Patenting and Licensing Fundamentals and the Nature of the Access Problem
Debra Leonard, M.D., Ph.D.

DR. LEONARD: Ta-da. Okay. We have Reed's attention until 10:00 o'clock and that's when the Ghana-Brazil game starts.

(Laughter.)

(Slide.)

So first I'd like to review for everyone since we have new members of the committee where we are, why we got—in case you missed what Reed said.

(Slide.)

So basically we set gene patents as a priority for SACGHS but tabled it basically because the National Academy of Sciences had been charged by the NIH, NHGRI specifically, to investigate intellectual property, not just DNA but protein—all intellectual property issues related to research and clinical practice. The NAS focused predominately on the research questions surrounding intellectual property so that report came out in November, I believe, and at the previous October meeting a task force was formed from SACGHS and charged with reviewing the NAS report to assess whether the issues that SACGHS had identified during its priority setting process were addressed by the NAS report.

So the task force reviewed the NAS report and presented at the March SACGHS meeting of this year. And basically we—at the presentation the task force and then the committee agreed that the first 12 of the 13 NAS recommendations addressed fully the research issues that SACGHS had raised as concerns for gene patents and those recommendations focus on ensuring the public investment in genomics and proteomics is optimally benefiting society.

So we were fairly satisfied that the research concerns that we had were addressed as well as we could ever address them for research issues.

The committee agreed that the clinical practice and economic issues were for the most part not addressed by the NAS recommendations and that the one NSAS recommendation relating to diagnostic testing was of questionable feasibility of whether or not that could actually be implemented in practice, and that recommendation was to establish procedures to assure that patented tests could be independently verified.

A laboratory—a clinical laboratory is not going to develop a test that the only thing they can do is second opinion testing. It's just not financially feasible and work load feasible.

(Slide.)

So at the March session there were many new members. The membership of SACGHS had changed such that the patent discussion we had back in 2003—'04—2004, not everyone was up to speed. So what we decided was that we should have an informational session basically to look at the clinical practice issues and economic issues of gene patents and decide whether or not this was something SACGHS wanted to work on.

So I want you to focus on that is what the first question is that we need to answer is gene patents and access of patients and economic issues surrounding gene patents something that SACGHS, this committee, wants to look at, investigate and eventually possibly make recommendations to the Secretary of Health and Human Services.

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So today we are going to have three presentations. I'm going to change hats in a moment and I will give the first talk which basically gives some basic information about gene patents and then the clinical practice issues surrounding gene patents, and some information about why we might want to care about this.

Mildred Cho from Stanford will be giving a talk on data analysis to the impact of DNA based patents on access to genetic technologies and services.

And Mark McCamish will be giving a talk on more of the industry viewpoint of gene patents.

We will then have a roundtable discussion of the committee to determine whether there are areas that warrant further exploration and/or attention by us. And "us" is going to be you soon.

So let me get my presentation up here.

(Slide.)

So now I am taking off my hat as an SACGHS member and I am putting on my hat as a molecular pathologist who does all types of DNA based testing, including genetic based testing.

(Slide.)

What I'd like to talk about is what are patents and gene patents, and then talk about patent enforcement experiences that I had at the University of Pennsylvania when I was director of the molecular pathology laboratory there, and then talk about maybe medical significance of gene patents and why we should potentially care about this issue, and then options for consideration as to ways this may be addressed.

(Slide.)

So what are patents? Patents grant the right to exclude others from making, using or selling inventions for a limited period of time. An invention is anything that is made by man that meets three criteria. It has to be new. It has to be non-obvious and it has to be useful.

This protection is granted in the U.S. Constitution and the purpose of patents as defined in the U.S. Constitution is to promote the progress of science and useful arts by securing for a limited time to inventors the exclusive right to their discoveries. As part of this protection for inventors, they have to publish or make available what the invention is to the public. And part of this rule is that you cannot patent a product of nature or a basic principle such as $e=mc^2$ or gravity.

(Slide.)

So when someone holds a patent on an invention, they have a number of options of ways that they can control the use of that information. They can completely restrict use of the patented

information by anyone, including themselves if they don't want to use it. They can also create a monopoly situation in which the patent holder is the only user of this information or they can provide an exclusive license to a single user, and then that person or entity becomes the only person or entity able to use that patented information.

There can be oligopolies in which there's limited licenses granted to selected users. There can be pure competition in which there's broad licensing and use of the patented information or technology or the patent can be held for the public good in which case anyone can use the patented information. So there is a lot of different options by which this patent can be used.

