, especially as to patents that have issued or will issue from patent applications already pending. And if the proposed compulsory licensing as to independent second opinion genetic diagnostic testing is enacted only prospectively, this will not address the BRCA gene issue, the strawman that in my opinion has been propped up by those having the agenda of eliminating DNA patents. Accordingly, I do not see the proposed legislation pertaining to independent second opinion genetic diagnostic testing as addressing the alleged basis for the legislation.

I hope that my voice may be considered in the debate on the ongoing Congressional activity to exempt certain infringements of certain patents, and that Congress from my testimony and the submissions of others appreciates that the protection afforded by patents pertaining to isolated nucleic acid molecules or isolated DNA or, more broadly, genetics should not be watered-down by an

unconstitutional compulsory uncompensated licensing for independent second opinion diagnostic testing, as Representative Wasserman Schultz proposed, for a number of reasons, including because access to patented technology is available under current law, and moreover because the issues of access to patented technology -- especially on their face in *the Myriad case* -- are not issues of patent law. They are issues of health care or health reform.

Indeed, in all of this discussion there has been silence on how the issue of Section 27 of the AIA arose in connection with patents that, on their face, name the United States of America as an assignee. To me, the face of the patents in issue in *the Myriad case* show that attention should not be focused on U.S. patent law, but rather on health care and health reform issues.

I appreciate that Congress wishes to zealously address perceived public policy concerns associated with *the Myriad case*. However, a watering-down of the protection afforded by patents pertaining to isolated nucleic acid molecules, or isolated DNA or, more

broadly, genetics by an unconstitutional, compulsory, uncompensated licensing for independent second opinion genetic diagnostic testing, in my opinion, is premature, not warranted by the lone situation of *the Myriad case*, and will wreak substantial damage, including on future innovation in genetic diagnostic testing, personalized medicine, and biotechnology in the U.S. in general, and hence will be counterproductive to the overall interests of the American people. Moreover, the lone situation of *the Myriad case* can be readily addressed by actions other than watering down the protection afforded by patents pertaining to isolated nucleic acid molecules, or isolated DNA, or genetics by an unconstitutional, compulsory, uncompensated licensing.

With regard to the unconstitutional, compulsory, uncompensated licensing being premature, the law under Section 103 is evolving. The patenting of inventions pertaining to isolated nucleic acid molecules, or isolated DNA, or genetics has become more stringent in view of case law such as *KSR International Co. v. Teleflex*

Inc., and *In re Kubin*, and in this regard I also invite review of Section 2143 of the MPEP that instructs examiners in applying *KSR and Kubin*.

I submit that perceived basis for Section 27 of the AIA and for the previous legislative proposals prior to Section 27 as enacted, namely the suggestion of an unconstitutional, compulsory, uncompensated licensing as advanced by Representative Wasserman Schultz, do not exist because the impact of *KSR*, *Kubin*, and the Federal Circuit's decision in *the Myriad case* have yet to be fully felt. Indeed, arguments that one can make genetic diagnostic tests today do not suggest that unconstitutional, compulsory, uncompensated licensing should be adopted, but rather argue against enacting such legislation and allowing the law of obviousness under 35 USC 103 to continue to evolve. In the same vein, in the brief of amicus curiae, Christopher M. Holman and Robert Cook-Deegan in support of neither party in *the Myriad case* -- which I call the Holman and Cook-Deegan brief -- the authors argue that the claims at issue in *the Myriad case* have yet

to be fully judicially analyzed, including under Sections 102, 103, and 112 of the Patent Act. And hence, the relief sought by the plaintiffs in *the Myriad case* should not be awarded.

Further, the Holman and Cook-Deegan brief identifies many instances in which an alleged infringer successfully designed around a human gene patent as another basis for why the relief sought by the patents in *the Myriad case* should not be awarded.

In that same spirit, I submit that because *the Myriad case* itself is not yet resolved, the full impact of *KSR* and *Kubin* cases and the Federal Circuit's decision in *the Myriad case* have yet to be fully felt, and gene patents of AIA Section 27 may not necessarily impede design around with regard to genetic diagnostic test activity. It is thus premature to consider unconstitutional, compulsory, uncompensated licensing.

Simply, the assumption in Section 27 of the AIA, namely that there is a current lack of second opinion testing, to me has not been demonstrated. In this regard, it has not been

demonstrated that no license to any BRCA patent is unavailable, especially through either the U.S. Government ownership of certain patents in suit in *the Myriad case*, or through Myriad itself.

To me, it has not been demonstrated that there has been an outright refusal to deal by the patentees. That laboratories may need to take a license to perform certain tests does not mean that patients and health care providers are unable to obtain and administer the desired testing. In other words, that laboratories may need to go through the U.S. Government as assignee or Myriad to license patents does not mean there is a current lack of independent second opinion testing.

Moreover, from my experience patents pertaining to isolated nucleic acid molecules or isolated DNA or genetics create critical incentives that attract substantial investment necessary to fuel the discovery and development of lifesaving products and the biotechnology industry overall. Patents pertaining to isolated nucleic acid molecules or isolated DNA or, more broadly, genetics constitute core

intellectual property for many entities and have provided the fuel for research and development.

A study by Holman, which I shall call the Holman study, did not identify a single instance in which basic research activities or non-commercial genetic diagnostic testing led to a patent infringement lawsuit. The Holman and Cook-Deegan brief also identifies DNA hybridization assay technologies, the Affymetrix gene chip technology, and the Illumina bead array technology as involving patents pertaining to DNA that fuel research and development in the U.S.

Despite the thinking that patents pertaining to DNA would have made it prohibitively burdensome to obtain licenses or freedom to operate to make, use, or sell hybridization assays, the Holman study found that hybridization assay technology has never been the subject of a patent infringement lawsuit involving a patent pertaining to DNA.

While I question for many reasons that I have observed in my practice and in my studies before appearing today, the wisdom of the National Institutes of Health, or NIH, alone,

studying gene patents and licensing practices and their impact on patient access to genetic tests, including because the U.S. Government is an assignee in a number of patents-in-issue in *the Myriad case*, the Holman and Cook-Deegan brief asserts that the Secretary's Advisory Committee on Genetic Health and Society, or the SACGHS, report of the NIH identifies only a potential for a substantial negative impact on genetic diagnostic testing and admits that there is currently no conclusive evidence that gene patents have had a negative impact on the availability of genetic testing.

In my own experience, I have observed not-for-profits and universities out-license technology, including patents and patent applications, and use revenues received from licensing to fund further research. Thus, in my personal experience, I have observed that patents pertaining to isolated nucleic acid molecules, or isolated DNA or, more broadly, genetics, create critical incentives that attract a substantial investment necessary to fuel the discovery and development of lifesaving products and

biotechnology.

With regard to Section 27(b)(2) of the AIA, I submit that another effect on existing patent and license holders of providing independent second opinion genetic diagnostic testing would be a diminished value of the patents and licenses, a diminished value of the technology, a significant reduction in licensing revenues and, hence, a significant reduction in funds for further research.

Regarding the impact on the practice of medicine, of current exclusive licensing and patents on genetic testing activity, my experience has been that such exclusive licensing has advanced the practice of medicine, including by providing funds for further research that has advanced medicine by providing such tests at competitive prices. Especially in this economy, when government from local to federal must make due on less and less, we cannot expect public funding will fill the reduction in research funds that will be caused by the proposed independent second opinion genetic diagnostic testing, or the unconstitutional, compulsory, uncompensated

licensing, as I've called it.

The Holman and Cook-Deegan brief also identifies the SACGHS report as stating, "one surprising finding from the case studies was that the per unit price of the full sequence BRCA test … was actually quite comparable to the price of other full sequence test[s] done by polymerase chain reaction (PCR), at both non-profit and for-profit testing laboratories."

Historian Miles Jackson, the plaintiff's expert in *the Myriad case*, in the Jackson declaration submitted to the District Court in *the Myriad case*, identifies one of his areas of study as the history of the CCR5 gene. It has been found that to enter a human's cell, HIV uses either the CCR5 co- receptor encoded by a nucleic acid molecule that Miles Jackson calls the CCR5 gene, or the CXCR4 co-receptor, also encoded by a nucleic acid molecule. HRI is the patentee and licensor of patents pertaining to analysis of HIV1 co-receptor use in the clinical care of HIV1-infected patients.

My experience concerning the HRI technology provided me with an interface with

historian Jackson, and in preparation for today I researched his materials. Interestingly, I came across a presentation by him entitled, "Intellectual Property and Molecular Biology: Biomedicine, Commerce, and the CCR5 Gene," where he quotes the price for a Monogram Biosciences Lab Corp. test, or Trofile assay, as being $2,800. Interestingly, I understand that the Monogram test is not under the license granted by HRI. My understanding is that the genetic diagnostic test under the HRI patent license is the test by Quest Diagnostics and that test by Quest Diagnostics, I understand, costs approximately $900. In other words, patenting and patent licensing has provided a lower-cost diagnostic test to patients and revenue to HRI for further research.

My experience is, therefore, wholly consistent with the SACGHS report and the Holman and Cook-Deegan brief that patenting and exclusive licensing did not drive up the cost of the diagnostic test, but rather it resulted in a reduction in cost to patients along with the added benefit of generating revenue for further research.

Accordingly, with regard to Section 27(b)(2) and (3) of the AIA, I submit that these benefits would not have occurred if the previously proposed unconstitutional, compulsory, uncompensated licensing for independent second opinion genetic diagnostic testing is enacted. It is, therefore, my opinion that Congress and the President should vigorously resist enacting such into the U.S. patent law.

Indeed, the chilling effect that I see that will result from the previously proposed unconstitutional, compulsory, uncompensated licensing includes diminished interest in licensing by companies and diminishing licensing revenues for not-for-profit licensors. I therefore submit that if enacted the previously proposed unconstitutional, compulsory, uncompensated licensing will wreak substantial damage, including on future innovation and genetic diagnostic testing, personalized medicine, and biotechnology in the U.S. And, hence, will be counterproductive to the overall interests of the American people.

In this regard, the Holman and

Cook-Deegan brief advances that the future of genetic testing will be more complex and costly, including identifying patterns of genetic variation involving a number of genes, or the identification of complex gene expression patterns, and an active role by the FDA as well as possibly by the Centers for Medicare and Medicaid Services or private health insurers, demanding clinical studies, before diagnostic tests are covered.

Clearly, a strong patent system as to genetic testing is needed to meet the challenges of researching, developing, and bringing to market the future genetic tests. Gutting the U.S. patent system as to genetic tests, in my view, by enacting the previously proposed unconstitutional, compulsory, uncompensated licensing will diminish the incentives for research, development, and bringing to market of genetic tests and, hence, will impair future innovation as to the up and coming diagnostics. Accordingly, for this reason, too, I submit that if enacted the previously proposed unconstitutional, compulsory, uncompensated

licensing will wreak substantial damage.

Furthermore, in my experience how Myriad may have engaged in enforcement activities seems to be an isolated practice. That is, the situation that is reported as to *the Myriad case* is an isolated or lone situation, not warranting gutting the U.S. patent system as to genetic testing. To me, there is insufficient evidence that the situation complained of in *the Myriad case* is pervasive or warrants a broad, unconstitutional, compulsory, uncompensated licensing for independent second opinion genetic diagnostic testing.

Indeed, in my experience with regard to IAVI, patent-holders have encouraged IAVI to pursue IAVI's mission of ensuring the development of safe, effective, accessible preventive HIV vaccines for use throughout the world and, hence, have encouraged research and development as well as patenting but have not used patents as any roadblock to research and development.

In my prior user rights testimony, I detailed my extensive experience in international or global patent practice. Except

as to Uruguay, I have not seen compulsory licensing widely practiced in foreign countries. My understanding, for example, is that in Canada there was compulsory licensing but it was abolished by Bill C91, the Patent Act Amendment of 1992, and thereafter in 2004, Canada enacted the WTO decision allowing member countries to issue compulsory licenses only for the production of generic versions of pharmaceutical products for the sole purpose of export to nations that require drugs to combat public health crises, and in almost a decade, that limited compulsory licensing scheme was used exactly only once.

Similarly, I understand that the European Union advanced similar compulsory licensing registration, but none of its member nations actually used such a law to get generic drugs to low-income nations. Accordingly, I do not see compulsory licensing directed at genetic diagnostic testing as the answer. It is simply not part of the laws of other countries or consistent with the laws of other countries.

If the AIA endeavors to harmonize U.S. patent law with the patent laws of other

countries, adopting the unconstitutional, compulsory, uncompensated licensing for independent second opinion genetic diagnostic testing will, in my opinion, be a step backward on the road of the U.S. moving forward with harmonization. For this reason, too, I urge that the USPTO report not recommend the independent second opinion genetic diagnostic testing advanced by Representative Wasserman Schultz.

Further still, I have interfaced with and reviewed statements by Mr. Daniel Ravicher, counsel for plaintiffs in *the Myriad case*. I respectfully submit that he and his Public Patent Foundation would object to compulsory licensing. Specifically, Mr. Ravicher as executive director of the Public Patent Foundation has publicly recognized that compulsory licensing "penalize[s]small businesses" and "undercut[s the patentee's leverage] in negotiating a license." I recognize licensing as a form of patent enforcement and am also opposed to the compulsory licensing suggested by Representative Wasserman Schultz because I agree that such compulsory licensing vitiates the exclusive

rights granted by a patent, penalizes patentees, and undercuts the ability to enforce patents.

Furthermore, the Holman and Cook-Deegan brief asserts that what sets the U.S. apart from the rest of the world in the context of *the Myriad case* is not the strength of the U.S. patent system but the weakness and inaction of other stakeholders in the U.S. health care system. I agree.

I started my testimony today with a quote from a movie. As I begin wrapping up, I'd like to start by citing Elizabeth Wurtzel's June 3, 2011, interview on the National Public Radio, or NPR, show Studio 360. In that interview, in my view, Ms. Wurtzel opined on what makes the U.S. Intellectual Property System the greatest in the world, akin to the question Joey Naylor was asking his father in "Thank You for Smoking". My take on Ms. Wurtzel's interview is that she espoused that the Founding Fathers had the foresight to include an Intellectual Property Clause in the Constitution; and that the U.S. is the only country to have such a clause in its Constitution, whereby the U.S. Intellectual Property System is

a free market system, not a system of government intervention; and that as a result, the U.S. Gross Domestic Product, or GDP, is now 47 percent Intellectual Property, with almost every major innovation over the past 235 years having arisen from America.

I am then reminded of how in January, in the State of the Union address, the President mentioned General Motors as being "back on top as the world's number one automaker." And on January 28, GM's CEO, Daniel Ackerson, was interviewed on NPR. With regard to the derisive term "Government Motors," Mr. Ackerson pointed out that the U.S. has hybrid capitalism, stating, "we have never been a truly 100 percent unadulterated capitalist system," and mentioning how people who cannot produce, such as "your mother as she aged in time," are not kicked to the curb.

