Public Comments

DR. TUCKSON: All right. With that, the public. I've got written comments from the College of American Pathologists. They are in the table folders. Are they going to speak also?

MS. CARR: No.

DR. TUCKSON: Okay. They have comments on the patents issue, so we'll be looking at that during the break because we're getting ready to go to patents in a minute, so you might want to pay attention. In fact, you really do want to pay attention to what the College of American Pathologists has to say about patents.

Let me ask Anthony Lakavage -- did I say that properly? Say it right.

MR. LAKAVAGE: Lakavage.

DR. TUCKSON: Lakavage. That wasn't even near what I said.

Anthony is from the Research Use Exemption Coalition.

Thank you for taking the time to join us. You can either have the podium or one of the chairs, wherever you're most comfortable. That's fine. Thank you. Welcome.

MR. LAKAVAGE: Thank you.

Good morning, everyone. My name is Tony Lakavage. I'm senior director of Government Affairs and Public Policy at Applied Biosystems, which is headquartered in Foster City, California. Just a little context for those of you who don't know who we are, our gene sequencing equipment was used by our sister company, Celera Genomics, to be the first commercial entity to map the human genome a number of years ago.

But actually, I'm here on behalf of the Preserve the RUE Coalition, of which Applied Biosystems is a member. We greatly appreciate the opportunity to comment on the recommendations made by the National Academy's Committee on Intellectual Property Rights in Genomics and Protein Research and Innovation. Specifically on behalf of the Coalition, I'd like to comment on the committee's recommendation to broaden and codify the research use exemption, known commonly as the RUE.

First, by way of background, the Preserve the RUE Coalition is a coalition of life sciences and biotech companies and organizations, including some academic organizations, dedicated to maintaining the fundamental and underlying objectives of the patent system. To that end, we strongly support preserving the existing research use exemption, which has functioned well for the past 200 years.

Our companies are part of the $17 billion commercial life sciences industry, and we are dedicated to improving the human condition. We provide essential life-saving life science technologies for disease research, drug discovery and commercial bioproduction, and our products can be found in nearly every major laboratory in the world, probably in almost every room on this campus. We share with policymakers, researchers and other key stakeholders the desire to ensure that the patent system is a tool to drive rather than inhibit innovation. So in the interest of our companies

and society, to have innovative research tools available to researchers and pharmaceutical and biotech companies to support advances in public health and in human health.

The fundamental policy underlying the patent system is to provide exclusive rights for a limited time period to investors in new and useful technologies in exchange for those technologies being fully disclosed to the public. The disclosure of these new technologies then promotes further innovation by allowing even newer, more innovative technologies to be developed from the foundation space upon the patents of the previous innovators. In effect, the patent system encourages the development of new technologies by balancing the benefits of innovation to society with the interest of investors.

In keeping with these principles, there are only a few very limited circumstances under which the use of a patented invention is in the broader public interest. One of those exceptions is the common law doctrine of research use exemption, or RUE, to patent infringement. The RUE allows conduct that would otherwise constitute infringement of the patents when that conduct is purely for philosophical and non-commercial inquiry. In its report, the IP in Genomics and Proteomics Committee diverges from current application of the RUE and recommends that the RUE be expanded and codified to provide a regulatory or statutory exemption from infringement from research "on" a patented invention. Paradoxically, the committee at the same time acknowledges that today and historically there has been little evidence to suggest that the RUE as currently applied imposes any significant burden on biomedical research.

Academic researchers acknowledge that patents rarely inhibit their ability to perform research. That fact is one that's in the proceedings of the committee that made this recommendation. Notwithstanding these facts, the committee made the recommendation predicated on the hypothetical concern that future academic and non-profit research could potentially be frustrated or limited and that universities could be subject to greater licensing demands in the wake of recent court cases.

Since its inception nearly two centuries ago, the courts have confirmed and narrowly applied the RUE. The courts have distinguished between, on the one hand, profit and business motivated conduct, including organized scientific research, and on the other hand activities strictly limited to scientific and philosophical research, protecting the latter from liability for infringements.