(Slide.)

So what DNA is being patented? Well, DNA, RNA, messenger RNA and other gene products are being patented usually as cDNA sequences so they don't usually patent the gene sequence itself, although some do patent the gene sequence itself. Probes and markers, transgenic organisms, vectors that can be used for cloning or gene therapy, cell lines and microbial strains are being patented. Also DNA methods are being patented. Genetic diagnostic methods that can be used for diagnosis of specific gene types or SNPs and methods of using probes or test kits, et cetera.

(Slide.)

So when I talk about gene patents, this is a small and rapidly growing subset of these broader DNA patents and these gene patents claim basically an individual's genetic sequence at a disease associated gene when that sequence is determined for the diagnosis of that specific disease. Usually these gene patents cover all methods of looking at that gene or locus. And it rests on the basic discovery of a relationship between a genetic variation and a disease that is caused by the genetic variation. It's really a unique type of patent because it permits true monopolization, which patents allow, of a medical service and in many cases almost monopolization of a disease. When you sequence the single gene and when you patent the single gene that causes a disease then by patenting that gene you prevent anyone else from using that gene sequence and looking at it for diagnosis, et cetera.

(Slide.)

And these are samples. I know this is small but the list goes on and on and on. BRCA-1 and 2 for breast cancer, HNPCC for colon cancer, Alzheimer's disease, compulsive disorders, hypertension genes, Gaucher's disease, canavan disease. So the list goes on and on.

(Slide.)

So I would like to now turn to what my experiences have been as a laboratorian with patent enforcement. So I am a physician trained in medical school. I have an M.D. and I am a molecular biologist with a Ph.D. in molecular biology. I did my residency training in pathology and I understand the use, performance and interpretation of laboratory tests in general but my focus has been on the translation of genetic and genomic science into diagnostic tests for patient care.

This is my medical practice. I would like to distinguish that this is medical practice that I'm talking about and not research. Basically gene patents have limited my medical practice.

(Slide.)

So this is a letter that I received from Athena Diagnostics and Athena Diagnostics had acquired exclusive rights to U.S. Patent #5508167 that covers the ApoE allele for Alzheimer's disease. It's only by using Athena's testing that this can be done and they are happy to do this testing for $195 per specimen. That was in 1997. At the time I received this letter, we were performing this test for $100.50. So one of the issues with a single provider of a medical service is that they can set whatever price they want for that test and no one can really argue. So we had to stop doing Alzheimer's disease testing and send this test to Athena Diagnostics when we were doing this test for Alzheimer's disease.

(Slide.)

This is a second letter that I received that covers hemochromatosis. It's from SmithKline Beecham Laboratory who had gotten exclusive rights to three different patents and these had been exclusively licensed to SmithKline Beecham and they requested that we call SmithKline Beecham to make necessary arrangements to avoid any inconvenience or interruption of services to your clients, my patients. And those necessary arrangements consisted of a $25,000 up front fee plus a fee per test when we performed hemochromatosis testing. They were also happy if we didn't want to pay the $25,000 up front fee, they were willing to bargain for any intellectual property that the University of Pennsylvania held that could be used in lieu of the $25,000 up front fee. When I told the vice chair of laboratory medicine, my boss, about the $25,000 up front fee, he was not too pleased.

(Laughter.)

In fact, he started laughing just like Steve did because the molecular pathology laboratory doesn't make a lot of money, which most of you should be familiar with from the coverage and reimbursement document that we worked on.

(Slide.)

This is another letter received in 1998 from Athena Diagnostics. This is a different one covering U.S. Patent #5741645 that covers a disease called spinocerebellar ataxia type 1. The spinocerebellar ataxias are a clinical group of diseases that cause movement disorders and the SCA or cerebella ataxias can be caused by mutations in a number of different genes. This SCA1 is one of those genes of about 12 now that have been identified that cause spinocerebellar ataxia. Again Athena has exclusively licensed this patent and it's only by using Athena's facilities that this testing can be done.

One of the issues here illustrated is that SCA since it's caused by up to 12 different genes, you have to do testing for at least the most common of these genes and SCA1 is one of the most common. So we were doing at the time testing for SCA1, 2, 3, 6 and 7. These are five different genes. If we take SCA1 out of this mix, we will not be doing any SCA1 testing or any SCA testing at all.

