This is a transcript of the event “Who Owns the Genome?” that took place at the Woodrow Wilson International Center for Scholars on September 24, 2002. The event was co-sponsored by the Affymetrix Corporation. The Wilson Center and Affymetrix are making the transcript available for educational purposes.

Speakers:

Lee Hamilton (Opening Remarks)
Stephen Fodor (Opening Remarks)
Justin Gillis (Moderator)
Eric Lander
Todd Dickinson
Pilar Ossorio
Scott Brown (Panelists)
__:Unidentified Male/Female from audience

Questionable words and phrases [in brackets]

LEE: For tonight’s discussion and debate on the Genetic Age, Who Owns the Genome? I’d also like to welcome our virtual viewers who are joining us over the Internet for the live Webcast of this event.

Today’s event is co-sponsored by the Wilson Center and Affymetrix Corporation. I’d like to thank those people at the Center and at Affymetrix who over the past several months, have turned an idea into today’s event.

We’re very pleased to -- here at the center -- to co-sponsor this event with Affymetrix, a firm that is both a leading developer of new genetic technologies, and an advocate of broader public education about the challenges facing us in the genetic age.

As many of you know, the Woodrow Wilson Center was created to bridge the worlds of scholarship and policy making. And part of our mission here is to address future long-term challenges to our society and government. And we've set that up with a new project under Dave Rejeski's leadership, very excellent leadership on foresight and governance with the specific goal in mind.

Few areas will have a more profound impact on our society than genetics. Future historians, perhaps some of them writing here at the Wilson Center, will refer to the sequencing of the human genome as one of the great scientific accomplishments of human kind.

Indeed, I picked up the "New York Times" Science section this morning and thought to myself that that sequencing may rank with science's most beautiful endeavors, which the "New York Times" featured this morning. The experiments of Newton, Cavendish, [Millikan], Young, Rutherford and others, like these examples, the sequencing of the genome, combines a simplicity of analysis in the words of the "New York Times" with the beauty of science grappling with the mysterious.

But the application of this knowledge will be just as stunning and profoundly challenging to public policy. How we prepare both the public and our policy makers to deal with the flood of new genetic knowledge and its applications, will be

critical to our ability to harvest its benefits in this new world coming.

Last November, the director of the National Science Foundation, Dr. Rita Colwell, said from this podium, “We need to develop a broader, more anticipatory perspective in our research. We need to increase our emphasis on envisioning future possibilities, good or ill, as a mechanism to predict. The rewards of new scientific knowledge will flow to those persons, organizations and nations that put a premium on anticipating and shaping the future rather than simply reacting to it. But anticipation is not an easy task, and the science of genetics will challenge us in many ways. Thus, we need a much more vigorous and open debate on both the science and its implications.”

Woodrow Wilson once said, “I use all the brains that I have and all those that I can borrow.” You can help us as we borrow your brains tonight to better understand the present and prepare us for a future that will certainly hold many surprises and present many challenges.

We’re joined this evening by a stellar group of panelists whom you will have the pleasure of meeting in a moment. It’s now my pleasure to introduce Dr. Steven Fodor, the Founder, Chairman, and CEO of Affymetrix. Steve?

Stephen: Thank you, Lee for that thoughtful introduction and for setting the stage for tonight's program. I'm also pleased to welcome

[drop in taping]

...[audience] here in Washington and those joining us via the worldwide Web for what will no doubt be a provocative discussion. I can think of no better place to hold tonight's program than the Wilson Center, a site known for the president, who in so many ways embodied a passion for public discourse and debate. To build support for the League of Nations Treaty after World War I, Wilson undertook a grueling trip across the country, personally making his case to the American people.

Wilson felt that this was not a matter to be left simply for politicians, but that in a rapidly changing world, the understanding, acceptance and support of the public is essential in formulating policy.

It's hard to imagine a world changing more rapidly than the world of genetics. Next year we mark the fiftieth anniversary of Watson and Crick's discovery of the structure of DNA, one of the most profound scientific discoveries of this 20th century.

But for tonight's debate, I think it's more appropriate to recall that the sequencing of the human genome was announced just

over two years ago. So I ask you to think not how far we've come in 50 years, but how far we've come in just those two years.