In Madey v. Duke University, the federal court reiterated the narrow scope of the RUE and found Duke University's use of patented technology in furtherance of other research not protected by the RUE. The court stated that the RUE "does not immunize use that is in any way commercial in nature. Similarly, the RUE does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications."

While the Madey decision was met with alarm because when it was first issued it found the university guilty of patent infringement, these facts were unique, and there's no empirical evidence that there has been an epidemic of university researchers being sued or threatened with suit for patent infringement since the decision, nor has there been significant evidence that patent holders are holding universities or other non-profit research institutions hostage by increasing patent licensing fees or dictating more onerous licensing fees.

We believe that any expansion of the RUE, such as that proposed in the NAS report, would be counter-productive, discourage innovation, and have serious consequences for those who would have traditionally invested in the innovative research tools industry. Expanding the RUE would do a number of things to diminish the value of research tool inventions, undermine innovation in

developing new time- and money-saving tools, increase litigation uncertainty where little uncertainty exists today, delay access to technologies and the overall research to market period while litigation makes its way through the courts, and limit access to valuable research as patent holders might seek to invoke trade secret law to protect their intellectual property.

More broadly, the committee's RUE recommendation is not based on sound public policy or legal reasons. First, the recommendation presumes that there's a genuine functional problem with the current state of law concerning the RUE. In our view, those advocating a change to the RUE should carry the burden of presenting clear, convincing and quantifiable evidence that a practical problem exists. Anecdotes should not suffice given the serious potential consequences the change would present. We do not believe that this burden has been met. The record simply does not include concrete evidence of a real problem.

Second, the RUE as currently applied in patent law is working. Preclusion from access to research tools is rarely an issue, especially within the academic community. The primary commercial goal of the research tools industry is to further research, and their principal market is research applications. Therefore, such patent holders seek to widely distribute their products and/or license their inventions. In general, patent holders do not wish to obtain the negative public relations impact associated with suing research institutions over patent infringements.

Third, we believe that an exemption expansion of the RUE will weaken the current patent system. The research-intensive companies that comprise our coalition and the burgeoning life sciences industry needs certainty in their ability to protect and enforce their patents. Without it, these companies will have difficulty attracting and maintaining investment capital, may forego investments in research tools, and may limit access to their existing research technologies, all of which would reduce access to valuable research tools and ultimately hinder scientific innovation, particularly in the genomics field.

Fourth, with the RUE expansion, tool inventors may seek to protect their intellectual property under trade secret protection law, eliminating access to those innovations altogether.

As the advisory committee considers these recommendations, we hope that you will consider our views and not support any expansion or codification of the RUE, again noting that the NIH's own report makes clear that patents are not inhibiting the work of academic researchers, and in light of the potentially devastating impact such an expansion could have on innovation.

Sorry about those sort of long remarks. It's just that it's a complicated issue.

DR. TUCKSON: No, actually, I found it well written and cogent. Do we have hard copies of that, by the way?

MR. LAKAVAGE: If you don't, you're going to.

DR. TUCKSON: Let's make sure you do.

So you're sort of seeing it differently than this report. Is that it in a nutshell?

MR. LAKAVAGE: That's right. Actually, the recommendations don't seem to have their basis in that report. If you look at the proceedings of the committee making the recommendations, there's presentation after presentation where they say that patents are not inhibiting research. Apparently

the deliberations, from what we understand, were some academic researchers simply concerned that this could become a problem in the future.

DR. TUCKSON: Will you be around when our good friend Dr. Korn testifies, or do you have to fly back?

MR. LAKAVAGE: I will, I will, and we'd be happy to come back and have a longer substantive conversation.

DR. TUCKSON: Any other questions?

Please don't apologize. It was very well presented and very well written, and we'll take a good hard look at what you have. Thank you very much. We appreciate your time.

MR. LAKAVAGE: Thank you.

DR. TUCKSON: Next will be Mr. Jaydee Hanson from the International Center for Technology Assessment.

Mr. Hanson, welcome. Your choice as to sitting at the table or going to the podium, wherever you feel most comfortable.