DR. TUCKSON: Debra, not to take you off track but let me just make sure. Your ability as a laboratory to test for that condition, for that set of genes, you don't need Athena's kit to do it?

DR. LEONARD: No. Athena is a reference laboratory.

DR. TUCKSON: Right.

DR. LEONARD: So Athena is not selling a test kit.

DR. TUCKSON: So you can—you have the ability to go in and test this for a patient and deal with it.

DR. LEONARD: All of these tests that I'm talking about, we were doing at the time that we got these.

DR. TUCKSON: Right. So all of a sudden they say, "We own this. We own this set of genes in a sense. You can't look at these genes in a patient unless you pay us money."

DR. LEONARD: Right. Well, no, in the case of Athena—so in the case of—in the previous case it was we had to pay money to SmithKline Beecham Clinical Laboratories. In the case of Athena, they have exclusive enforcement that you cannot do the test. The only way to have this testing done is to send it to Athena.

DR. TUCKSON: Okay. I'm sorry. Just because I—you're making such a cogent coherent presentation. I just want to make sure. Your—the knowledge—so are they alleging from their statement that the knowledge basis by which you have the ability in your laboratory to study these particular genes—

DR. LEONARD: Not study, do clinical testing.

DR. TUCKSON: To do the clinical testing.

DR. LEONARD: I just want to be clear we're talking about medical practice here.

DR. TUCKSON: Right. That's right. You said not research.

DR. LEONARD: Right.

DR. TUCKSON: Your ability to actually do those testing, is it based—they're claiming they developed the intellectual—

DR. LEONARD: No, they actually didn't. They have exclusive rights to a patent that's held by someone else. So for ApoE it's Roses, I think, at Duke, who holds the patent and exclusively licensed that to Athena Diagnostics. I don't know who had SCA1 that exclusively licensed it but that's another issue is that most of these gene patents are held by academic institutions. So I don't know if Mildred will be talking about that at all but she has done some research on that with John Merz.

DR. TUCKSON: Thank you for allowing me to interrupt you.

DR. LEONARD: Okay. So basically by controlling or limiting the testing for one gene, you basically—or the patent holder or exclusive licensee controls the testing for more genes because you aren't going to do the testing for SCA2, 3, 6 and 7 unless you can also do testing for SCA1 or no physician would send you the testing.

(Slide.)

This is a letter I received from Miami Children's Hospital Research Institute in 1999 that holds the patent—they hold the patent for canavan disease mutations, the specific patent, and they are willing to provide a license if we pay $12.50 per test, and they set volume limitations within their contract. So if we were doing 50 tests this year then when we got to the 51st patient we could not do that 51st patient. We would have to send it to another laboratory.

This particular negotiation was a little rough because when we decided that we would not take a contract because we weren't doing that many canavan tests at the time, we received an agreement that would allow us to pay the $12.50 for all the back tests that we had done since the license had been granted—since the patent had been granted. And we received a contract that basically said that we would pay the back amount of money that we owed and we would not send any testing out to any laboratory for canavan disease testing.

The lawyer had sent me this contract and I reviewed it and I said—I called my lawyer and I said, "That means we can't do any canavan testing on University of Pennsylvania patients." He said, "No, that can't be what it means." And I said, "Look. Call them and find out." He called them and, indeed, that's exactly what they meant. We could not send out—we couldn't do ourselves and we couldn't send out canavan testing on any University of Pennsylvania patients. So, of course, my lawyer said, "No, that won't work."

So they sent us a second contract that said we'll pay the back amount of money that we owe. We will notify Miami Children's Hospital Research Institute any time we are sending tests out and we will have documentation in writing that that laboratory has a license to do this testing and if the laboratory we're sending it to doesn't pay the $12.50 per test then we were responsible for paying that. My lawyer got this one by himself and said, "No, we weren't going to do that one."

So finally we got a third contract and said we will just pay the back amount of money that we owe and we will not do the testing in house. So we stopped doing canavan testing and that also had to be sent out but that illustrates the ability of a patent holder to control this medical information to any extent.

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So canavan disease is part of an American College of Obstetricians and Gynecologists recommended screening panel for Jewish women. It's part of a Jewish genetic panel. If you can't do canavan disease testing then you really—it's like the SCA1—you can't do the Jewish panel testing and this Jewish panel consists of Tay Sach and canavan disease, Gaucher, Niemann Pick. There are a number of diseases that are common in the Ashkenazi Jewish population.

(Slide.)