The public policy changes in modern genetics are formidable, made even more so by the speed with which life sciences are advancing. A combination of public and private resources are now driving progress and we now have tools to enable whole genome analysis, yet we should all realize our knowledge of the human genome is still vastly outweighed by what we do not know.

Nowhere are these challenges greater than in the field of intellectual property. Policy makers face the daunting task of constructing, interpreting and administering a framework of laws and regulations that must strike a balance between the private sector's need to reward innovation and the public's right to reap the benefits and advances in genomics to improve the quality of our lives.

This is the second in a series of genetic age programs supported by Affymetrix. Programs aimed at fostering a greater understanding of human genome research and its implications for society. Before introducing our moderator, let me say again how delighted Affymetrix is to be co-sponsoring this event, and how much we appreciate the efforts of Lee Hamilton, Dave [Rejeski], and their colleagues at the Wilson Center for their encouragement and support.

Let me also express my appreciation to our panelists, Scott Brown, Todd Dickinson, Eric Lander, and Pilar Ossorio for their time and effort to be here tonight.

Our moderator for the evening is Justin Gillis. Those of you who follow science in the news will recognize Justin's byline from The Washington Post, where he's covered biotechnology since 1997. Prior to that time, he enjoyed a distinguished career in both Miami and Washington as an investigative reporter. I might add that Justin is regarded as one of the most thoughtful reporters covering our industry today. We're delighted to have him here this evening.

Welcome again everyone, and Justin, I will now turn the program over to you.

JUSTIN: Thank you very much, Steve. And thank you all for coming. We have a lot of information to cover this evening and a lot of points to get into, so I'm going to do it, get us into that as quickly as possible.

I think it's probably safe to say that Watson and Crick when they published in April of 1953 could not have imagined that their field would eventually become a battleground in quite the way that it has. It is a battleground. But two years ago of course, we all tuned in as the President and the Prime Minister of Britain hooked up by satellite and announced this monumental achievement, the draft sequences of the human genome.

Even as they spoke of course, commercial interests were following that research and for 20 years really have been sort of shadowing, if you will, the public science of genetic research, because they want to ultimately produce cures for disease. And the means by which they aim to do that is by patenting genetic sequence. And we have had a policy in this country now for two decades that permits a private interest to patent pieces of the genome, genetic sequence. We're going to talk about a little later tonight exactly how that's done.

That was sort of low-grade and kind of under the radar for quite some time, and not a whole lot of public discussion about it and not a lot of complaint about it. And boy, in the last few years, it has taken off so extensively that we now have kind of a walloping argument about whether the current policy is the right policy, whether we're creating problems for ourselves down the road.

I'm very pleased to have an excellent panel to discuss these issues tonight and they're people who've taken, they all have sort of pretty sophisticated positions on this. But we may manage to get an argument going.

I'm going to start from the audience's far right and introduce them to you. Pilar Ossorio down on the end, is both a microbiologist and a lawyer. That's kind of a new thing, by the way. She is more to the point, a leading voice in this country in bioethics, she holds appointments at the Law and Medical

Schools at the University of Wisconsin at Madison, a place where many of you know a lot of the cutting-edge biomedical research is being done. And we're very glad to have her.

Next to her is Scott Brown. Scott is Vice President and Chief Patent Counsel of Millennium Pharmaceuticals Inc., in Cambridge, MA, seat of all wisdom.

SCOTT: Cambridge or Millennium?

JUSTIN: Cambridge I think. He oversees patents and intellectual property for that company, which is recognized as one of the most innovative and intriguing of the nation's biotechnology companies. And we're glad to have him with us.

To my right, your left, is Todd Dickenson. He is a distinguished patent attorney. So distinguished as a matter of fact, that the Clinton administration in 1997 asked him to go run the Patent Office, U.S. Patent and Trademark office, which he did for four years I believe.

TODD: I was Deputy and then Commissioner for a total of four years.

JUSTIN: Right. And so he knows the nuts and bolts of that system and how it works. And we're grateful to have him.