MR. HANSON: Thank you. I'm glad you provided an opportunity for public comment here today.

Our organization is working with a number of other groups, mostly in the progressive side of the political spectrum, on these issues. We are glad that the National Research Council has taken on this issue to advise NIH. I need to preface my comments by saying we actually flat-out oppose gene patents. While we welcome the comments of the National Research Council, we think they're moving in the right direction, we think there are ethical, scientific and health reasons to not patent genes to begin with. So that's the context for the rest of my comments.

We look and see that thousands of gene patent applications have been granted. Recent estimates suggest that about 20 percent of human genes have now been patented. Knowing the chemical makeup of a gene does allow researchers to determine which mutations in a gene cause disease, and subsequent research could lead to the development of techniques to produce the protein created by the gene in a laboratory to provide pharmacological treatment for the genetic disease. Research has also been undertaken to find ways to correct copies of the mutated genes in patients, and NIH has been very involved in gene therapy. We're concerned that future developments in gene therapy could also be limited by gene patents.

Patents covering human genetic material are a recent and, we would argue, controversial development. They claim exclusive control over naturally occurring human genes and limit how the genes can be used in research and diagnosis. More than 10 years ago, some 200 religious leaders called for an end of gene patenting and animal patenting for a variety of reasons. One of the religious leaders said, "What we're seeing is the new colonialism, where whoever gets to something first gets to claim it. Once we divided up the continents of the world; now we're dividing up the human genome."

Because many human gene patents either directly claim or include genes and the corresponding proteins that are essential to genetic diagnosis, a grant of exclusivity may hinder both health care

and the advancement of scientific technology. Patents can obstruct future innovations by preventing researchers from looking for alternative uses of a patented gene. Bob Cook-Deegan, who is the director of the Duke University Center for Genome Ethics, Law and Policy, says it rather well. "You may find dozens of ways to heat a room besides a Franklin Stove, but there's only one gene that can make human growth hormone. If one institution owns all the rights, it may well work to introduce a new product, but it may also block other uses, including research."

The U.S. situation with gene patents is not universally shared. Gene patents are under siege worldwide because they have granted exclusive rights to specific sequences of genes. Gene patents are being challenged in courtrooms and legislatures. International organizations such as the Council of Europe's Committee on Legal Affairs and Human Rights and UNESCO now view genes as belonging to the common heritage of humanity. Intensive opposition to gene patents is also coming from researchers and politicians and organized religion. Since the religious leaders statement, a number of denominations -- the Southern Baptists, whose perspectives on issues are probably more conservative than mine, has called for an end to gene patenting. The United Methodists have, and the World Council of Churches has. Indigenous groups have called for an end, patients groups, and some medical associations.

I disagree with the previous speaker. I believe that evidence is increasing that gene patents have a detrimental impact on health care and research. Patents held by a company on one or two genes may prevent another company from offering a test that covers all known genetic mutations. A patient may be told they don't have a gene that causes a certain kind of cancer, only to later learn they have another kind of gene that also causes the cancer. This is already happening with breast cancer gene testing. The study published this year in the Journal of American Medicine found that 12 percent of persons from high-risk families with breast cancer and with negative wild-type commercial genetic test results for BRCA1 and BRCA2 nonetheless carry other mutations that could lead to cancer.

Increasingly, the appropriate treatment for an individual patient may include diagnostic testing, but having a particular gene for a disease does not mean that person will develop the disease. Most genetic tests offer only an estimate of the chances for developing a particular disease and fail to account for the influence of other genes and environmental factors. As we learn more about the human genome and how genes interact, we need the ability to look at all genes together and not be prevented from looking at them together.

Myriad Genetics says it's going to be developing broader tests that will help detect additional mutations, but we should not have to wait on just one company to develop a test. Allowing one company to control the market for one whole area of testing does harm patients. We think it already is.

One commercial aspect of diagnostic gene patents requires doctors to either obtain a license to provide such a test or else charge the patient a fee for sending a sample to be tested at a corporation or research institution that holds the patent. In many situations, this fee can be exorbitant. As an alternative to utilizing a patented procedure that may cost the patient, the insurance company, the managed care organization, or the government a significant amount of money, the doctor may choose to perform an inferior procedure, resulting in inaccurate results or even failure to screen for a particular disease.