This was a letter that—this is an enforcement I did not receive but Arupa Ganguly, who was in the Department of Medical Genetics at University of Pennsylvania, received a letter enforcing BRCA1 patents. So BRCA1 mutations increase the risk of breast cancer and mutations are spread out throughout the entire gene. If there's no common—there is no common mutation identified so there are about 17 common mutations. Then you basically have to sequence the entire gene to identify the presence of a mutation or look for a mutation. Myriad Genetics is the patent holder for the BRCA1 mutation and is the exclusive provider of full BRCA1 sequence testing.

This also captures BRCA2 testing because if you can't do BRCA1 no one is going to send you BRCA2 testing if you're not also testing for BRCA1. Myriad will license laboratories for testing of the common specific mutations, the 17 mutations, but not for gene sequencing. So the only place to have the full gene sequencing done in the United States is from Myriad Genetics so Arupa Ganguly had to stop providing BRCA1 testing.

(Slide.)

This is another letter received in 1999 from the University of Michigan that covers the cystic fibrosis Delta F508 mutation. So for cystic fibrosis about 70 percent of the disease mutations are caused—are the Delta F508 mutation which is a deletion of three nucleotides that causes cystic fibrosis, and that's covered by a patent held by the University of Michigan. They were offering nonexclusive worldwide in house diagnostic testing licenses and that was if you were providing diagnostic results to patients at cost or using one of the test kits that had a license from the University of Michigan to provide a test kit.

If every license or every patent was being licensed like this cystic fibrosis Delta F508 mutation, I probably would not be standing up here and we would not be having this discussion as to whether there was an issue that needs to be addressed.

(Slide.)

This is another. This is a draft license agreement. I left the University of Pennsylvania when this was still being negotiated. This is with Invivoscribe Technologies and basically there are two patents that cover testing that can be used for the diagnosis and monitoring of leukemias and lymphomas. So Invivoscribe was basically almost required to take an exclusive license to these patents so they're not the patent holder. They had been making test kits for doing this testing and they were enforced upon by the patent holder so they had to take a license.

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These patents basically cover rearrangements, testing for rearrangements of the B and T cell antigen receptor genes. So when you do this testing you can basically determine whether or not a leukemia or lymphoma is derived from one cell and more than likely, therefore, malignant or whether it's a population of many different polyclonal cells and, therefore, not likely malignant. This can be used both for diagnosis and for monitoring of disease remaining after chemotherapeutic or transplant treatment. So IVS cells the kits for B and T cell antigen receptor testing.

Interestingly, this method has been widely used for clinical testing without the use of test kits since about 1990 and the testing community was actually pleased that IVS was developing test kits because it would offer some standardization of this testing but we were not pleased when Invivoscribe had to start enforcing patent—their license.

(Slide.)

So basically there was no payment required for previous tests as that was what had been done by canavan disease patent holder, Miami Children's Hospital, but we didn't have to pay for previous tests performed. We had to have a license fee that was in the $10-100,000 is the most that I heard from talking with colleagues, although none of them really talk to me because you're not allowed to talk about this. And then there was a per test fee from $0-60 per test. This varied depending

upon whether or not you were using the Invivoscribe kit. So if you used the kit that had the license then the fee was lower and it also depended on whether or not we were doing reference testing, whether we were testing University of Pennsylvania patients or tests that we received from outside sources referred to the laboratory. If we were doing our own patients it was a lower price. So it was zero if it was a University of Pennsylvania patient using the Invivoscribe kit and it was $60 for a non-University of Pennsylvania patient not using the Invivoscribe kit.

(Slide.)

So at that time we were performing the T cell receptor testing by our own laboratory developed method and we were doing the B cell testing using the Invivoscribe kit. The cost to perform each test is approximately $300. That's not our charge. That's what it costs us. So we had no per test for University of Pennsylvania patients in which we were doing the B cell IGH testing. And $40 or $60 per test for the T cell testing, depending upon whether it was a University of Pennsylvania patient. So we would end up paying between $8-10,000 per year plus the license fee charge.

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Interestingly, Medicare reimburses $55.39 for this test. So the $60 per test was more than even what Medicare reimburses so you could argue that this is causing an economic burden for the laboratory.

(Slide.)

So we had to stop doing testing for CMT1a, which I did not talk about, ApoE genotyping, BRCA1 and canavan disease. We negotiated agreements for cystic fibrosis and B and T cell gene rearrangements. We had notification letters that kind of stopped midway in negotiating those for hereditary hemochromatosis and SCA1. And we're aware of potential for patent enforcement for spinal muscular atrophy, myotonic dystrophy, EGFR, Gleevek, BCRAbl mutations and the list goes on and on.