In this regard, too, I am sensitive to footnote 3 in the Federal Circuit's decision in *the Myriad case* where the Court stated: "We fail to see how the inability to afford a patented invention could establish an invasion of a

legally- protected interest for the purposes of standing." That is, I also see this hearing as a dialogue on what may be done to address the concerns of those who do not have standing in *the Myriad case* but with a view towards maintaining the U.S. Intellectual Property System as the best in the world. In this regard, I cannot understand how the issue of AIA Section 27 arose in connection with patents that, on their face, name the United States of America as an assignee.

If there are really serious issues with how Myriad is enforcing the BRCA patents upon which the United States is also an assignee and there is really a serious need for independent confirming genetic diagnostic test activity as to BRCA tests, I suggest that the U.S. Government step up and step in by way of march-in rights under the Bayh-Dole Act and authorize a third party to provide such independent confirming genetic diagnostic test activity as to BRCA tests. Or authorize a third party to provide such independent confirming genetic diagnostic test activity as to BRCA tests pursuant to 28 USC 1498. Thus, one approach to address the concerns of

those who do not have standing in *the Myriad case* is the U.S. Government exercising its march-in rights because under the Bayh-Dole Act, the U.S. Government can exercise march-in rights to alleviate health or safety needs which are not being reasonably satisfied by the rights holders.

Another approach to address the concerns of those who do not have standing in *the Myriad case* is for the U.S. Government to act under Section 1498 of Title 28. Under Section 1498 of Title 28, the U.S. Government can use or authorize the use of patent rights. In short, if independent confirming genetic diagnostic test activity as to BRCA tests is so critical that we are here today to consider the possibility that the patent system may be gutted by the enactment of the previously proposed, unconstitutional, compulsory, uncompensated licensing for independent second opinion genetic diagnostic testing, it seems that the U.S. Government should employ the laws already existing on the books. Namely, march-in rights under the Bayh-Dole Act, or U.S. Government authorization to use patent rights pursuant to 28 USC 1498. In other words,

there is no need for Congress to consider altering the patent system as to genetic testing. Rather, the U.S. Government should look to acting within the already existing laws to provide independent second opinion genetic diagnostic testing in cases where such is needed on a case-by-case basis. This brings me back to a very basic proposition. Any issue in *the Myriad case* involving a need for independent second opinion genetic diagnostic testing is a health care issue or a health reform issue, not a patent law issue.

Finally, while I concur with Ms. Wurtzel that the free market nature of the U.S. Intellectual Property System is what makes it the best, and while I oppose government intervention, especially as proposed, if there is such a strong desire to legislate then I suggest that the Department of Health and Human Services, the Food and Drug Administration, the Federal Trade Commission, and the Patent Office collectively work together through an interagency committee that includes both personnel of those agencies and practitioners to study whether the U.S. should enact antitrust legislation, akin to what

is known as competition legislation that may be found in various countries in Europe pursuant to the provisions of the Treaty of Rome.

For example, I suggest that there be a study as to whether the U.S. should have legislation akin to that which is in the UK, under which, as I understand, a refusal to deal may lead to a compulsory license when the working of any other patented invention which makes a substantial contribution is prevented or hindered, or the refusal to deal unfairly prejudices the establishment or development of commercial or industrial activities. In other words, rather than altering the patent system as to genetic testing any alleged issues should be more comprehensively studied, including in the context of antitrust law and across the board as to all inventions.

If a study of that sort concludes that it is appropriate to change the law, then I suggest that the changes be across the board as to all inventions with a law that provides a very limited, particular, product-specific compulsory license, prospectively, if and only if

there is a truly anti-competitive refusal to deal that prevents or hinders the working of other patented inventions that make a substantial contribution, or as a result of that anti-competitive refusal to deal the establishment or development of commercial or industrial activities is unfairly prejudiced.

In conclusion, any necessary current lack of independent second opinion testing in any field of genetic diagnostic testing is the product of the U.S. Government failing to act as to health care or health reform issues, and failing to utilize already existing laws, such as march-in rights under the Bayh-Dole Act, and the ability of the U.S. Government to use and authorize the use of patented inventions under 28 USC 1498.

It is premature to consider enacting compulsory uncompensated licensing for independent second opinion genetic diagnostic testing, and consideration of enacting such and thereby gutting the patent system as to all genetic diagnostic testing is not warranted by the lone situation of *the Myriad case*.

Furthermore, if enacted, compulsory uncompensated licensing for independent second opinion genetic diagnostic testing will be unconstitutional and will wreak substantial damage, including on future innovation, genetic diagnostic testing, personalized medicine, and biotechnology in the U.S. in general, and hence, will be counterproductive to the overall interests of the American people.

Rather than altering the patent system as to genetic testing, any alleged issues should be thoroughly studied, including in the context of anti-trust law across the board as to all inventions, and if such a study concludes that change in law is appropriate, then there should be a law that provides only very limited, particular, product-specific compulsory licenses, prospectively, if and only if there is truly an anti-competitive refusal to deal that prevents or hinders the working of other patented inventions that make a substantial contribution, or as a result of that anti-competitive refusal to deal the establishment or development of commercial or industrial activities is unfairly

prejudiced.

I, therefore, respectfully ask the USPTO to report to Congress that it should not further consider enacting the previously proposed compulsory, uncompensated licensing for independent second opinion genetic diagnostic testing.

Thank you for your attention and for having me testify today in this study on genetic testing. I hope my testimony is helpful.

MS. GONGOLA: Thank you, Mr. Kowalski. Do we have questions from our PTO panel? Stu Graham.

MR. GRAHAM: First, thank you, Mr. Kowalski, for the testimony and raising so many interesting and important issues.

I did want to ask a specific question. In your testimony, you suggested that the way in which the legislation presumes -- essentially presumes a problem, that's what you suggested, the quoted current lack of independent second opinion testing, and the impacts that has had.

You'll appreciate that in our role as being the authors of a congressionally-mandated

study that we need to fully ventilate this issue. And so, while your testimony suggested that we needed better evidence on whether there is, indeed, a significant problem across the at least 2,400 diseases for which we have genetic testing, we did hear from Congresswoman Wasserman Schultz a statement that this is a problem in 20 percent of the cases.

So, I will ask you. Can you point us to any evidence about the extent of this problem and/or the implications of this situation?

MR. KOWALSKI: Thank you for the question. Initially, let me start with if I imagine that the universe of patent-eligible subject matter is a circle, as in a Venn diagram, I don't believe that we should be punching holes in it for genetic testing, but rather that if you were going to look at compulsory licensing it should be across the board.

More importantly, when we say that there's a 20 percent question here my question back is, is there a refusal to deal by those patent-holders such that there is no way to have a license granted to a second party? That, to me,

hasn't been actually shown.

More importantly for example, in the case at issue, the BRCA case, when I come across a number of patents where the U.S. Government is the assignee on its face, I have to question whether or not we have a problem with the patent system or with the U.S. Government not stepping up and stepping in. So, in this instance where I hear that there's 2,400 tests and 20 percent are exclusively licensed I'm not sure that in that 20 percent realm there aren't also government-owned patents that are just in the same instance as the BRCA case, or that there are patents where there can be a sub-licenses but people do not avail themselves of taking the sub-license.

That's where my question to everyone is at, and I'm sorry to answer a question with a question but how can we say there's a problem when I haven't seen a detailed analysis of any refusals to deal.

MS. GONGOLA: Other questions from our PTO panel? No?

Thank you very much, Mr. Kowalski. We'll now turn to receive testimony from Dr.

Mercedes Meyer, who is here today as a member of the Board of Directors of the American Intellectual Property Law Association.

MS. MEYER: Thank you very much for holding this hearing to consider the important question of patent protection in health care.

As stated, I am pleased to be appearing on behalf of the American Intellectual Property Law Association as a member of its board of directors. The American Intellectual Property Law Association is a national bar association of approximately 15,000 members engaged in private and corporate practice in government service and in academia. Our members represent both owners and users of intellectual property, and they have a keen interest in a strong and efficient patent system.

First and foremost, the American Intellectual Property Law Association agrees that continuing to provide patients with access to the finest possible medical care and diagnostic tests is an important policy concern that is impacted by many factors, including availability of confirmatory testing for

patients facing very important medical decisions. AIPLA supports efforts to examine the complex issue of access to diagnostic testing, including the role of patenting and licensing. However, we also recognize that the promise of patent protection and the right to license diagnostic testing inventions create important incentives for inventors and owners to pursue and fund development of those tests.

AIPLA believes that the non-patent factors may in fact be more important in determining whether a confirmatory diagnostic test will be available to a U.S. patient. A principle factor is whether the test will be paid under relevant Medicaid, Medicare, and private-payer policies. Additional factors include the effects of FDA regulations, contractual limitations, institutional policies, malpractice, and other tort concerns, practice patterns, professional talent distribution, financial and time restraints, and more. In some situations, regulatory issues and government reimbursement policies may also serve as barriers to diagnostic companies who would

otherwise elect to offer tests at little or no cost based on financial need.

To the extent that patient concerns suggest that multisource tests should be mandated, AIPLA believes that patent protection can assist in ensuring that those offering a test are properly qualified to do so, that databases are properly maintained, and that important testing information relating to reliability will be made available to the FDA and other regulatory authorities.

More importantly, criticisms of how a given diagnostic patentee may have chosen to commercialize its test are more than outweighed by other factors. Most diagnostic tests would never have been developed or commercialized in the first place were in not for the incentives and protections offered by our patent system. The United States patent system, with its high standards for patentability, high predictability, robust enforcement provisions, and strong licensing tradition has been and will continue to be essential to the creation and commercialization of diagnostic tests that

benefit patients. It is still the best system for promoting progress of the useful arts and for bringing a steady stream of innovative products and services into our economy. Without commercially available tests, no patients have access, even to primary tests.

Unfortunately, the essential role patents and licensing play in bringing diagnostic testing to market is not widely understood. Insufficient knowledge about patenting and licensing of such tests, about the relationship between genetic patents and product commercialization, and about the complexity of the genetic diagnostic business can lead to misunderstandings and misconceptions. This can lead to misplaced efforts to weaken or eliminate patents. Fortunately, these concerns have been demonstrated to be unfounded in repeated studies of the issue. These studies have instead determined that current laws permitting patenting and licensing of genetic tests do not restrict availability of genetic tests.

The American Intellectual Property Law Association believes that it would be a mistake

to weaken the patent system to resolve issues not demonstrated to have been caused by the patent system. Objective consideration of data from several well-respected studies requires a conclusion that patenting, on balance, promotes rather than hinders patient access to health care.

We cannot lose sight of the fact that our patent system is based on a dual benefit. The constitutional mandate of a limited reward for invention and discovery is balanced against the duty of the patentee to disclose the invention. By encouraging invention, new technology is given to the public in perpetuity. While some might say this cost is high, it is a short-term cost whose long-term return in patient care, technology access, and future innovation has proven over and over again to give a vastly net positive benefit to the public. This system for advancing innovation has served the U.S. economy well. This is demonstrated by the rapid public dissemination of human genomic data and concomitant rapid growth of the biotechnology industry in the United States, while countries

with weaker patent systems lagged behind.

Today, we are beginning to see the promise of personalized medicine that is increasingly visible in approved genetic diagnostic products and services. These new genetic diagnostic tools do not simply identify if a person is at risk for a disease, but offer particular answers to a patient's expected prognosis, response to a particular drug, the correct dose for a patient, and much more. This new era of personalized medicine requires even greater innovation to meet the needs of the different groups of people that need and respond to different treatments.

Said another way, application of bioinformatics is expanding the need for innovators and adaptation of new observations to practical solutions. We need more, not less, innovation and the patent system's quid pro quo relating to invention disclosure is more important than ever. We need to continue to encourage the use of open disclosure rather than reliance on limited licensing and trade secrets that hold new discoveries as closely guarded

corporate property.

Rapid advancement of these tools and the recent lawsuit against Myriad Genetics challenging gene and medical diagnostic patent claims has caused the patent system to fall under intense scrutiny once again. Even though the practices of a few actors have been questioned, the few cases where technology has been sequestered or priced beyond the reach of the general public are relatively small in number, and even these actors are beginning to change their behavior in light of public scrutiny.

We note that the impact of patenting on the availability of health care and diagnostic testing has been studied and reported many times. The Health and Human Service Secretary's Advisory Committee on Genetics, Health, and Society conducted a study on the impact of gene patenting and licensing practices on patient access to genetic tests. This study arose from suggestions that patents may be limiting the availability, cost, and/or quality of genetic tests. It was also suggested that patents could potentially be responsible for quality control

issues. For example, where an exclusive license to a single test lab might prevent verification of test results by unlicensed labs.

The report acknowledges a trade-off between potential social costs incurred from the patents relating to genetic testing and the incentives provided by patents to develop new genetic tests. AIPLA believes, however, that the report overstates those costs and fails to adequately value the incentives derived from patents.

Notwithstanding the report's conclusion of a lack of evidence that patents pose any problem with access to genetic testing, it nevertheless concludes that there are or will be problems and leaves it to commentators to make the contrary case. A dissenting opinion from the report is worth noting: "It is our position that statutorily modifying the gene patent system, including the creation of exemptions from liability for infringement upon such patents as defined in this report and proposed in the recommendations would be more harmful than helpful to patient access and to the quality of

innovative genetic diagnostics."

The dissent emphasized the role that Medicaid and Medicare, as well as private-payers and other factors such as practice patterns and professional talent distribution, play in determining which genetic tests are conducted in what regions of the country. Their assessment of the study's data suggested that clinicians are often significantly limited by contractual and financial barriers placed on them by their institutions, or cost containment restrictions imposed by public and private payers.

Other countries have also looked at this issue. For example, the Australian Law Reform Commission conducted a multiyear study of the impact of gene patenting on the availability of medical services in Australia and produced a lengthy report titled, "Genes and Ingenuity Report: Gene Patenting and Human Health." The Commission concluded that it had found no firm evidence of increased costs, limited access to genetic testing, lower quality of health care services, or lower levels of clinical research and development.

However, it did note the existence of excessive worry about hypothetical exploitive activity, but an absence of evidence that patent-holders were aggressively enforcing their patents against genetic testing laboratories.

Consequently, the commission concluded that there were no grounds to justify changing Australia's patent laws, that the patent system was adequate to handle the system as it existed, that any reforms should be based solely on extremely difficult or hypothetical cases, such as *Myriad*, and that all reforms should conform with Australia's international IP obligations, particularly TRIPS.

Most pertinently, the Commission recommended against a medical or diagnostic treatment exemption in the absence of demonstrable harm for fear of hampering health care innovation. It also recognized that framing the scope of the exemption would be difficult.

Likewise, in 2009 to 2011, a committee of the Australian Senate while considering a bill to ban patents on biological materials that are

substantially the same as those found in nature reviewed prior studies of the impact of gene patenting and took additional testimony. The committee concluded, in part, one, no evidence received by the committee that patents on human genes or biological materials are systematically leading to adverse impacts on the provision of health care in Australia. Two, the bill would not resolve the issue concerning BRCA1 and BRCA2 genetic testing. And three, the bill could lead to significant adverse consequences for health care, including delays for access to new diagnostic tests, medicines, and treatments, reduced access to clinical trials, and reduced investment in medical R&D in Australia.