Furthermore, there's concern that the monopoly over genetic testing inevitably leads to a loss of expertise and information among researchers and physicians. This arises from the fact that researchers and physicians are often completely barred from using any gene or protein sequence

claimed within the patent, and thus prevented from undertaking or improving diagnostic technology related to that particular gene. A complete bar to use may have a deleterious effect on innovation and future research and ultimately result in an intellectual standstill. Because researchers and physicians cannot use the patented gene itself, no improvements to the inaccuracies of current testing mechanisms will be discovered.

Research and diagnosis has undoubtedly already been hindered in the U.S. by the exclusivity of genetic material essential to human gene detection. In the United States, 35 percent of geneticists reported that even sharing basic data and research material substantially decreased between 1992 and 2000, and 21 percent claimed that failure to access such data from another researcher resulted in their abandonment of a promising line of research. A 1998 survey of 200 genetic testing laboratories found that 25 percent of the laboratories even then had been prevented from offering a test due to the enforcement of a patent or license. In addition, approximately 50 percent reported they did not attempt to develop new tests due to commercial constraints brought on by a patent.

DR. TUCKSON: Mr. Hanson, by the way, I need you to sort of start to get to closure. You're terrific, but we've got to start to close.

MR. HANSON: I've got three paragraphs left.

In 1998, SmithKlineBeecham sent letters to labs ordering them to stop performing or developing tests for the hemochromatosis gene. Research collaboration is being stifled as well. A 2002 study found that 47 percent of geneticists surveyed had been denied requests from other faculty members for information, data or materials regarding published research. When geneticists were asked why they intentionally withheld data, more than 20 percent listed the need to protect the commercial value of their results. Even more troubling, 28 percent of geneticists reported that they were unable to duplicate published research because other academic scientists refused to share information, data or material. This goes to the very heart of science, which is supposed to involve hypothesis testing and replication.

We are delighted that the National Research Council was so concerned about the effects on patents on research related to genetics that it is recommending that the U.S. Congress should explicitly provide an exemption to patents for research on the effectiveness of the research tools related to genetics. We also are glad to see that the Council has called to reject claims of patent infringement when gene patent monopolies threaten public health. We, like the Council, are especially concerned that independent testing verify the accuracy of genetic tests.

Finally, we think the U.S. could follow Europe's example in protecting its citizens by denying broad patent claims on genes that correlate with particular diseases.

In closing, we'd say we're not opposed to all kinds of patents in this field. To use an analogy from many, many years ago, we think that granting patents on genes is a little bit like granting Galileo a patent on the moons of Jupiter. We think that there should not be patents on naturally occurring objects, whether they're in the heavens or whether they're in your bodies. We do think that if Galileo were here today, he should get a patent on his improved telescope, but not a patent on the moons of Jupiter.

DR. TUCKSON: Thank you very much. We appreciate it.

Unfortunately, we're not going to be able to take questions at this point. I assume you'll be around for the discussion later. If you'll please give the team a copy of your remarks so that we might be able to refer to them during that discussion. Thank you for taking the trouble to come.

Lastly but not leastly, our good friend and colleague Joann Boughman, who is going to -- I have no idea, but it's going to be wonderful.

(Laughter.)

DR. TUCKSON: Update us on something, and I know one thing is that I'm listening carefully.

DR. BOUGHMAN: Thank you very much.

My name is Joann Boughman, and I'm the executive vice president of the American Society of Human Genetics. Today I'm not going to ask you to do anything specific but rather thank you for your time and effort on many of the issues that are priorities for the American Society of Human Genetics, as well as priorities on your agenda. I would like to share with you just a few points of information that I think you may find useful as background in your deliberations.