(Slide.)

So I would argue that this places constraints on medical practice. I argue that the sole provider of a medical service basically eliminates competition for pricing, reduces innovation and testing methods, dictates medical practice. So I didn't talk about CMT1a but when Athena Diagnostics had the exclusive rights to do CMT1a testing, they did not want to do prenatal testing for CMT1a. So you can have a provider who decides whether or not you can do prenatal testing for a specific disease or not, whether or not—and you could argue ethically that you may not want to do testing for CMT1a prenatally but the idea that a single provider dictates medical practice for the entire United States, I don't think is necessarily in the best interest of the public health. It places constraints on clinical scientific observation and slows the new discovery process as you basically have one person, one laboratory doing the observations that happen during normal clinical practice. It limits education of medical students and residents, and I would argue is not in the best interest of the public health. There are unreasonable licensing fees, control of one gene controls testing for many genes.

There can be royalty stacking so with the Jewish panel you would have to take a license for Delta F508, canavan disease, Gaucher. There are a number of fees that would be stacked up on top of each other in order to do that Jewish panel testing. One of the patent holders set limitations on test volumes and the IVS case limits the use of methods that are already used in clinical practice.

(Slide.)

So this is—I argued whether to do this or not. This is adapted from something that John Merz did. "The Vatican announced today that it has entered into an agreement with Miami Children's Hospital Research Institute that grants to the Vatican exclusive rights to U.S. Patent #5679635. This patent granted in 1998 to Reuben Matalon at MCHRI claims the gene responsible for canavan disease which causes brain degeneration and death by about age 20. The patent covers both diagnostic and prenatal canavan testing. MCHRI sold the patent to the Vatican for an undisclosed sum. The Vatican's statement made clear that the church intends to enforce its exclusive patent rights and prevent further use of the test in the U.S. for prenatal diagnosis of canavan disease." This is made up but it is totally realistic that a patent holder does control the ability of how a patent can be used and I don't think that this is a good situation.

(Slide.)

So what is the—why do I care about all of this? Why am I all hyped up? So basically you could argue that it's from my economic standpoint but the molecular pathology lab doesn't make money so I don't come at it from an economic viewpoint. I really come at it from a physician's perspective.

(Slide.)

So current medical genetics are basically diseases that are caused entirely by duplication or deletion of an entire chromosome such as Down's Syndrome or alteration of a sequence of a single gene, which is cystic fibrosis, Huntington disease, spinal muscular atrophy. Current medical genetics focus on diseases due to mutations in a single gene that are inheritable so it could be passed from parent to child. These genetic diseases are very important to affected individuals and their families. However, these conditions are relatively rare. Very few people are affected. It's a relatively small part of medical practice with minimal impact on society.

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And health care for these genetic diseases are provided predominately by medical geneticists, genetic counselors and involvement by other medical specialists such as pediatricians and primary care physicians.

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We are moving toward a different type of genetic or genomic medicine which will be medical practice based on understanding the role of genetic variations in common diseases. This genetic variation information will be used for diagnostics—for diagnosis, for risk assessment of common diseases, for treatment choice, therapeutic monitoring, prognosis, prevention, potentially prenatal diagnosis, pre-implantation testing and pharmacogenetics.

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So if you look at the leading causes of death in the United States, basically more than nine out of ten of these are influenced by genetics. I say more than nine out of ten because if you think about accidents, hedonistic behavior, alcoholism, there are a lot of underlying causes of accidents that also have a genetic basis.

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So by illustration: "Jim Fixx was 5'10", 150 pounds, and a marathon runner, promoted a healthy life style and died at the age of 52 of a heart attack while running. His father had died at the age of 43 of a heart attack."

Contrast with "Winston Churchill, 5'8", 270 pounds, didn't exercise, he smoked, had an unhealthy life style, and died at age 90."

This is the impact of genetics and where we are going with the future of medical practice.

(Slide.)

So in the future we are thinking of genetic medicine more as common diseases affected by variations in many genes with both germ line and somatic variations. It includes any disease identified now by family history plus many that we don't currently take family histories for. It affects virtually every person and it will be practiced by virtually every physician.

(Slide.)