In summary, these and other studies examining the impact of patenting on continuing research and on patient access to medical diagnostics have failed to demonstrate a net negative impact of intellectual property. Rather, they each determined exactly the opposite. The potential for other non-patent factors to negatively impact patient access to confirmatory diagnostic testing may be more

relevant than patenting.

It may be that patients who undergo genetic testing may have reason to doubt the accuracy of a specific genetic test, or the performance of the test by the particular test laboratory. However, addressing the perceived problem by limiting intellectual property rights does not appear to be an effective solution. Instead, confirmatory testing should be addressed on a global scale by working with test providers and technology licensors to establish best practices for licensing. We can point to the approaches recommended by AUTM, OECD, and the NIH that have been adopted by many test providers.

In conclusion, the American Intellectual Property Law Association believes any change to the patent statute should be made only on the basis of credible and substantial evidence that access to confirmatory testing is being broadly restricted, and that the change will improve access. Two, we must include reasonable compensation to the patent owner or exclusive licensee if the change would render patents non-enforceable. And lastly, must be

very narrowly tailored.

AIPLA does not support legislation limiting patent rights in genetic diagnostics without clear evidence that such legislation is required. Innovation and economic growth in the growing genetic diagnostics industry should not be constrained absent a definitive and overriding need. The American Intellectual Property Law Association appreciates the opportunity to present comments on this important issue. We will present additional detailed written comments in due course.

MS. GONGOLA: Thank you, Dr. Meyer. I believe we have a question from Stu Graham.

MR. GRAHAM: Thank you, Dr. Meyer. Thank you for your comments.

As we move forward in our consideration of these issues and the authorship, one of the more pressing issues on us is whether and how to collect the evidence necessary for the Under Secretary to make whatever recommendations he may or may not want to do. What I've heard now in your testimony and Mr. Kowalski's testimony is a set of potential solutions or recommendations here,

some of which each of you have considered to be more desirable or less desirable. We might put them across an entire spectrum from a "let the market work" approach all the way on the other side of the spectrum to a "compulsory, uncompensated license."

Mr. Kowalski appeared to make a recommendation toward the end of his statement that would be a solution that is somewhat in the middle, a limited remedy in the circumstances in which there is bona fide evidence of a failure to negotiate which would be, you know, actually broader outside the realm of genetic testing. Do you have a sense of where your recommendations may lay along that spectrum? Or if you have a recommendation or your organization has a recommendation that is lying somewhere else along that spectrum?

MS. MEYER: I think we're still developing our written comments. The brevity of time in which to throw something together, literally, given the nature of the questions -- some of which lie, as you well appreciate, outside the purview of

patenting -- we want to provide a document that is very educational and informative, but the time has not been sufficient and I don't think I can make that conclusion for the committees involved at this time.

MR. GRAHAM: Understood, thank you.

MR. ELLIOTT: I just have one question regarding -- and this doesn't go together in fact, so much, but more opinion. Both Mr. Kowalski and you have alluded to the damage to the patentee, to the licensee -- exclusive licensee -- of some sort of what I'll refer to as a safe harbor-type of situation for second testing. I'm wondering if you could expound a little bit on how extensive you think that problem is, or how much damage there would be to an exclusive licensee assuming that that exclusive licensee were in the position of having to provide the first test and any potential safe harbor was only applied to a confirmatory test.

MS. MEYER: I think it depends greatly on the nature of the confirmatory test and whether it is a repetitive test of the exact same assay, and whether you can have the systems in place and,

unfortunately most of the LDT, the laboratory- developed tests, are not under FDA supervision right now. So, if you don't have the exact same test and it's done by another lab, can you guarantee that the right precautions are being done? And it also depends on whether the test is a hereditary test or a somatic-based test. They give different answers, especially for somatic where you can have different answers in time during the course of disease.

MR. ELLIOTT: Okay, thank you.

MS. GONGOLA: Other questions from the PTO panel? Thank you, Dr. Meyer. We will take at this time a 10-minute break. So, we will return at quarter of 11 to continue our pre-scheduled witness testimony.

(Recess)

MS. GONGOLA: If we could please begin to take our seats, we would like to resume the hearing very shortly.

Our next witness is Mary Williams, the Executive Director for the Association for Molecular Pathology.

MS. WILLIAMS: On behalf of the

Association for Molecular Pathology, I thank you for the opportunity to provide testimony today. AMP is an international medical and professional association representing approximately 2,000 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Our members also include scientists from industry.

AMP is the lead plaintiff of 20 plaintiffs represented by the ACLU in a lawsuit challenging the validity of patents on 2 hereditary breast and ovarian cancer genes, BRCA1 and BRCA2. AMP joined to bring the litigation because of its members' firsthand view of the harmful effects of gene patents on patients with genetic diseases and their at-risk family members. AMP members know full well the dilemma suffered by Representative Wasserman Schultz and other patients. Some AMP members have stacks of cease and desist letters to force them to stop testing, and they have letters to refuse to grant licenses to test. Enforcement of gene patents has forced many providers to discontinue

preexisting test offerings. AMP members in industry have invented and developed amazing new technologies, but if they're not able to access gene sequences they're not able to put new tests on these new platforms.

So in practice, gene patents discourage rather than encourage the widespread provision of genetic testing services. Moreover, gene patents serve as a disincentive to innovation because they deny access to vital genetic information that cannot be invented around. The threat of litigation for infringing on the patents has created a chilling effect, as manufacturers and clinical laboratories are reluctant to develop new tests that could directly benefit patients. All of these adverse effects are in direct contravention to the purposes underlying patent exclusivity.

AMP believes previous scientific and federal advisory committee publications and the common knowledge of practitioners in the field provide ample evidence for the harms to patients and negative impact on testing that result from gene patents, and argue against human genes and

genotype/phenotype associations as patentable subject matter. AMP is also concerned that because the USPTO is not a health care-focused agency, it does not possess the needed expertise and resources to adequately assess the impact of patents on patients' ability to obtain confirmatory testing, particularly in so short a period of time.

For these reasons, AMP strongly urges the USPTO to base its assessment of the impact of gene patents on genetic testing on the report published in April 2010 by the HHS Secretary's Advisory Committee on Genetics, Health, and Society, also known as the SACGHS titled, "Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests." This almost 400-page report represents approximately 4 years of active investigation and study, and is an important reference on the subject.

The SACGHS task force included SACGHS members, nongovernmental experts appointed as ad hoc members, technical experts from federal agencies. The individual task force members had the necessary expertise to produce a reliable and

accurate assessment of the impact of gene patents and licensing.

To complete the study, the task force conducted a review of the scientific literature, consulted with experts, solicited public comments, and completed original case studies. The SACGHS found, "The patenting and licensing of genetic tests has limited the ability of clinical laboratories to offer genetic testing. This limitation, in turn, can affect patient access, the quality of testing, and efforts to innovate."

Specifically, the committee found that where patents and licensing practices have created a sole provider of a genetic test, patients are unable to obtain insurance-covered access to a sole provider's test if that provider does not accept the patient's insurance. Additionally, they found that patients cannot obtain testing from an independent lab to provide a second opinion or to confirm the prior results. The committee also concluded that patients have difficulty accessing lifesaving genetic testing when a patent-holder delayed or chose not to develop or license the sequence to develop a

clinical test. In addition, SACGHS also included that gene patents threaten the quality of genetic tests when they are provided by a sole laboratory.

Every day, AMP members witness the ability of genetic testing to better patients' lives and improve their health. Unfortunately, they also experience firsthand the challenges imposed by gene patents that interfere with the practice of medicine. In the case of hereditary breast cancer, genetic testing for mutations in the BRCA1 and the BRCA2 genes enables patients to opt for preventative surgeries, additional cancer screenings, and, most importantly, the ability to warn other family members that they may also be at risk.

Process patents on genes such as FLT3, which is used to qualify patients with an aggressive form of leukemia for bone marrow transplant are forcing laboratories to split and ship small, irreplaceable bone marrow samples because they cannot perform FLT3 testing in-house due to an exclusive license on the gene. This imposes many unnecessary medical risks simply

because an entity owns a patent on the FLT3 gene sequence. These are just several examples of ways in which gene patents and licensing practices harm patient access to lifesaving tests, including tests for second opinions.

AMP is unwavering in its commitment to the right of patients to obtain second opinions on genetic testing. However, we believe creating a safe harbor for infringement on patents solely for the purposes of confirmation testing will not result in patients having access to confirmatory genetic tests on patented genes. Laboratories invest significant resources in developing and maintaining tests and are not likely to use scarce resources to validate or verify tests used solely for confirmation purposes. Further, documenting that a test has been ordered solely for the purpose of a second opinion may be difficult or impossible, placing an onerous burden on clinical laboratories. The existing chilling effect due to potential litigation would remain. Finally, health insurers and Medicare most likely will not reimburse the cost of these tests, as they will

be viewed as duplicative.

The profound disincentives associated with second opinion testing of patented genes will discourage laboratories from providing these services, and patient's access to genetic tests will continue to be hindered. The SACGHS had more than four years to complete its report on the impact of gene patents on genetic testing. The task force had access to clinicians, health service researchers, insurers, patient representatives, molecular pathologists, industry, and many more experts within and outside of the task force to advise them throughout the process. Because the USPTO has been given only several months to complete this report to Congress and has limited access to the needed professional expertise to produce a valid assessment of the impact of impacts on genetic testing, AMP once again strongly urges the agency to adopt the recommendations of the SACGHS report.

This report includes data to answer the vast majority of the questions posed in the Federal Register notice, and also presents six

recommendations to minimize the burden, interference, limitations, and harms on patient care attributed to gene patents. It's time for a change in policy that will enable manufacturers to access gene sequences so that they can develop tests using their impressive new technologies and so that patients can fully access needed testing.

AMP supports patents on technologies and on tests. These are true inventions. AMP believes that gene sequences are natural phenomena, whether inside or outside of the body. Therefore, in light of the recommendations in the SACGHS report and the solicitor general's brief for the United States and the ongoing litigation challenging the patents on the BRCA1 and BRCA2 genes, AMP respectfully requests that the USPTO place a moratorium on issuing gene patents, including process patents on gene or variant correlations and clinical phenotypes while the issue receives full legal, legislative, and administrative consideration.

Thank you very much for your consideration of AMP's testimony today. Addressing the challenging issue of gene patents

has been a priority for AMP and we offer ourselves as a resource to the USPTO as you complete this report to Congress.

Thank you.

MS. GONGOLA: Thank you, Ms. Williams. Do we have questions from our PTO panel?

Stuart Graham.

MR. GRAHAM: Yes, thank you. Thank you for your testimony, first of all.

You'll appreciate that we need to have answers to the congressionally mandated questions, and a few of those that I believe are not adequately covered and which you may be able to help us with in pointing us toward evidence. Let me just ask one and then the other.

So, the first. Can you point us to evidence that tells us anything about doctors providing altered care or a different type of care or less quality care because they cannot get access to confirmatory tests in this space?

MS. WILLIAMS: I believe that we can provide that information from AMP members, yes.

MR. GRAHAM: Okay, that would be very useful. And secondly, it would be useful to us

to get evidence specifically on the circumstances or the prevalence with which exclusive licensing itself is limiting the ability of doctors to make the best or the most relevant recommendations to patients.

MS. WILLIAMS: I believe we can get that as well through our membership.

MR. GRAHAM: Very good, thank you.

MS. GONGOLA: Deputy Director Rea?

MS. REA: Thank you so much, Janet, and thank you, Ms. Williams, for your testimony.

I have a quick question. The development of diagnostic tests is very active right now and very ongoing. Do you or any of your member companies happen to know if that research is, indeed, ongoing with different groups and patents are not being filed on those diagnostic tests?

MS. WILLIAMS: I don't know whether patents are or are not being filed. I do know that the area is very, very active. There's lots of new tests being developed, lots of new exciting technologies being developed.

MS. REA: I would be interested in

finding out if indeed patents are being filed on all or most of those tests at this time, since you would rather have patenting --

MS. WILLIAMS: Now, this would be patents on tests or patents on gene sequences?

MS. REA: I guess either one. I'd be interested in data for ether one for our report. Our focus of our study today is, indeed, genetic diagnostic testing. That's the focus today is the second confirmatory test, but any data and information that you could provide may be helpful in our report.

MS. WILLIAMS: All right. I think off the top of my head data on whether patents are being filed would probably be in your purview. You would know whether patents are being filed. I'm not sure that AMP would know whether companies are filing patents.

MS. REA: If there's ongoing research where the company elects not to file a patent, I wouldn't necessarily have access to that information.

MS. WILLIAMS: We can look in to see if we can help you with that, certainly.

MS. REA: Thank you so much.

MS. WILLIAMS: Sure.

MS. GONGOLA: Ms. Williams, I also have one final question for you. Do AMP members have any experiences with patients' ability to secure insurance coverage for testing that you could provide either anecdotally or with actual evidentiary data in the form of statistics as to what insurance providers are doing? Are they making testing available under insurance plans? Have they discontinued testing? What are the circumstances for which testing is available?

MS. WILLIAMS: Well, a couple of instances that I do know about, of course, as one of the plaintiffs in the ACLU lawsuit. Elizabeth Ceriani, of course, could not access BRCA1 and BRCA2 testing because Myriad would not take her insurance. In addition, there was an abstract at a recent AMP annual meeting from an author, one of our members in Louisiana, that was outlining the tests that they do for their indigent patients to kind of -- like that second-best sort of test. You know, the best kind of thing that they can do because the patients cannot afford to pay out of

pocket for the Myriad test and because the state of Louisiana cannot afford to pay for them. So they're trying to do the best that they can, but it is not the BRCA1 or the BRCA2 testing.

MS. GONGOLA: A follow-up question. Do you have any suggestions on where we might be able to access this information about insurance coverage for genetic testing?

MS. WILLIAMS: I'll work with you to find that information.

MS. GONGOLA: You're walking away with a lot of homework assignments today.

MS. WILLIAMS: I know. Well it's an important issue. We're glad to do it.

MS. GONGOLA: Thank you, Ms. Williams.

MS. WILLIAMS: Certainly.

MS. GONGOLA: We have next testimony from Lori Pressman, who is an independent consultant on technology transfer.

MS. PRESSMAN: So, thank you very much for inviting me. Thank you for holding this hearing.

I have been a self-employed consultant and advisor in the midst of the U.S. innovation

ecosystem since 2000. I evaluate technology-based businesses, including sometimes medical diagnostic businesses, for venture investors and for academic institutions.

Can everyone hear me? I guess I should.

MS. GONGOLA: Ms. Pressman, on the right, I share the same problem with you. We have the height gene.

MS. PRESSMAN: Yes.

MS. GONGOLA: And so, on the right of the podium if your reach underneath you can lower the podium if that's more comfortable for you.

MS. PRESSMAN: No, this is good, I think. Right, yes? Everyone can hear? Let me know if you can't.

An important but not sole component of this evaluation is an evaluation of the patent portfolio of the business. I also advise on the development, management, licensing of patent portfolios for companies, investors, and major academic institutions. I was employed by the MIT Technology Licensing Office from 1989 through 2000, from 1996 on as assistant director with

signatory authority.