First of all, our 2005 ASHG annual meeting happened to be in Salt Lake City, Secretary Leavitt's home territory, and we were able to arrange to have Secretary Leavitt, in fact, open our meeting. He was there in conjunction with the NHGRI announcement regarding the HapMap, and although the logistics weren't quite easy, we were able to have him come over and open our meeting. I can tell you that the Secretary was clearly engaged in genetics topics and issues, including the advancement of genetics research, investigation in gene/environment interactions, the importance of bioinformatics in the enhancement of health care, including electronic medical records, and the importance of predictive and quality information in personalized medicine.

This is the first time our organization has ever had an elected or an executive branch official, and we were pleased that it was Secretary Leavitt. His remarks were very well received, and we also heard very positive feedback from the Secretary's office. So, in fact, you are talking to an engaged Secretary, which I think is helpful for you to know.

On the topic of genetic information non-discrimination, our board of directors chose D.C. as their spring meeting site this year, the first time we have met in D.C., and the entire board did what I call storming the Hill one of the days they were here. We met with eight House offices, five representatives actually sat through those meetings, and 10 Senate offices. We believe we got commitments from four representatives to co-sponsor H.R. 1227, but I have to follow up on that. I would reemphasize that engaging the representatives directly and informing them is a very important first step in getting them to sign on.

I also think we have an energized Society leadership when it comes to legislative and policy engagement.

Finally, I'd like to address Chairman Tuckson's comment and his articulated issue about public education and just update you very briefly on a major educational effort at the American Society of Human Genetics. We have a new director of education and we have greatly expanded our educational resources for K through 12 at a Web portal we're calling GenEdNet, for Genetics Education Network. It contains the teaching standards for every grade and in every state and province related to a dozen key words around genetics. Therefore, our mentored network of 1,200 volunteer members of our organization can now go to this website and, for example, if a

colleague of mine is asked to teach 6th graders in Ohio or 12th graders in Colorado, they can go to this website and find exactly the genetics content in that grade curriculum in that area.

In Phase 2 of this website development which is now underway, every standard is being related to at least one vetted website with information that is age appropriate and accurate in genetics content. Phase 3, which is a few months off, will add active teaching activities and actually hands-on activities for the classroom so that teachers as well as other people can engage directly in these activities.

While this is not public education in the general sense, we think it does support one aspect of what we call our pre-K to gray educational initiatives. We also have under graduate education activities going on, and in addition we are working with NHGRI on DNA Day activities. Don't forget, April 25th is DNA Day, including an essay contest where we now have almost 400 submissions. One of the two questions that students are asked to answer is why is it important for everybody to know about genetics, and about 250 of the essays are answering that question.

We also are engaging in a special initiative in the northeast around this DNA Day, with between 50 and 100 geneticists already identified to go into classrooms during that week.

The 2005 presidential address by Peter Byers at ASHG focused on genetic advocacy of all types, including the essential partnership with patient and advocate organizations. His presidential symposium was entitled "Genetics in the Public Eye" and brought other perspectives to the genetics research community. So I think we are actively engaging in bridging gaps that have existed. We believe that these activities will also enhance public education in the fullest sense.

The genetics community is more active than ever in areas of translational research, including pharmacogenetics and genomics, with several scientific sessions planned for our 2006 meeting in these areas.

Again, ASHG applauds the members of SACGHS on their important endeavors. We look forward to your next products, and our society will be responsive in any way that you might find helpful. Thank you again.

DR. TUCKSON: Thank you so much. That's terrific.

Can you get that website to the team so that we can have that distributed to everybody?

DR. BOUGHMAN: Absolutely.

DR. TUCKSON: I think everybody was sort of trying to jot that down and seemed pretty excited by getting that news. Terrific.

DR. BOUGHMAN: Thank you.

DR. TUCKSON: Thank you.

We're going to go to a break a few minutes late. By the way, Debra and I were teasing during the session on the survey business, and she was saying did I not want to take comments on the efficiency with which I run the meetings, and I really don't.

(Laughter.)

DR. TUCKSON: So see me at the break so you can beat me up, because I didn't want this to happen, but your break is going to be short because I'm inefficient.

Bottom line, we're going to start on the hour because we've got guests coming. So you have to go now and then run right back because we've got guests. That's the way it is, so thanks.

(Recess.)