And I argue that gene patents limit this future. National practice standards will be set by one provider. There's no competition for test costs, quality or method. There are limits—it limits the advances in scientific knowledge gained through broad clinical practice and observation. It limits medical education. It limits medical practice and limits broad availability of genetic testing.

(Slide.)

So I have argued and written that a sole provider of a medical service is not in the best interest of the public health so I feel like I'm doom and gloom here but everyone has been e-mailing this last week because the Supreme Court did make a decision on LabCorp versus Metabolite Laboratories.

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Which is this homocysteine related to--elevated homocysteine levels related to the vitamin deficiencies case that we had talked about at the March meeting. Basically they dismissed this case as improvidently granted. So they sent it back down to the lower courts.

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However, I took the time to read the dissenting opinion and I would like to read you parts of this because Justice Breyer, who wrote this, and Stevens and Souter signed on to this dissenting opinion, are very relevant to our discussion today. So he wrote in four different parts and from the first part, "The relevant principle of law excludes from patent protection laws of nature, natural phenomenon and abstract ideas. The justification for the principle does not lie in any claim that laws of nature are obvious or that their discovery is easy or that they are not useful. To the contrary, research into such matters may be costly and time consuming. Monetary incentives may matter and the fruits of those incentives and that research may prove of great benefit to the human race. Rather the reason for the exclusion is that sometimes too much patent protection can impede rather than promote the progress of science and useful arts, the constitutional objective of patent and copyright protection."

From Part III, he states, "One can reduce any process to a series of steps. The question is what those steps embody. And here in this association between homocysteine levels and vitamin deficiency, aside from the unpatented test which they describe as part of this patent, the steps embody only a correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view that correlation is an unpatentable natural phenomenon and I can find nothing in claim 13 that adds anything more of significance."

(Slide.)

And from Part IV: "If I am correct in my conclusion that the patent is invalid then special public interest considerations reinforce my view that we should decide this case. To fail to do so threatens to leave the medical profession subject to the restrictions imposed by this individual patent and others of its kind. Those restrictions may inhibit doctors from using their best medical judgment and may force doctors to spend unnecessary time and energy to enter into license agreements, may divert resources from the medical task of health care to the legal task of searching patent files and may raise the cost of health care while inhibiting its effective delivery."

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I couldn't have said it better myself.

(Slide.)

So the are some philosophical questions which we could get embroiled in. Should gene patents be granted? So are gene patents really inventions? What has been made by man in these correlations between a genetic variation and a disease? Are gene patents really claiming a product of nature? Now that—I don't know if we want to go there. Do gene patents inhibit or promote the progress of science and useful arts? In this case medical practice. Are patent incentives even needed for discovery or clinical implementation of patented genetic information? I would argue we take this information very rapidly into clinical practice at least for diagnosis. Should exclusive licensing of fundamental medical knowledge be allowed to continue? Is sole ownership of a disease in the best interest of the public health?

(Slide.)

So there are various options to consider and SACGHS may decide that it doesn't have the purview to recommend any of these but the options basically are going to the courts, going to congress to change the laws or changing the practices of the U.S. Patent and Trademark Office.

Some specific things that have been discussed are—one possibility is to exempt medical personnel who perform genetic tests from patent infringement actions. This would basically be an extension of a 1996 law that protects physicians from patent infringement lawsuits when they are using medical process patents but pathologists and laboratorians were specifically excluded from this protection.

There was a bill introduced by Lynn Rivers in 2002. I learned all about the legislative system in that she was not—her district was redrawn. She was not elected and the bill died.

The other possibility is by some mechanism to mandate broad licensing at reasonable royalty rates to prevent the exclusive licensing for genetic tests.

(Slide.)

So I'd be happy to take questions.

Maybe, Reed, you could moderate this little bit because if people have questions for me, I want to be able to wear my laboratorian hat and not my SACGHS hat.

DR. TUCKSON: Actually let me just ask one question before you take questions.

DR. LEONARD: No, you can't preempt Julio.

DR. TUCKSON: I'm not going to ask a question about a question—about—do you want to take the other presentation and then do all the questions at once or do you want to take your questions now? That's a question.

DR. LEONARD: I think we can go through the presentations if that's okay.

DR. TUCKSON: Yes. I think it might make sense because I don't want to preempt—some of the questions may come up and we'll have better questions after we listen to the other presentations.

DR. LEONARD: That's great. Okay.

DR. TUCKSON: Then I can do that. So I didn't actually preempt Julio.

DR. LEONARD: Good.

(Laughter.)