I am a member of the Association of University Technology Managers, a current member of the AUTM Public Policy Committee, and I was chair of the AUTM Survey, Statistics, and Metrics Committee from 1999 through 2001. I've received the AUTM President's Award twice.

I'm also an inventor on a half-dozen U.S. patents, on a fiber used in laser surgery, not on diagnostic tests. I have a bachelor's degree in physics from MIT and a master's degree in electrical engineering from Columbia University.

I have also received NIH funding in the area of patent policy. In particular, I've conducted studies on licensing practices and outcomes of patents with nucleic acid sequences in their claims, managed both by academic institutions -- that would be AUTM members -- and also by the NIH Office of Technology Transfer. These patents are found via a bioinformatics search algorithm described in a paper I wrote in 2006 in Nature Biotechnology and called, by definition, DNA patents. So whenever I say DNA

patents now, here, I mean patents found by that bioinformatics search algorithm.

DNA patents are thought to be associated with diagnostic tests. Before focusing on patient access to diagnostic tests, I need to discuss and challenge the precision, and thus the usefulness, of two phrases which occur in the Federal Register notice. First, exclusive license and, second, genetic diagnostic testing.

License exclusivity is analog, not digital. It's a matter of degree. Patents can be and are licensed exclusively or, indeed, nonexclusively in virtually any category the negotiators can define, for example, exclusive in Asia, nonexclusive in Europe; or by market, exclusive in ophthalmology; or by technical platform, exclusive with any on-chip assay; or by time, exclusive for five years; or what is sometimes called a co-exclusive defined by the number of subsequent licenses a patent-holder can continue to grant, for example, “licensor agrees to grant no more than three other licenses.”

Greater scope of exclusivity is

associated with more diligence in license agreements. Diligence means the built-in contractual requirements to commercialize the invention in a timely manner or lose the license. Of course, the scope of exclusivity is also inherently delimited by the scope of patent claims.

More exclusivity in the license is generally warranted when products are expected to take longer, cost more, and be much more difficult to commercialize. Diligence aligns business and patient interests as all stakeholders want high quality, safe, useful, appropriately regulated products available as soon as possible.

The phrase "genetic diagnostic test" is also problematic. Not all diagnostic biomarkers are nucleic acids, and not all tests informed by an understanding of the underlying genetics use a nucleic acid as the analyte. Many tests for infectious agents measure the presence of antibodies against a pathogen-specific antigen. In the oncology space, there are two tests used clinically to measure the level of HER2 protein in cancer cells, and predict the response to the

drug Herceptin, a breast cancer therapeutic. One test measures nucleic acid expression directly, and one test uses antibodies to detect the presence of the protein.

There is a scientific journal and a field devoted to mutation-specific immunohistochemistry, protein biomarkers for nucleic acid sequence mutations, or for proteins made by those mutated sequences. Note that antibodies are scientifically, at least, relatively easy to design around.

A study I conducted in collaboration with the NIH Office of Technology Transfer using NIH OTT data on licensing outcomes for those DNA patents and patents in the same family as DNA patents -- and I use "family" the way it's used in the patent office, patents sharing the priority date with the DNA patent -- shows that the presence of nucleic acid sequences in patent claims is a poor predictor of the type of product that a DNA patent or other patents in its family may cover. The study also shows that refinement of the computer selection criteria by expert human curators did not help. Both the computer

and the combination of the computer plus experts were insensitive and nonspecific.

If the criteria are set not to miss any diagnostic products, so that the true positive is 100 percent, then the false positive is 79 percent. Get it right all the time and wrong most of the time. Under conditions where the false positive rate is about 26 percent, then the true positive is only about 50 percent. You can't read a patent and predict accurately what type of product it will cover, and I am submitting figures and data tables along with this report for your inspection.

The most sensitive and specific by a considerable margin predictor of the type of product a patent will cover is the field of use and the license agreement. When the parties sit down to negotiate a license and one says to the other, “we're working on a diagnostic test”; or, “we want to develop a laboratory reagent”; or, “we are working on a targeted therapeutic”, this discussion predicts the type of product ultimately associated with the patent much more accurately than the patent claims.

The true positive rate for the license field of use is 88 percent and the false positive is only 15 percent. In my opinion, these observations support keeping the existing broad patent eligibility criteria as modulations on the scope of proprietary rights with the intent of fostering patient access to diagnostic tests can clearly be most intelligently accomplished at the license and not the patent level.

DNA patents do appear, however. At least for the NIH data set, DNA patents and patents in the same family as DNA patents, which issued between late 1976 and mid-2007 to be mostly, though not entirely, associated with reagents and diagnostics and not, for the most part, with therapeutics.

Of course, some products take longer to develop than others and some diagnostics take longer to develop than others. The study conducted in collaboration with the NIH OTT also suggested that diagnostics generally take longer to develop than reagents and both generally speaking, consistent with expectations, do get to market more rapidly than therapeutics.

Generalizations aside, it is clear that some diagnostics such as Genomic Health's Oncotype Dx product took a large investment, more than $100 million, to become broadly available. All the data in here is footnoted and, so.

A presentation at the AUTM 2010 annual meeting, which showed an overlay of the dates of insurance reimbursement decisions over a graph of the growth of Oncotype Dx product sales speaks directly to Federal Register Topic 14 and, in my opinion, suggests that Genomic Health's advocacy for insurance reimbursement played a positive role in product availability and, thus, patient access.

The line between easy to develop and hard to develop is not bright. Two trends, targeted therapeutics and companion diagnostics, are blurring the distinction between therapeutics and diagnostics. In my opinion, it is likely that preserving the existence of patent incentives and broad patent eligibility in the diagnostic space will become more and not less important to patient access.

I speak from more than 20 years of

personal experience when I say that proprietary rights lower the perceived risk in investing in products which require time, talent, and money to develop. AUTM data show that more than 90 percent of patent licenses to startups have at least some exclusivity. My 2006 paper shows that this is also true for startups which license AUTM member-managed DNA patents.

There are recent biomarker-based diagnostic startups, such as Allegro Diagnostics and SynapDx, which report exclusive patent licenses on their websites. Though, of course, we cannot be certain about the scope of their license exclusivity.

Allegro Diagnostics was founded in 2006 to commercialize pulmonary diagnostics for lung cancer and reports having raised $9.6 million in venture funding. SynapDx will develop diagnostics for autism spectrum disorders and reports raising its Series A round of $9 million in 2010. These companies did not start with physical science inventions as, say, Illumina or Helicos did, but with patented inventions on biomarkers and methods of making diagnoses using

the biomarkers, some of which are nucleic acid sequences; and again, in my footnote you can pull up the patents. I'd be happy to send you the patent claims.

In my opinion, these companies can do a lot of good for patients. Future biomarker patents will look less like past biomarker patents. The publication of the human genome sequence February 16, 2001, limited and continues to limit the scope of novel and claimable subject matter, as does the growing universe of all technical publications.

Future biomarker patents will have to disclose new, likely multi-loci genotype/phenotype associations and, thus, methods of medical management, or newly-characterized mutations, or new combinations of existing markers which together are not obvious. And I need not remind you, the Patent Office, that "new" is a moving target. Much of the concern raised about patents potentially interfering with a second laboratory provider of a diagnostic test is based on simpler patents filed more than a decade ago.

The current patent system has a robust set of tools for prudent definition of patentable subject matter; the novelty, non-obviousness, written description, and enablement requirements. The written description and enablement requirements are particularly important to the non-predictive arts, namely biology, and by their nature limit the scope of claimable subject matter.

Licensing practices evolve, too. The licensing community -- and I include the for-profit and the not-for- profit licensing community -- is always refining licensing and diligence terms and approaches and tailoring them to the expected difficulty, dollars, and time required to commercialize inventions. When a diagnostic looks like a reagent, then modest if any exclusivity is warranted. When a diagnostic looks like a therapeutic, then more exclusivity along with more diligence is warranted.

It's a dynamic world. In my opinion applying a poorly defined filter to patent eligibility will not help patients. Modulation of the scope of exclusive license rights and the

accompanying scope of diligence obligations informed by a realistic and honest assessment of the difficulty of bringing products to market is the most flexible and powerful approach to assuring patient access to diagnostic tests.

Thank you.

MS. GONGOLA: Thank you, Ms. Pressman. Questions? Stuart Graham has a question.

MR. GRAHAM: Thank you, Ms. Pressman. I'm going to lean a bit on your experience with technology licensing to help us understand a little bit about how the market for licensing works in helping us to get at this question I asked of others previously. So, you know, if we have these two polar opposites here, one is the view that the market works, which of course is undercut by the testimony of Congresswoman Wasserman Schultz earlier, because there is a very -- you know, that's a very real instance in which the market did not work for her in providing something that she was demanding as a consumer. And then on the other polar opposite we have the "horribles" associated with uncompensated and compulsory licenses.

There have been some other solutions that have been suggested in the middle, and I'm trying to understand, and your expertise can help in this. If there is a situation in which a patentee is able to control the exclusive right over providing the first test, what are the circumstances in which that second test -- you know, and why is it from licensing perspective that for that second test the patentee couldn't in an effective licensing regime extract all the profits and even extract all the data on the procedure being implemented by that second party back to the patentee?

And this goes to the situation that has been -- you know, I'm trying to inform this comment that's been made several times now that, you know, there's an essential problem with the innovation incentives here. I'm trying to understand how the market can't work to make the patentee better off by having an arrangement in which there is a second market for their product, right, which can't compete and can't substitute for that first test?

MS. PRESSMAN: Boy. So, I guess first

of all, you know, it's an imperfect world and a lot of what you're talking about is how to have the best possible world. And I think a lot of us -- I put myself in that category, you know, that if you sort of turn the knob way, way down on exclusivity and proprietary rights, my personal belief is that the net result will actually be worse off.

In terms of the very specific details, I think what you've seen is an evolution toward modulating the exclusivity. You know, if you want to talk about the Myriad patent specifically, you know, they're all filed before publication of the human genome. They're really all fairly old patents, and in the current world would they have been given a life of patent exclusive? Maybe not.

You know, there are also pricing issues and I think that what's sort of buried in -- or not even buried, we're talking about it more -- well, I mean, I can't speak for Myriad, they're not here. But of course they would, for the right price is kind of -- I mean, is that really what you're asking me? An economic -- why

don't they just grant sub- licenses because they'll --

MR. GRAHAM: I'm trying to understand the comment that you made that we don't want to undercut the incentives to innovate, which I think is foremost as one of the considerations that we're considering, you know, across the range of these questions. Just trying to understand more about these intermediate possible solutions or recommendations and what the impact on that in the narrow slice of innovation incentives they would potentially have.

MS. PRESSMAN: So, I have a ton more data on that. Boy, to try to sound bite it.

I think that there is a -- let's see, how do I sound bite this? So, the study that was done was that licensing at universities was compared with licensing at the NIH, and the NIH, I imagine, a non- -- you know, they are sort of on the nonexclusive side and the universities are on, you know, a little bit more, a little bit more focused on incentive creation. And this is emphasizing my personal opinion, absolutely

my -- just my personal opinion.

I think that there is a happy medium and I like to think that the university is sort of there. You need some, in my opinion. You can't -- the public will lose if it's too watered down. We can get wiser and cleverer about it, I firmly believe at the license level. I mean, to me this data shows it would really be silly to try to do it at the patent level.

There's also another -- I'll give you a very creative solution. So, I'm an engineer and I'm familiar with how the semiconductor industry works, and very big buyers, you know, like Intel. You know that they won't purchase a chip from a sole supplier? So, I know this because I would do license agreements in the physical sciences and the sub- licensing terms that you'd negotiate would always be high and the licensee, on the other side, would say, well, of course, I have to do this. I have to set up my own competitor or I'll never sell to Intel. I mean, that's another purely market approach, you know, for the insurance companies to say or do something.

You know, I'll also -- have you read the SACGHS report? Yeah. So --

MR. GRAHAM: We should say this on the record. Yes [we have read the SACGHS report].

MS. PRESSMAN: It's on the record, yeah. Right. Let's see.

So, you know about the $40 per amplicon, right, that it was remarkably consistent? And why did I go -- lost my train of thought. What was the question? You were asking other --

MR. GRAHAM: I was asking about the innovation incentives and you were talking about different market organizations and solutions.

MS. PRESSMAN: Right. So if you read the SACGHS report -- so, Myriad did something extremely valuable, which is that -- so also, BRCA is a very long gene, a very large number of the mutations are personal, right? They're unique, right? You do actually have to sequence the whole thing, and they gathered an enormous amount of very valuable data, so that also is valuable, right? You know, they -- it's valuable that having a champion is valuable.

You know, another -- do you ever read

the AUTM Better World Report?

MR. GRAHAM: I'm familiar with AUTM but I don't admit to having read that.

MS. PRESSMAN: So, I'll send you a vignette. They had a vignette on a preeclampsia diagnostic in which the licensing office spoke about needing to grant an exclusive license because they needed a champion, and then that champion sort of further diffused it out in a nonexclusive manner. And there's a discussion about -- I wish they'd had more discussion, but anyway -- that there was some sort of skill involved in crafting that kind of a license. You know, now we're 2010. Myriad was a long time ago.

I don't know if --

MR. GRAHAM: Thank you.

MS. PRESSMAN: Yeah.

MR. GRAHAM: I do encourage you to share those data with us across many types and differing subject matters of transaction, because of course we are interested in a much wider scope of genetic testing and confirmatory testing activity than a single particular provider.

MS. PRESSMAN: Thank you.

MS. GONGOLA: Other questions from -- no? Thank you, Ms. Pressman.

Our next witness is Dr. Hans Sauer, Associate General Counsel for Intellectual Property from the Biotechnology Industry Organization.

MR. SAUER: So, good morning. I think I can still say that. I'm Hans Sauer. Yes, I'm deputy general counsel for intellectual property for the Biotechnology Industry Organization, on whose behalf I testify today. So, we want to thank you for giving us this opportunity.

BIO is the nation's largest biotechnology trade association. We represent more than 1,100 companies, academic institutions, and biotechnology centers in all 50 states and in countries around the world. BIO members undertake research and development of biotechnology health care, agricultural, environmental, and industrial products. So, there's a big diversity of our members who work in very different industries with very different market dynamics, but the unifying aspect is the

use of biotechnology to address very disparate problems and develop very different products.

The vast majority of our members are small companies. You know, we do range from startup businesses and university spinoffs to Fortune 500 companies, but the vast majority are small companies that have yet to bring products to market and attain profitability. Such companies, for that reason, depend quite heavily on their patents to attract the massive investments in funding and resources that are needed to bring biotechnology products to market. They depend on venture capital and other private investment for their growth as well.

Biotechnology products, medicines, and biotechnology crops typically require close to a decade of development work and a fully capitalized investment in the range of $1.2 billion. Biotechnology companies, again, need patents to protect such substantial investments of time, resources, and capital.

MS. GONGOLA: Excuse me, Dr. Sauer. We're having a difficulty hearing you. Could you please raise the microphone?

MR. SAUER: My pleasure. Can you hear me better on the web? Okay.

MS. GONGOLA: I think that's improved, thank you.

MR. SAUER: Very well. So, as a general proposition devaluation of patent assets leads, from our perspective, to a reduced incentive for companies to conduct research, development, and commercialization of new biotechnology products. This is definitely true for new therapeutic products, it's true for agricultural products, diagnostic kits which receive clearance by the FDA as devices, medical devices of other kinds, and instruments.

It is, we believe, also true for advanced molecular diagnostic services which require significant investments to procure the clinical data packages that are necessary for coverage determinations and payer and physician adoption, even though the investments perhaps in developing the service itself are not as high as those for new medicines or crops. But these investments aren't insignificant. We heard from Lori Pressman just earlier, she made a reference

to an approximately $100 million investment by Genomic Health in their Oncotype DX assay. Myriad as well, which will testify later in these hearings, will probably tell you that their investment in driving payer adoption and getting a reimbursement system in place was in the range of, I want to say, $200 million or something like that. So, that's not insignificant. It's not like developing a drug, but it's nothing to sneeze at.

Only few BIO member companies are in the market for advanced diagnostic services, and yet the PTO's Federal Register notice has generated considerable interest among our membership, many of whom hold so-called gene patents on isolated or purified DNA molecules on which they rely to protect, for example, the production technology for recombinant biologic drugs or recombinant traits for genetically modified crops or microorganisms.

Again, we heard it earlier. Just looking at a patent, you would never quite know what kind of product it will end up covering, and that is definitely true in the biotech space where

we often hear -- we have this discovery, we don't know where it's going to go, hopefully it will be a new medicine, hopefully a new diagnostic, and so on. The prediction, however, is very difficult.

So, many BIO members have expressed concern that the public -- the current public discourse about gene patents takes place really on the sole platform of genetic diagnostic testing services, and is focused at least implicitly on a single diagnostic testing company. That company is not a BIO member, Myriad is not, but we have member companies who do research on sugarcane genes or oil palm genes and the like who are incredulous that the validity or propriety of their patents would be drawn into question based on the purported marketplace behavior of a single diagnostic testing company.

We trust that the PTO will not lose sight of possible unintended consequences outside the genetic testing area as it develops its policy recommendations from the study. The same is true for any positions the Patent Office might advocate to the U.S. Government, for

example, in the context of ongoing litigation.

The role of patents in the development, patient utilization, and other aspects of advanced genetic tests generally has been studied before. It's been said before in this hearing, as well. Without firm conclusions, most recently the Secretary of Human Services' Advisory Committee and Genetics Health and Society, which I will call the SACGHS Committee going forward, published the already mentioned report two years ago which relates to gene patents and genetic testing. The report and policy recommendations in that report generated controversy, including very public dissents from the majority opinion. And so you know, for that reason, too, it should be taken a bit with a grain of salt. But we believe that the underlying research studies that were commissioned and subsequently published are valuable and high-quality contributions to a discussion that had, up to that point, been dominated largely by anecdotal reports, opinion surveys, and other soft data.

So, the SACGHS commissioned

publications were published as a special supplement to Genetics in Medicine in April 2010. If you don't have them already, they are available on the web without a subscription from that publication, and we believe these publications will prove valuable to the PTO but they, too, contain grist for every mill and they are unlikely to conclude the never-ending debate about patents and patient access.

Fortunately for the PTO, your mandate is rather narrower than that. Section 27 of the America Invents Act directs the PTO to conduct a study on ways to effectively provide independent confirmatory genetic tests where gene patents and exclusive licensing exists.

Now, a word. Lest we get the impression that we've all already agreed that there is -- you know, that we're embarking on this study having agreed that there is a problem with patient access to second opinion genetic testing, and that creating an entitlement to such tests would automatically translate into a patient benefit, lest we get that impression that we agree on that we want to offer some observations, from

our perspective, actually, that has yet to be established to us. That's not at all clear.

So, the AIA uses the term "second opinion testing." The clinical practitioners with whom we spoke tell us that in clinical practice it's actually quite rare for a patient to ask for a repeat of an advanced molecular diagnostic test, just like patients are quite unlikely to ask for a repeat of, say, an MRI scan or an X-ray. What patients, we are told, ordinarily mean when they ask for a second opinion is a second medical opinion. It's in the nature of doctor, now that we have this test result, what should we do? Oh, my, is that really your recommendation? Can I get a second opinion on what to do?

Absent a reason to believe that the original test was somehow defective or unreliable, neither patients nor their physicians would seem to have a reason to ask for repeat tests. Absent a reason to believe that the original test provider will, again, provide an unreliable test result, there is no reason to request a repeat test by an independent

third- party laboratory. So again, we're told -- and, fortunately, it's kind of hearsay -- that such instances are actually quite rare in clinical practice. You know, doctors tell us that doesn't seem to happen very often, and when it happens it happens whether or not the test is available from multiple test providers.

In fact, we think the PTO should, in the course of this study, evaluate how often patients actually procure confirmatory tests where independent alternative providers are available, or in other words for you to figure out the availability of confirmatory tests where gene patents and exclusive licensing exist that almost presupposes that you also figure out the utilization of such test when gene patents or exclusive licensing don't exist. All right? So it's part of, I think, the task that implicitly Congress may have intended you to solve as well.

Our understanding is that for the vast majority of genetically transmitted diseases, multiple providers are available and, therefore, independent confirmatory tests are available and it should, therefore, be possible for the PTO to

gauge at least anecdotally the actual patient and physician demand for such re-tests, to the extent such demand exists.

Predictions are, from our perspective, that the demand -- the actual demand -- is probably very low and that is, in fact, a conclusion even the SACGHS committee drew in its 2010 report when it said that there would probably not be a market for second opinion confirmatory testing, even if that were available to other labs to do.

Irrespective of whether there even is real demand for second opinion testing, BIO hasn't identified a single genetic test for which an independent confirmation would truly be unavailable. Even in instances where the U.S. market is served by a single-source provider samples could, for example, be sent to ex-U.S. laboratories or be referred to research laboratories. Also, for most tests non-infringing alternative tests are available, too.

So to take BRCA as an example, some decision trees in Europe actually use a sequence

of different tests involving, for example, at the beginning protein truncation tests -- which are, you know, non-patented, not covered by Myriad's patents -- which cover a lot of mutations and which after that, progress to maybe full-scale sequencing at a later stage. So it's a different decision tree where, in fact, if you will the genetic sequencing test confirms the protein test that was done before. So it's not a re-test, but it's a form of confirmation that's already taking place in practice. To not lose sight of non-infringing alternative tests that may be available, I think, is going to be important. We're all thinking about re-tests, but what about other tests that would accomplish the same thing? Wouldn't that serve the patient's purposes as well?

So, in any event we think the barriers to access for plain, confirmatory re-tests will always be higher than for the first test because payers are unlikely to pay for confirmatory testing, irrespective of how many providers are available. Most importantly to our mind, though, is the notion of independent re-testing

as an entitlement. We don't think that necessarily translates into a patient benefit without further thought.

Think about it. Re-testing, if that is brought up as a big entitlement concept, could lead patients to incur significant and unnecessary out-of-pocket cost because payers won't pay for a repeat test. Independent confirmatory testing as a concept can prolong uncertainty for patients, can give rise to unrealistic hopes, and can delay treatment decisions that would otherwise be made. That, too, I think these potential negatives ought to be weighed in the context of policy recommendations that you might develop.

To the extent the PTO might find that systematic confirmatory testing is unavailable but needed to ensure the quality and reliability of genetic diagnostic testing services, it has been suggested by others that non-patent- based policies could provide a more directly applicable tool. So, for example, it has been proposed that as a condition of CLIA approval, test providers would have to provide -- if they're sole-source

providers -- would have to provide for independent validation of testing procedures, and exchange samples with outside laboratories for quality assurance for example, and the like. So that, too, has been proposed. I don't know why it hasn't gotten much traction.

BIO takes no positions on such proposals, but we believe they at least are directed at the question raised and would present a much more logical avenue for exploration than going down the patent route. In fact, in BIO's view one has to strain quite hard to trace existing problems with patient access and utilization of genetic tests back to patents.

First of all, coverage of genetic diagnostic tests appears to be quite good for the majority of patients who have private health insurance. Where private-payer coverage is adequate, it is adequate independently of patent status. Actual access concerns have been raised mainly for patients who must rely on public payers. So, the problem seems confined to a certain class of patient and a certain kind of payer.

So, I want to show you two maps that I got this morning real quick. This is for the Oncotype DX breast cancer assay. It's a prognostic assay and it's an advanced molecular diagnostic. It shows coverage in the U.S. under Medicare and private-payer, so you see pretty much a green map across the country, and then this is the same test covered -- whoops -- under Medicaid. You see big gaps across the country. So, we have a rather different picture depending on what kind of payer we're talking about.

If you're talking about the same kinds of patients and the same kind of test but different payers and you start seeing these disparities, to us this doesn't immediately point at a patent problem. Clearly, there's something else at play here that also factors maybe much more prominently into the picture that we're seeing.

All right, so I might bring this map back out again. Where was I?

Differences, right? Between public and private- payers. Not sure whether that exactly points at a patent problem in the first

instance. So, what are some of these differences? The screening exclusion, for example, under Medicare limits coverage for genetic counseling services and access as to a predictive or predisposition tests, and that limitation, too, is regardless of patent status. Also, because states are responsible for making coverage decisions under Medicaid programs for at least some genetic tests, there exist as I've shown you significant geographic disparities that result in disparate access to genetic tests and counseling services for poor patients, depending on where they live in the country.

Non-uniform access across the country would seem to indicate, again, that there are other forces at play in the acknowledged access problems than patent issues. So for example, revenue shortfalls at the state level and public health priorities at the state level may cause some state Medicaid programs to cover genetic tests either not at all or only at a fraction of the reimbursement rate that other states are paying.

The SACGHS reported instances where

public payer reimbursement rates for some genetic tests were actually at or below the participating provider's cost, and also SACGHS found in an earlier report that there are very significant rates where claims are not reimbursed at all by public payers. Anecdotally, there are quite a few reports that tell us that irrespective of patent status, state funding shortfalls and pressure for non-utilization can mean that participating in state Medicaid programs can be a difficult proposition from any provider's perspective.

It's really hard to make money in this business that we're told. You have to be a special kind of company to be commercially successful, even if you have a winning product. It's not like making drugs, and we're learning that, too.

So importantly, I think it bears repeating. Monopoly pricing is unlikely to have anything to do with non- uniform access to genetic tests and services. As Robert Cook-Deegan and his colleagues have demonstrated, there is no price premium on patented, single-provider

genetic diagnostic tests when you compare them to equally complicated tests that are available from multiple competitors. So in other words, these tests are expensive and they're equally expensive regardless of whether they're only available from one provider or more than one. That's been found. So, we should at least move off from the oft-repeated assertion that patents drive up prices for these kinds of tests that put them out of reach of patients. That doesn't seem to be the dynamic at play.

My time is up. There is a lot of food for thought in the questions that the PTO raised and the questions that we hope we raised, but I just keep coming back to these coverage maps. These kinds of distributions, they don't cease to fascinate us and we look at this and we say, you know, how can it be that a poor patient in Nevada doesn't have access to advanced molecular diagnostic tests and the same kind of patient just across the border in California does? Is it a patent problem in Nevada but not a patent problem in California? That's not the way we understand patents to work, so clearly I think there are very

significant other forces at play here that we must take into account. And you know, I encourage you to go down these roads, to explore these avenues, and to not too easily home in on what has been suggested to you by Congress, and that is to seek the culprit in the patent system. We think it's elsewhere.

Thank you very much.

MS. GONGOLA: Thank you, Dr. Sauer. Questions from our panel? Stuart Graham.

MR. GRAHAM: Thank you, Dr. Sauer, for the thoughtful comments and for, you know, helping us with many of the issues that we have been struggling over.

I do take it as part of the mission and stated by the mandate in Congress to consider a lot of these other potential complicating factors in the marketplace on the role of insurance, the role of the doctor/patient relationship, and I think that's well within our bailiwick.

I would be interested in hearing more from you about -- you made some general statements if you can inform us or provide us with those instances in which they are backed up with hard

data from disinterested sources, that would be very helpful, number one.

And the second is to try to get a better sense of how this -- you explained this complicated marketplace in which genetic tests and confirmatory genetic tests may be offered that in many circumstances, there are substitutes that may be available for the tests or the confirmatory tests. I think what is probably -- it's very well-taken -- that there are alternative ways in which the kind of licenses that are being played out in the marketplaces are being effectuated, not only with the exclusivity of patent rights but certainly other ways in which actors exert power in the licensing space, the data on which they're holding, other ways in which companies are competitively advantaged with their tests.

I'd like to just get a better picture, if you could give us one, of that complicated scheme and the way in which we ought to be thinking about this and whether there are distinctions that you can point to in the genetic testing space along which we can start to draw some conclusions,

right? Are there strata running through this that would be helpful to us in understanding differentiation in this space?

MR. SAUER: I think, you know, much of the most informative information you'll get in that space will be from people who understand the public-payer reimbursement market, which is a science unto itself. Basically genetic diagnostic tests, like any high-end advanced molecular diagnostic, you know, typically what the developers drive for is a value-based reimbursement level, right? So based not on the cost of doing it, like simple clinical laboratory tests, but based on the value that they provide to the payers and to the patients and the doctors who order them.

So, I don't know if this will answer it, but certainly it goes into the calculus of a company that develops these products, right? So they develop a test, they validate it, and then they say, how do we build a market for this? And to what extent do we need exclusivity for doing so?

In order to get value-based

reimbursement, you have to go and demonstrate to the payers clinical utility. So, my test works at this level of precision, for this kind of patient it has this kind of predictive value. And you also have to demonstrate, then, the clinical value of that. How is it going to drive treatment decisions and so on? That's going to -- that's my understanding. It's going to determine how the medical community, the medical societies will adopt your technology, embody it in treatment guidelines, and make it -- which is what you're hoping for -- the standard of care.

So, you can do this conceptually whether or not you have exclusivity or whatever kind of license you're under. You want to build a good franchise, and this is part of what you will have to do as a business. It does, however, create -- once you have a good reimbursement structure in place prospectively -- from the licensees' perspective, it creates an enormous free-rider problem. Right?

You've created, unlike a regulatory FDA approval which applies only to your test. You've built, if you will, a market. So now, there's

kind of a market for my test, people will reimburse it at a really high level because even though my test might cost $3,000 it saves health care providers $100,000 in follow-up costs if the condition had gone undetected or undiagnosed. So, these companies work hard to justify the value-based reimbursement of their tests but they do create in their own minds an incredible free-rider problem if they do all this, because there's nothing that will prevent the next company from coming in and saying, hey, I have a validated test for exactly that condition as well. It may work differently from yours but it falls into your CPT code or whatever you might have, and it's going to get reimbursed at the same level. And the wonderful thing is I don't even have to undercut you very much in price because it's all reimbursed according to a relatively fixed level anyway that was already established. So, we're going to collect roughly the same level that the originator is going to collect.

That's my understanding. I think, you know, it will -- if that kind of helps you elucidate some of the dynamics. But again,

there's a lot of pressure or downward pressure on the reimbursement rates that these companies are able to collect and we're told again, you know, it's -- the profit margins are nowhere near what they are for other biotechnology products for these services.

The concern about exclusivity -- because there is nothing but patent exclusivity available, really. Our big -- drug makers are lucky because they have other regulatory barriers that stand in the way of follow-on competitors. That's not quite the case in the market for laboratory services. So, maybe that kind of helps a little bit.

I'm sure you'll get better witnesses later who can talk about that in a more informed way.

MR. GRAHAM: Thank you.

MS. GONGOLA: George Elliott has a question.

MR. ELLIOTT: I'm curious about the -- you mentioned the protocol in Europe that provides a decision tree that starts with, essentially, non-patented or different

non- infringing type of tests and works its way down, where the final genetic test may simply be a confirmatory test of all that went before.

I was unaware of this before, and I'm just curious to know what extent that exists and whether you can give us some information about whether similar trees like that exist for different tests in the United States.

MR. SAUER: I can point you to the source. Myriad will be able to talk about that. I can point you to the publication.

My understanding is -- I was referring to, I think, a decision tree that's used in England under their health care system where, you know, they have a preference to not do the expensive full sequencing, you know, unless they have a cheaper test that's going to catch most of the mutations. In the U.S. -- again, because we're most informed about the BRCA test -- I understand -- I once looked up, I want to say, Aetna's decision tree for what they're going to reimburse, for example, for BRCA, and I -- without getting too specific, I recall it saying that if the patient falls into a certain category of

patients. Say Ashkenazi Jewish ancestry. The health care -- the payer will first, as a first step, only pay for the panel of the three Jewish mutations. That's what they'll pay for. If doctors order something else in the first instance, there's going to be an issue.

So, it's three identified mutations that the payer believes will capture most of what's likely to occur in that population. That test is about one-tenth the cost of the full sequencing, all right? So from their perspective, that makes sense. Do that first, it captures most mutations, we pay a fraction of the cost, there's this cost benefit.

If those come back negative and the health care provider still believes that there is a genetic component that must be tested, then they can order the full BRCA analysis. That's my understanding. You know, which is more expensive and it's the second step, therefore.

That, by the way, raises a definitional question about second opinion testing, by the way. You know, one thing that Stu was going after earlier -- and we can talk about that -- was, you

know, why would it be a huge problem for the provider of an original test if there were some kind of, whatever it might be, exemption for a second provider who merely confirms the first test, provided that the first provider got to do its patented tests, right? Why would that be a problem?

I think intuitively a lot of people would say, yeah, you know, there's nothing particularly wrong with that as a concept. I think there are definitional questions of how do you define what really is a confirmatory test? In the example I just gave you, I think the originator of the test would probably object to the notion that having provided a $300 3-mutation panel test that came back negative, that the full sequence analysis for $3,000 could then be done by somebody else under the guise of a confirmatory test. That's really a very different kind of service that's being provided. It does serve to kind of confirm the first test, but it's not a re- test.

So, I think those issues are in the nuts and bolts, and definitional issues, in fact, is

what we hear most from BIO's members when they've discussed this idea of, well, what's up with second opinion testing? How problematic would that be to kind of solve?

But the thing we can't get past is a great skepticism in the membership to begin with to acknowledge that, you know, does this problem even really exist? We're not quite sure it's been proven to be there. So, do we need to go after a solution for something that we're not yet quite certain about?

MR. ELLIOTT: Thank you.

MS. GONGOLA: Dr. Sauer, I have one final question for you. Early in your testimony, you spoke about BIO members anecdotally explaining that patients don't want a second test in many situations. And you suggested that's an area that the Patent Office should/could conduct further research to try to get at that information. Do you have any particulars as to how we might go about tracking down that information? Perhaps a survey, certain patient interest groups that we could contact, any further thoughts?

MR. SAUER: We've wondered about that. First of all, you know, I didn't say patients don't want a second opinion, it's more like the doctors tell us that patients rarely ask -- well, patients ask for a second opinion but it's more a second medical opinion about what course of treatment should we follow based on these tests. So, it's a bit rare that patients say, Doctor, I don't trust this result. Can we do this again? So that's more what I meant. That doesn't seem to happen often.

Well, you know, we got it anecdotally from doctors that we talked to, and I think there's probably no better way to get at this than going out to practitioners and ask them, when patients ask for a second opinion in this context, in your clinical experience what do they mean? What do they ask for? And you know, under which conditions do you, Doctor, order repeat tests? Right? Have you ever done this, how often has it happened, and why?

I assume that if repeat tests are ordered and done, they are more often done not at the request of a patient but for some reason that

the health care provider injects into the calculus. Maybe the health care provider is worried about sample switching. Certainly the biggest cause of error in clinical laboratory diagnoses is the switching of samples, right? Confusion there. So, that gives rise, for example, to concerns about liability for hospitals and so on, where the problem might not so much be the test provider whose test result is unreliable, but maybe something might have been wrong at our end, we're not quite sure. So, there's a whole bunch of things that I believe practitioners will be able to inform you about, but I can't think of a really systematic way other than calling up a whole bunch of people.

I think if you put out a call for such information and you were to go and ask doctors, report to us what you think about this matter, you will have to take into account that there's going to be a self-selection effect as well. You're likely to get doctors who are gravely concerned about this issue, and it's quite possible that for every doctor who phones in there are a hundred doctors named Bob who don't care about this issue

one way or another because it doesn't occur in their clinical practice. But that's always, I think, a problem with surveys of this kind, right? Self-selection, how big is your sample. At the end of the day it's going to be more qualitative than anything else, I believe.

MS. GONGOLA: Thank you, Dr. Sauer. So our next witness is Lisa Schlager, who is Vice President of Community Affairs and Public Policy for FORCE.

MS. SCHLAGER: Thank you. As she just indicated, I work for FORCE, better known as Facing Our Risk of Cancer Empowered. We are a national nonprofit that represents individuals and families who are affected by hereditary breast and ovarian cancer. So, the majority of our constituency consists of people with a BRCA1 or a BRCA2 genetic mutation, which puts them at extremely high risk of breast and ovarian cancer. These genetic mutations have also been associated with melanoma, prostate cancer, and pancreatic cancer.

Just to provide you with some context, we're talking about an estimated three-quarters

of a million Americans who carry a BRCA mutation, and an estimated 2-1/2 million women are considered high-risk. So those individuals, 2-1/2 million, may be referred for genetic counseling and potentially testing based on their family history or family risk.

We appreciate this opportunity to share our concerns regarding gene patenting, and we are here to provide you with our organization's perspective on the detrimental impact that exclusive patenting has had on the BRCA1 and BRCA2 community. The patent which is held by Myriad Laboratories has had a significant effect on the community we serve.

As the USPTO studies this issue, we would like you to consider a number of important concepts. We feel that the patenting BRCA1 and BRCA2 has negatively affected the community, which already carries a significant and disproportionate burden due to the cancer risk it shoulders. FORCE would like to comment specifically on the impact exclusive licensing has on the areas of clinical care and research.

We feel that gene patenting stifles

research. We feel that the BRCA gene patent has had a profound effect by delaying and slowing the development of targeted cancer therapies for people with BRCA mutations. PARP inhibitors are a class of drugs that were developed based on scientists' knowledge of how hereditary cancers develop in people with mutations. The drugs showed activity and early studies were very promising in several types of hereditary cancers, including breast, ovarian, and prostate. PARP inhibitor research has been ongoing since 2005, and today seven years later, the drugs have yet to gain FDA approval.

After meeting with the FDA, we were told that for targeted therapies that benefit a certain population, such as the BRCA population, to receive FDA approval they require a companion laboratory test identifying a target population that must be FDA approved as well. In other words, the test that identifies the population must be FDA approved.

BRACAnalysis is not an FDA-approved test. It's a CLIA-approved test. Basically, BRACAnalysis was never required to receive FDA

approval in order to market their test, and it doesn't appear that they have any plans to seek FDA approval. Because Myriad holds the exclusive patent to this gene, no other lab can develop an FDA-approved test to identify BRCA mutation carriers. As a result, drug companies have basically been forced to open up their registration studies to a wider breast and ovarian cancer population, comprised mostly of people who are not BRCA carriers. The two largest registrations did not meet primary endpoints, likely due to the broader population they studied.

Ultimately, this has derailed the development and approval of these therapies that could benefit the BRCA community. Thus, the exclusive patent is actually hindering research for the BRCA community.

The Breast Information Corp, also known as BIC, is a large international consortium organized by the National Human Genome Research Institute, which is part of the NIH. BIC's goal is to provide critical research to determine gene changes that may be cancer-causing, versus those

which aren't. Around 2004, Myriad stopped contributing data to the BIC database. About 7 percent of BRCA tests return with what's considered an inconclusive result, and data from BIC is used to help better classify these variants to determine if they are cancer causing.

According to the 2010 article in the Genomics Law Report the company, a.k.a. Myriad, quietly stopped contributing data to BIC in favor of building its own database to retain a competitive advantage over other gene testing companies once their patent runs out. Accordingly the article's authors, among other things, said such a strategy would be contrary, at least in spirit, to a policy against extending patent monopolies beyond their terms. In addition, the hoarding of immensely important clinical data does not seem likely to promote the progress of science and useful arts.

We feel exclusive licensing has a negative impact on test interpretation as well. Myriad no longer contributing to the BIC database has impeded research on the interpretation of a test known as a variant of unknown significance,

or VUS. Once the patent does expire, the fact that Myriad no longer contributes mutation information to BIC consortium will limit other laboratories' ability to interpret certain test results. In effect, this will extend Myriad's monopoly on testing.

According to a 2010 article from the New York Times, withholding this data may provide a competitive benefit to Myriad over other laboratories after their patent expires, but at the cost of critical information that could help provide families with information that have inconclusive genetic test results right now.

Excessive costs of testing impact clinical care. There is now evidence-based information demonstrating that identifying those who have the highest risk for hereditary breast and ovarian cancer can actually lower breast, ovarian, and all cause mortality through genetic testing and surgical intervention. The cost of prevention both in dollars and in human lives is less than the cost of cancer care once it is diagnosed. Yet people are being denied access to critical health information due to the excessive

cost of BRCA testing.

Financial assistance for BRCA testing is very limited, especially for people who have any type of health insurance, including Medicaid. Thus, if an insurance company denies coverage for BRCA testing, patients are often faced with paying 100 percent of the costs out of pocket or forgoing the testing altogether.

With patent exclusivity and a monopoly on the test, Myriad has increased the cost of their tests, even as the cost of genetic technology and gene sequencing has gone down. The full sequencing BRCA testing costs over $3,500, making it cost-prohibitive for many people. Further, Myriad charges an additional $750 for expanded testing known as BART. BART looks for mutations known as large rearrangements in some people who test negative with full BRCA sequencing. Due to the exorbitant cost of testing, some payers -- most recently TRICARE, which insures over 9 million members of the armed forces, including active-duty service members, retirees, and their spouses and dependents -- is no longer covering BRCA testing for their

patients.

This is a very real issue. In 2010, the Secretary's Advisory Committee on Genetics and Health, as you've been told by many people, submitted a report to the Secretary of Health on the topic of gene patenting. They studied these issues extensively and have expertise in regards to genetic testing, research, and the related costs, and we encourage you to adopt or at the very least cite the recommendations when reporting to Congress on these issues. Additionally, given the complexity of these issues it might be prudent to place a moratorium on the issuance of patents until their impact has been studied in greater depth.

Thank you for this opportunity.

MS. GONGOLA: Thank you, Ms. Schlager. Questions from the PTO panel? Thank you.

MS. SCHLAGER: Thank you.

MS. GONGOLA: Our next witness is Kristen Neuman, Executive Director of Librassay®, associated with MPEG LA.

MS. NEUMAN: Good afternoon, ladies and gentlemen. Thank you, Congresswoman

Schultz, Deputy Under Secretary Rea, and the other distinguished members of the panel for the opportunity to contribute to the public discourse on the topic of how to effectively provide easily accessible, widespread genetic diagnostic testing while also providing a reasonable return on investment to patent owners.

I am Kristin Neuman, the incoming Executive Director of Librassay®, a new patent licensing facility offered by MPEG LA, LLC. I am joined here today by Mr. Larry Horn, the CEO of MPEG LA.

I will begin by introducing MPEG LA and the trailblazing role it has played in providing mass market patent licensing solutions to unlock and accelerate technological advances. Then, I will introduce Librassay®, a patent licensing "supermarket" designed to accelerate the adoption and availability of personalized medicine technology, including diagnostic testing.

MPEG LA is the world's leading alternative intellectual property solutions source, enabling users to acquire patent rights

for technology standards and platforms from multiple owners in a single transaction.

MPEG LA was formed in the 1990s, when the MPEG-2 digital data compression standard, which is required for digital television applications, including DVD, faced a patent thicket that threatened widespread adoption of the technology. The single biggest challenge to MPEG-2 adoption was access to essential patents. Many MPEG-2 patents owned by many parties made it virtually impossible for most users to negotiate the number of licenses necessary to practice the standard.

MPEG LA offered an alternative--the first modern-day patent pool as a solution to the market's need for transactional efficiency. The solution revolutionized intellectual property rights management by enabling multiple MPEG-2 users to acquire essential patent rights from multiple patent holders in a single, nondiscriminatory transaction as an alternative to negotiating separate, bilateral licenses.

MPEG-2 became the most successful standard in consumer electronics history, and the

MPEG LA® licensing Model has become the template for addressing other patent thickets. Today, MPEG LA operates several licensing programs consisting of more than 6,000 patents in 74 countries with over 130 licensors and 5,000 licensees.

The MPEG LA® many-to-many licensing model entails many patent owners licensing patent rights in a given field to MPEG LA, as licensing administrator. MPEG LA, in turn, uses its well-honed and fine-tuned mass-marketing licensing techniques to sub-license the patent rights to many users on a nonexclusive basis in a single, cost-effective transaction.

So, let's now turn to the subject of today's hearing -- genetic diagnostic testing, particularly second opinion testing, patent rights, and patent licensing. Based on substantial input over a three-year period of time from stakeholders across the spectrum of the genetic diagnostics industry, MPEG LA has invested in the creation of a new "many-to-many" patent licensing model to address inefficiencies and potential patent thickets in the field of

molecular diagnostics and personalized medicine.

The solution is called Librassay®, and it is an easy-to-use, web-based catalog, or store much like Amazon or iTunes, for patent rights available for licensing on a nonexclusive basis to any and all users on reasonable, transparent, and nondiscriminatory terms. Librassay® licensees will be able to shop the Librassay® website store for the patent rights they need to clear, develop, and offer genetic diagnostic tests, bundle the patents into customized packages, and license the packages on a nonexclusive basis in a single, efficient, and cost-effective transaction.

The Librassay® many-to-many licensing model will be particularly useful and valuable in connection with multiplex genetic testing, where patent rights belonging to many different owners may need to be licensed in support of a single multiplexed genetic test.

Librassay® is expected to launch in the second quarter of this year. Right now, we are in the process of concluding agreements with the world's leading universities and research

institutions to include their patents upon launch. And the Librassay® website store is in beta test as we speak.

The licensor institutions see Librassay® as a welcome marketplace alternative giving them the opportunity to meet their Bayh-Dole obligation to license to a wide market in service of patients and the public, and to monetize their intellectual property in the diagnostics field while still preserving the right to enter into drug development and therapeutic collaborations where exclusive patent licensing may still be necessary.

MPEG LA acknowledges that there are different views surrounding the patentability of genes and diagnostic methods, as we've heard today, but we are not appearing here today to take a position in this debate. We do, however, note that exclusive licensing practices, market behavior, and related legal cases cry out for the need to provide nonexclusive access to essential patents in the diagnostics field of use. And MPEG LA, through Librassay®, intends to answer that call.

Our role is to take the market as we find it and to help patent owners and users come together in an efficient fashion to hasten transactions that incentivize technology innovation and adoption by balancing reasonable access to IP rights with a reasonable return on investment.

The nonexclusive licensing platform provided by Librassay® will promote the availability of independent, second opinion genetic diagnostic testing by providing a wide variety of patent rights to any and all users in a single, easy, and cost-effective transaction. As more and more patents become available through Librassay®, the medical community will experience greater levels of genetic test availability because no entity will be able to license patents from Librassay® on an exclusive basis. The Librassay® patent rights will be available to all. And all of this can be attained while still providing a reasonable financial return to patent owners for their innovation in this very important field.

Thank you very much for your time and

attention. Additional information may be obtained by visiting MPEG LA's website at www.mpegla.com.

MS. GONGOLA: Thank you, Ms. Neuman. Questions from our PTO panel? Deputy Director Rea has a question.

MS. REA: Hi, thank you so much. I have one very quick question. An earlier speaker helpfully pointed out that at least perhaps one company, Myriad, has ceased sending data to BIC and that the data also has value. So with your Librassay® licensing model, do you also accumulate data from the users of your information or your licensees?

MS. NEUMAN: We will not be accumulating data. MPEG LA will not be doing that. We will just be managing the licensing of intellectual property rights, just the patent side of it.

But you raise a very good point. The data is very important and it's necessary for the validation of the tests. You need the data as well as the patent rights. What we think Librassay® will enable is more crosstalk, more

linking, if you will, between the data holders and the data users in the community. And we hope to link to some of the sites where data is being accumulated today, like the Genetic Test Registry and some of these other portals for the data itself.

MS. REA: Thank you so much, that was very helpful.

MS. NEUMAN: You're welcome.

MS. GONGOLA: Other questions from the panel? No? Thank you, Ms. Neuman.

Our next witness is Dr. Ellen Jorgensen, president of Genspace.

MS. JORGENSEN: First, I'd like to thank you for allowing me this opportunity to testify. We've heard a lot about the rights of the biotech companies, and I'm sort of here to represent the consumer.

I'd also like to bring this discussion into the 21st century. My name is Ellen Jorgensen. I have a Ph.D. in cell and molecular biology. I conducted genomics research for many years, I was in the biomarker field, I do have patents that contain genes in them, I will admit.

But currently, I've turned my back on all of that and I'm president of Genspace, which is a nonprofit community biotech lab. This is dedicated to promoting citizen science and access to biotechnology for all.

Our members include a broad spectrum of people, everything from artists, biologists, architects, engineers, university faculty, and since 2009, we've served the greater New York area by providing subscription-based access to a biosafety level 1 lab where we run educational programs in life sciences, laboratory safety, and for independent research. I ask that the commissioner consider my viewpoint in light of my experience in scientific research and in biotech education, and I'm sort of an educated consumer, if you will.

I am appearing here before you today to affirm my conviction that the right of an individual to conduct an inquiry into his or her own genome is more important than genetic patents. The current debate assumes that individuals cannot perform the tests for themselves on themselves. Due to the rise of

citizen science and the democratization of technology, a growing number of individuals can and will test their own genotypes. The cost of setting up a home lab, performing genetic analysis on one's own DNA is less than $5,000 and could even be cheaper than that if you get everything off eBay.

Some day soon -- and this is happening right now -- sequencing one's own DNA will become as much a part of high school science curricula as dissecting frogs. At Genspace, I hold classes for adults and high school students that teach them how genetic tests are performed and give them hands-on experience in the lab techniques necessary.

So, I hold in my hand a vial of my own DNA. I extracted it at Genspace using a procedure that's simple enough for a middle-schooler, and I'm not allowed to analyze it because of patent concerns. By the way, the CCR5 test that was mentioned by one of the previous speakers costs about $10 bucks in reagents to do and is very, very simple.

Some of the other tests, obviously, are

more expensive, like the BRCA where you have to sequence the whole gene, but if you already have that information in your family -- say, your mother was BRCA positive and you know her sequence -- you could probably do it for a lot less. You could probably just zero in on a part of the genome that you know she has mutations in and, again, turn it into a very, very cheap thing to do and very easy. Because the science behind this, a lot of it, is 30 to 40 years old.

So, it's just incomprehensible to me that by seeking to know something so unique and personal as my own genotype, that I may be violating a patent and since 100 percent of known genes, according to a recent analysis by Dr. Chris Mason, who I know who has testified before this committee and is a professor at Weill Cornell Medical College at their computational genomics center. He's at Cornell Wyle Medical College in their computational genomic center. He estimates that 100 percent of known genes are all covered by some sort of patent at this point in time. So, this has the potential to shut down this whole area of science education, and

personal genomic exploration.

I feel this area is really important to promoting science literacy. These powerful technologies will change our lives, they'll impact everything from our health to energy to the food we eat, and the best way to inform the dialogue about 21st century science is to have the stakeholders understand it from a hands-on perspective.

So, should I avoid teaching these subjects completely because of genetic testing patents? I feel if the progress of science and education is to continue, that students, teachers, and the intellectually curious can't fear patent infringement or licensing fees, and I don't feel confident that current laws protect us sufficiently. I'm also just personally uncomfortable with the whole concept of patenting a naturally-occurring nucleic acid sequence, particularly since much of this information was gleaned through government-supported scientific research that all of us paid for with our tax dollars.

So, based on my experience as a

scientist, an educator, I'd like to see some sort of an exemption that permits individuals to perform patented genetic tests on their own genomic material, and an exemption for educators who teach individuals how to perform these tests because I think that in the end, it's critically important to all of us who strive to foster innovation and science literacy -- and also, from what I'm hearing here, there may be a problem with some people having access to some of these tests because of monetary concerns. And if you do it yourself it costs a lot less.

I'm sure we can do BRCA testing for a lot less than $3,500 a sample. If someone came into our lab and said they wanted to do it they could do it on themselves for considerably less, particularly if they had information from a family member's genomic material already.

So, that's all I really want to say. Thank you very much.

MS. GONGOLA: Thank you, Dr. Jorgensen. Questions from the PTO panel? No, okay. Thank you very much.

Our final witness of the day is Dr.

Kevin Noonan, who is a partner at McDonnell Boehnen Hulbert & Berghoff.

MR. NOONAN: Good afternoon. I can say afternoon now. I'd like to thank the Patent Office for inviting me to speak here today. I'm a patent lawyer and I was a molecular biologist back a long time ago, and I've written pretty extensively on these topics on our Patent Docs web blog, patentdocs.org.

So, I think the study the Patent Office is doing is really very important because it will give the office an opportunity to do something I think needs to be done, which is determine whether there's any evidence that patents are a problem. And with regard to patient access over liability of genetic testing, it's become kind of fashionable in most quarters, as we've heard some of that today -- mostly from the legal and medical academies, admittedly -- to make the argument that patenting doesn't promote innovation. And in fact, there are those who've analogized patents to attacks on innovation, and even contend that it can retard innovation, which has certainly not been my experience.

Some judges, even on the Federal Circuit and Supreme Courts -- and justices on the Supreme Court -- have proposed that there needs to be a balance between patenting that can promote and patenting that can retard innovation. It's a little like Goldilocks. They're trying to find some sort of golden mean of patenting that will determine whether or not we have innovation. And I would suggest that in some ways that's the wrong question because innovation will happen. The question is just whether that innovation will become commercialized, and if it is commercialized whether it will ever go into the public domain, which we're going to talk about today.

So, I would say -- and I would echo some of the arguments that we've heard before -- is that there's very little real evidence that patents have prevented anyone from enjoying the benefits of the new genetic technology. There's also little evidence that current genetic test providers are somehow beset with some rampant error that happens. It's not like anybody hasn't looked. There are at least a half a dozen studies

that I can think of, including the SACGHS report, where folks have looked for some negative effect and begrudgingly admitted that even though there's no evidence for that effect now, there could be or there might be.

In fact, the SACGHS report, which has come up a number of times, is -- and I think the dissent from that report is based on the fact that there was a great deal of evidence in the report, and most of it showed that there wasn't an effect, and yet the recommendations came down exactly opposite, that things needed to be done because there could be. I think that there is equally the likelihood -- in fact, a greater likelihood -- that both public and private payers and providers of insurance are more of a problem in this area than patenting.

One of the things that we know in the United States is that patients don't have an economic right to medical care. Healthcare depends pretty much on what you can afford or what your employer can afford for you, and the fact that you can't get a diagnostic test doesn't mean it's too expensive, it just means your insurer has

decided that they -- meaning you -- can wait for the price to come down whenever it does. So, I think that patents haven't created the solution in health care, and I don't think that changing or addressing patents is going to solve it.

So, we have to discuss, you know, I think today what might be done with patents. Supporters contending that we should do something to facilitate patient access and diagnostic reassurance, even in the face -- as it has been in many instances -- of really a dearth of evidence that patents are the problem.

So I propose that if we're willing to do that, then we would have to consider all the consequences of such an action and require whether either patient access or test quality would improve or not, particularly if as your actions are limited to the patent realm and there may or may not be other steps taken in other areas of health care to do that.

So, I'd like to propose that the future is very unlikely to be like the past, but I'd also propose that we should think about what's happened in the past to determine what we should

do in the future. And if you think about the last 30 years, the fact of the matter is that the biotechnology industry has been incredibly and remarkably successful. And if you think about it, 30 years ago we didn't really have a biotechnology industry.

As Judge Rader noted in his additional views in the Classen case, and Judge Moore in her concurring opinion in the Myriad case, biotechnology has prospered in America in large part because it was supported by the patent system. And the reasons for that really are twofold; tech transfer from universities under the Bayh-Dole Act, and investment in the products of that translated research that really was based in large part on the existence of patent protection.

So, I'll give you some statistics from actually ex- Senator Birch Bayh in an address he gave for BIO. That since the passage of the Bayh-Dole Act, there are 6,000 new companies that have been founded based on university inventions with more than 4,000 new products on the market, including at that time 153 new drugs, vaccines,

and medical devices. At least 279,000 jobs had been created between 1996 and 2007, and over $457 billion added to the country's gross national product.

So, it seems to me these are important because universities and research institutes have been able to provide basic research, and then if there were potentially any practical applications of that basic research, there have been incentives through patenting and the economic benefits both to the universities and to the companies to do that. So now, we have a country that's really in the forefront of biomedicine and if you've looked at any of the reports on the number of biologic drugs that exist today and the diagnostics exist today and how many are in the pipeline, that should increase. I think that proposals that would permit uncompensated second opinion testing, especially if it's the first wave of this sort of thing, would be a bad thing.

The Human Genome Project probably created the largest amount of scientific information within the shortest amount of time in

history, in human history. But in many ways, I think we have to remember it was what Bob Weinberg of MIT has said. The race to the beginning of the road. Because in the next 50 to 100 years, the real challenge and what I think science and technology will give us is figuring out something that's going to be a lot harder. Understanding how the genetic information that we know interacts with environmental factors to cause disease. And if you've looked at any of the popular reports of how many genome-wide association studies there have been and how many genes have been associated with this or that disease, and yet there really in many instances is not a clear-cut positive or necessarily a strong correlation with that. We still have a lot of work to understand how these things work.

The low-hanging fruit is gone. There are probably very few unrecognized single-gene genetic mutations that are associated with human disease that still exist. And in fact, if you think about it, most cancers, most diabetes, things -- diseases like diabetes and such involve genetic changes in more than one gene. So, it's

very much unlike the Myriad BRCA test, and to use that as our standard, I think, would be a mistake.

So, my message here is complexity will rule. And when something is complicated, when something is very complex, it's a lot harder to reverse engineer. And so, weakening patent protection raises a possibility, and not a good one. And I told you I was a molecular biologist but I'll confess, I haven't picked up a pipette in 25 years. But even I as a patent attorney can think of ways that we can protect future diagnostics, especially in complex diseases, without patents. We identify the genetic variants that are involved in half a dozen or a dozen genes, and then we put those sequences on a gene chip with 10,000 other genes. We encrypt every chip so that the position of the diagnostically informative sequences are in a complicated encryption algorithm, and then -- which really can't be identified without a key -- and then we provide the test to the public. No patents, no problems, no disclosure, and the end of any ability -- it would be essentially the end of any chance that I'm ever,

as the provider, going to have to charge any less than anything I want.

The only thing that prevents me from charging my $3,000 or $3,500 or whatever it is in perpetuity is the chance that somebody else will come up with the same test that I did. Maybe they will, maybe they won't, but that will have some consequences.

One of those is that this partnership that I talked about between universities and businesses kind of goes away because, you know, the universities can't, they shouldn't, we don't want them to not explain, not disclose to the public the results of their research. Someone said that we paid for it. Well, one of the things we paid for is that information, and we want universities to tell us what it is that they've done.

Not everything that's been made by universities has been patented, but I would dare say everything important that has been done in university labs has been disclosed, whether it's patented or not. And in some instances, support for those inventions has come from companies that

have been translating the benefits of that technology from the lab bench to the clinic. And the basis of that support would also evaporate if there's no chance that using the information would then be able to lead to protect-able products. So now you would have a move from the sort of research from universities, where I think it benefits everyone, including the public, that we now have free flow information, to not.

So people say, well that could happen under present law, but there's really not a lot of incentive for it do so because we kind of eat our cake and have it, too. Basic university research can be done because it can be a very blue sky. It can have absolutely no presently understood technological relevance.

I point out to you the Cohen and Boyer identification of restriction enzymes at the beginning, the biotech revolution, and Fire and Mello's SIR and ARNA interference phenomenon. Both of these were very unexpected basic scientific phenomenon, and they led in the Cohen Boyer case, obviously, to the biotechnology industry and four, you know, I think SIRNA has

been -- although it hasn't come to fruition -- one of the most active areas of trying to find new, specific drugs in the last five years.

So, it seems to me that you know, if what you change is the ability to protect these sorts of inventions, then you're going to change investment behavior. And it may -- I don't know, I can't tell the office how much or how little they can do, or how much of a change it will take to change that behavior, but I do think that certainly permitting anyone from performing a test that's been patented will change the calculus of when people at the beginning of the process are looking at whether they should invest.

It's important to keep in mind, we're looking at Myriad today but there was a time when Myriad was just a professor from a university who had identified some mutations and there was investment that had to be done at that time, not only in actually making the test and doing the things it would take for it to be reliable, but the infrastructure of payers and genetic counselors and all that, which was quite an

investment and an investment that was not necessarily going to succeed.

So, you know, if there were alternatives to legislation -- if there were no alternatives, if we had to do something, if there was evidence that this was really a problem that had to be addressed, well then maybe public policy would be a reasonable place to say, yes, this is a place where Congress should step in and do something. But I can think of, again, a couple of ways that we can fix things, make things better, that even if we don't do anything with insurance and payers and all the other complex part of the health care system, which I think we probably should address in parallel.

Some things in the Patent Office, for one -- and it happened in the last dozen years. The BRCA patents were granted back in the late '90s, and without casting any aspersions on the quality of the job the Patent Office did, at that time there was developing this idea about written description and enablement, the things that you had to provide as a patentee in the scope of the claims you were going to be given that was sort

of just beginning. And I think this is one of those things where you have to almost go through the exercise to figure out the right place to come out, and some 10 or 12 years later the chance of someone getting a broad, overarching patent for any mutation associated with a disease in a gene, is probably not going to happen.

So, this idea that there's going to be these patents that are going to stop all sorts of research probably not going to happen now, and I would argue probably hasn't happened all that much in the past -- with the one exception about the data that we just heard, and, frankly, the data is not patented so I'm not sure what patent law could have done for that anyway.

The fact of the matter is that there have been 8- or 9,000 basic research papers on BRCA since the BRCA gene patents came out, so basic research I think has been ongoing. Commercial use of the patents for profit, not so much, but I don't think that really is something that we want to permit anyway.

All right. How about another idea? There have been some robust patent principles,

patent exhaustion being one of them, that could be employed in the instances that the problem arises. The Supreme Court has in the Quanta case extended the principle of exhaustion to method claims. So, there's no philosophical or legal reason why it couldn't be extended here if an individual could give the second opinion tester proof that they had gotten the first test from the patent-holder. Then, I think we've talked about it a little bit before. There may not be any harm to whatever return on investment the patentee would have, because they would have gotten that test. That would probably be subject to limitations, one of which as I said would be proof that you actually had gotten the test from the patentee, but that might be a way in instances where it was proven to be a problem that we could solve it.

One thing I will say with regard to Congresswoman Wasserman Schultz. She did say that -- and Dr. Graham, to your point earlier -- she said that she didn't have the problem, that her test was definitive, and so personally she didn't have that problem but she

heard that other people would need a second opinion.

The problem, I think, is that there are many, many, many of the mutations that are found that are either personal or that are not really known whether they're real mutations or not because we all have a great deal of variability. So I think a question needs to be asked is, in fact, is there a problem where a second opinion would have made any difference? Or is this just another instance where the science is lagging behind the technology? And even if a second or a fifth or a tenth lab had done a test, we still would have for some people a question mark about whether this is, in fact, a mutation that they have to worry about.

We heard from the MPEG LA folks that there are ways to avoid patents thickets, if they were to form. I think the possibility they're going to arise are pretty low, not only because of that but because all of these gene patents that have caused such a stir will probably expire by about 2020. They were all pretty much filed around the turn of the century, and you get 20

years from filing. So, I think the likelihood of having this go on for another even half a generation is very low. On top of that, the MPEG LA people talked about the patent pools of the telecommunications industry has shown, industries can get this to work. I have a great deal of faith in that.

And finally, in egregious circumstances if there really is a problem the United States government has lots of ways to take care of that. You have the Section 1498 actions, you have the march-in rights under Bayh-Dole. I think I would counsel that the government use that sparingly, but the fact of the matter is it still exists, it's not like we're helpless.

So, two more things before I'm done. One is that I think that second opinion genetic testing, if we do anything to facilitate it happening, had to be a requirement that the lab that provides that test is at least as accurate, at least as reliable, at least as competent to provide it as the patent holder or her licensee. Because it seems to me that if it's not, then the important reason for getting a second test is not

going to be fulfilled. I mean, one of the things we have to keep in mind is that this isn't easy. It's one thing -- and I did not genetic testing, but molecular biology tests, PCR, things of that in the lab -- it's kind of easy to do on a lab bench, especially when it's just your research, and if you make a mistake you're the only one who suffers. To do a test on a human being and when they're going to actually make a decision, that has a whole host of other responsibilities that I think we need to remember, and we have to make sure that whoever gets to do that -- not just, you know, has a right but actually takes that responsibility seriously. If we permit genetic testing without those safeguards, pretty irresponsible.

I think that Mr. Kowalski talked about this. You know, you are going to be upsetting subtle expectations in a very important industry but you know, we are going to have to remember not just -- it is a taking, yes, but it won't be an uncompensated taking because it will be in action by the federal government, so there's going to be a cost that would be incurred if the federal

government has a taking. The government can take, but with just compensation. And so now, if we're going to try to factor in the cost to the public, I think we'd have to also factor in those same taxpayers that have supported genetic research and will also be supporting paying the just recompense to the patent holders if a second non-patentee is given the right to do that sort of genetic testing.

And if you think about the impetus underlying some of the proposals, the idea of we have a coming age of personalized medicine and a widespread use of genetic testing, that will make the problem worse. It will exacerbate the cost to the public if you permit someone to do a second test in the face of a patent right. And so on top of that, which is a cost directly to the public, there will be the cost in perhaps jobs in places like Massachusetts and California, where they have a preponderance of biotechnology companies, and what are the effects going to be there?

I think you also have to balance all of these costs on the fact that the gene patent is going to expire soon, and so are you going to

front-load all of these costs? And at the same time, then not really get the benefit that you're asking for.

So with these kind of considerations in mind, I would say that I would counsel the Office to cautiously consider the need for this. To be skeptical at claims that there is a need. It's a lot more complicated and I think you've heard some of that today.

I think that not only is it unnecessary but it's premature and ill-advised to consider these sorts of second opinion genetic testing outside the scope of the patent system, and I would hope that the Office include these reservations in a report to Congress.

I thank you.

MS. GONGOLA: Thank you, Dr. Noonan. Questions from the panel? No questions? Thank you.

MR. NOONAN: Sure.

MS. GONGOLA: That concludes our prescheduled testimony, and now we're going to open the floor for commentary from the audience. So, if you have a comment or would like to give

unscheduled testimony, ask a question, please proceed to one of the two microphones in the aisle. State your name and the organization, if any, that you are affiliated with.

Do we have any interest in questions, commentary? Yes, please come forward to the microphone.

MS. COX: Hi.

MS. GONGOLA: I don't think the microphone is on.

MS. COX: Is it on now?

MS. GONGOLA: It's on the side. The lever to turn it on is on the side. You're live now.

MS. COX: Okay, great. Thank you. Good afternoon. My name is Krista Cox and I am currently the staff attorney for a nonprofit organization called Knowledge Ecology International. I am an attorney and my background is primarily in public health, access to medicines issues. I pretty recently worked as the staff attorney for Universities Allied for Essential Medicine, and I have filed amicus briefs in the Myriad case, one at the Federal

Circuit level and one advocating for the Supreme Court to accept the writ of certiorari in this case.

As I mentioned, I work for a nonprofit called Knowledge Ecology International, which is an international nonprofit, nongovernmental organization that searches for better outcomes and new solutions to the management of knowledge resources, particularly in the social justice context.

Among other areas, KEI has expertise in access to knowledge as well as access to medicines and medical technologies. We have strong concerns regarding the USPTO practice of granting patents on human DNA, and the patenting of DNA leads to a decrease in further scientific development and progress. Additionally, patents are exclusive rights over human DNA detrimentally affect patients who either cannot afford the monopoly price over a diagnostic test or cannot receive a second opinion on the test, even when the right- holder's test has been shown to have a known error rate.

The currently litigated case of

American Molecular Pathology v. Myriad Genetics highlights these problems. In this case, patents were filed on the BRCA1 and BRCA2 genes, which are associated with an individual's susceptibility to breast cancer. These genes were isolated and discovered at the University of Utah using federal funding from the National Institute for Environmental Health Sciences, a subdivision of the NIH, before being patented by the University of Utah and then exclusively licensed to Myriad Genetics.

Women who have a mutation on the BRCA1 or BRCA2 genes are approximately 80 percent more likely to develop breast cancer. Myriad Genetics developed a diagnostic test to identify mutations of the BRCA1 and BRCA2 genes, and have prevented other researchers from developing their own tests and clinics from providing second opinions.

These exclusive rights on the genes have allowed Myriad Genetics to price their test at a monopoly price that is often out of reach for patients and not covered by many insurance companies because of the high price. We have

heard today, for example, that TRICARE, which covers insurance for military personnel, has denied testing on these cases, and that's something that is personal to me. My husband is in the Army. He's a military reservist and covered under TRICARE.

Also of great concern is that Myriad's test was found to have a high error rate. A study published in the Journal of the National Cancer Institute reported that Myriad's test failed to find up to 20 percent of known BRCA1 mutations. Additionally, another study found that the test had a 12 percent error rate in correctly finding the mutations it was tasked to find. The error rate is even higher for minority women than for women of Caucasian descent.

It is highly concerning to us that these patents over genetic material prevent patients from accessing the diagnostic tests they need and create further harm by prohibiting further development. Such results go against the constitutional rationale to promote the progress of science and the useful arts, permitting what Thomas Jefferson once called the embarrassment of

the exclusive patent, only because it serves the benefit of society.

We've heard a lot today about the Constitution, the progress -- to promote the progress of the useful arts and science. We need to remember that that constitutional rationale is -- not only permits patents, but also provides a limitation on what can be patented.

The rationale for patents is to induce investments and promote future progress. However, a report done by the Department of Health and Human Services' Advisory Committee on Genetics, Health, and Society concluded that DNA patents were not necessary to provide incentives for research or development of clinical testing.

Nearly two-thirds of all existing DNA patents have resulted from publicly funded research. And Francis Collins noted that the supposed need to provide an incentive for companies to develop DNA diagnostics is unconvincing. Researchers and companies do not need additional incentives to commercialize genetic knowledge.

The cost of developing a diagnostic

test has been shown to be several orders of magnitude less than the cost of developing a new drug. With the majority of identification in isolation of DNA occurring as the result of federal funds and the low cost of creating a diagnostic test, monopoly rates over the DNA is unnecessary in this field.

As the Myriad case illustrates, patents on DNA do not serve the benefit of society or promote the progress of science. Instead, it removes the gene from the public domain and stifles research, innovation, improved genetic testing, and development of treatment.

One study on the effects of gene patents on the disease hemochromatosis found that further development on a genetic disease dropped 30 percent when a patent was granted on the gene. DNA patents are blocking patents, preventing further research, thereby decreasing knowledge and information on targeted genes.

The highly detrimental effect patents have on diagnostic testing, future research and development, and the public health demonstrate that they are not an appropriate reward for the

isolation or identification of DNA. Numerous non-patent mechanisms exist to induce and reward research and development, and can represent a superior alternative to the current practice of patenting DNA.

Trade secrets, for example, may be used to protect investments in medical diagnostic technologies and biotechnology drugs. Although trade secrets are certainly not without their shortcomings, they represent an alternative to the patenting of isolated DNA and would permit multiple companies to develop their own diagnostic tests.

Cash innovation inducement prizes may also be a more appropriate reward mechanism to stimulate innovation and investments in this area. Prizes can provide a more efficient way to promote innovation without creating the barrier of a patent. Because DNA patents represent basic information, these patents can be impossible to invent around and preempt all other uses of the DNA, thereby foreclosing additional research and development. Exclusive rights, therefore, represent an inefficient, burdensome, and

inappropriate reward in this case.

The United States currently provides for other sui generis forms of intellectual property, often where patent protection is not available or is inappropriate. For example, exclusive rights on regulatory test data used to register new drugs or vaccines are available. Marketing exclusivity for development of drugs for orphan diseases, and tax credits in clinical trials for these drugs may be granted.

Furthermore, an FDA priority review voucher exists to reward research and development for rare tropical diseases. Such sui generis systems demonstrate that patents are not the sole means of reward, and that other ways to induce research and development are often necessary.

Patenting of DNA negatively impacts the progress of science, further research and development, the availability of primary genetic diagnostic testing, and second opinions. Patents eliminate competition and give the exclusive right- holder no incentive to ensure that their tests are of high quality, that effectively and accurately identify genetic

mutations. They are, therefore, harmful to patients.

It has been estimated that one out of every eight women in the United State will develop invasive breast cancer during her lifetime. Patents over the BRCA1 and BRCA2 genes may block many of these women from the opportunity to have testing done because of the high monopoly price, which is cost prohibitive and many insurance companies do not cover.

It is extremely unfortunate that women are being denied access to critical information about their own genes, and that those who can afford the testing cannot be assured of their accuracy. We therefore recommend that alternate forms of rewards be used to reward research and development in the field of genetic diagnostic testing.

MS. GONGOLA: Thank you, Ms. Cox. Questions from our PTO panel? No? Thank you.

Other commentary, unscheduled testimony, questions from our audience today? No? Okay.

Well, I want to thank everyone for your

wonderful participation in our hearing today. Your input is very much valued by the agency. A transcript of this hearing is going to be made available on our AIA microsite very soon. The address of the microsite is www.uspto.gov/americainventsact. It is our goal to make our report to Congress as comprehensive and thorough as possible. So to that end, a final reminder to you that written comments are due to the agency on March 26. They can be sent to genetest@uspto.gov. And for those of you who would like to pursue further testimony, our second genetic testing hearing will be held on March 9 in San Diego.

Now, before closing, I know we've been here a while today. I just want to take one moment to make a brief announcement about additional upcoming events related to our America Invents Act implementation. When you arrived this morning, you should have gotten a flier that lists for you a series of events that we're doing, starting yesterday and will continue for the next three weeks related to our road shows. We are going cross-country, from Boston to Silicon

Valley, to educate all of you on a series of proposed rules that we recently released related to patent-type proceedings, as well as contested cases, trial proceedings, before our board. So, we hope that you will consider attending one of these road shows and participate to learn more and be able to submit written comments to the agency during a 60-day notice and comment period on these proposals.

Now, the first road show, in fact, is tomorrow in this very room in Alexandria, and we have a flier handy at the exits that you can take with you and continue to help us advertise our road show events. So, I sincerely encourage you to either attend in person or participate through a webcast tomorrow.

Now I'm going to officially close the Genetic Testing Study Hearing in Alexandria, and I wish you all safe travels home today.

(Whereupon, at 1:13 p.m., the PROCEEDINGS were adjourned.)

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CERTIFICATE OF NOTARY PUBLIC

COMMONWEALTH OF VIRGINIA

I, Stephen K. Garland, notary public in and for the Commonwealth of Virginia, do hereby certify that the forgoing PROCEEDING was duly recorded and thereafter reduced to print under my direction; that the witnesses were sworn to tell the truth under penalty of perjury; that said transcript is a true record of the testimony given by witnesses; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this proceeding was called; and, furthermore, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

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Notary Public, in and for the Commonwealth of Virginia

My Commission Expires: July 31, 2015

Notary Public Number 258192