And then over on the far end is Eric Landor. I may be tempted here to get into a little more of Eric's bio. He's really a corrupted sort of mathematician. Eric's been making noise in mathematics in this country since he was in high school, but sort of decided at some point that it was kind of a lonely

trade and he'd rather do something else. So he was a teacher at the Harvard Business School, economics and mathematics and all sorts of other things. And sort of snuck across the river and got people at MIT to start teaching him biology, and has slowly over time become -- or not so slowly really -- become one of the leading geneticists in the world.

He runs the Whitehead Genome Center at sort of not really part of MIT, although it's kind of right next to it, and that center many of you may know, produced about I think 25% of the total genome sequence. So the largest and most productive center in the world in this great project of sequencing the human genome.

So that's my panelists this evening. And if you would welcome them all, I'd be grateful. Thank you.

So we reporters like to deal in facts, or purported facts anyway. So, we're going to start this evening by asking our panelists to attempt to suppress their own views of these matters just very briefly and give us a kind of factual base for our discussion, essentially. And I'm going to start with Todd and ask him to do a couple of things if he would.

We'd like to have him explain to us just how big this whole business of genetic patenting has become, sort of how much has it taken off. What's happening out there on the ground in the patent offices you might imagine, where he has it's finger on the pulse of technology in America. It comes rushing in the door in

the mail everyday. So he should be able to give us a handle on that.

And then secondly we'd like to ask him to walk us through a sort of [thumb-ly] a legal history of how it is we got to this position of allowing patenting of genetic sequence in this country. And we'll ask him particularly to talk about a doctrine called the products of nature doctrine. And why that's not applicable to patenting genetic sequence.

TODD: All right. Thanks Justin, and also thanks to the sponsors tonight. Let me actually flip those around a little bit and start off by talking about what patents are and what the patenting process is and how it relates to genomics. Because one of the first questions I often get asked in this area, as do others, is how can they do that? I don't quite understand how this works in the first place.

Many people I think know what patents are. They're basically a grant from the government, the Federal Government in our case, which gives to an inventor of any invention that meets the statutory requirements, the right basically to prevent others from copying their invention.

There's a little bit of a misunderstanding at that stage. I think people believe and tonight's program for example is Who Owns the Genome? You don't own the actual invention. What you own is the right to prevent others from copying your invention,

for a period of time. Currently it's 20 years from the date that you file your patent application.

Why do we have this system? Several reasons. First of all, we've had it since the [days], it's in the Constitution and the first patent law was written by the first Congress. It's basically to encourage innovation and it's also to, as a secondary thing, encourage people to disclose their inventions. Not to keep them as secrets, or trade secrets as we say today. And in so disclosing them, allow others to take that information and build on it and move technology forward.

It also, these days, provides an economic incentive and an economic underpinning for a lot of investment, particularly in high-tech or startup companies, particularly biotech companies who go to their venture capitalists and very often are asked, what kind of patents do you have? How can you protect these new inventions? And I'm sure Scott will probably talk a little bit about that.

We grant patents in the United States to a variety of things in broad categories. Chemicals, which is the category we're going to talk about tonight, processes, which affects us a little bit, machines, apparatuses and other things. It's basically a four-part requirement to get a patent. First of all, it has to show a use, a utility. And a lot of our debate I think tonight's going to be about where that utility level is in the law at the moment.

Secondly, it has to be new. You have to be the first inventor. You can't have had, if it's discovered that somebody's invented it before you, and we do a search at the patent office, you don't get the patent. And what's interesting is a large part of what happened during the course of the human genome project was the National Institute of Health, for their piece, they kept putting every night they would put their database of what they discovered that day up on the Internet, creating what's called [priority], and because they did not seek patents on what they put up on the Internet, or what they invented rather, others, that creates priority against others.

It has to be what's called non-obvious. It can't be so incrementally different from what's come before that it's obvious to what's called the skilled practitioner. And finally, it has to be fully disclosed.

The rules are set by statute, they're also interpreted by the courts, so Congress and the courts do the principal interpreting. But at the ground level, as Justin suggested, the Patent Office has to deal with that every day of the week. And we have a number of folks here today who, from the Patent Office, who have to deal with that question on a regular basis.

Anybody can, any inventor can apply for a patent. Justin suggested that private interests are applying for patents here. The public, any public inventor, any public institutional inventor could apply for a patent. Anyone at a non-profit

organization or university who's an inventor, could apply as well. Anybody's who's an inventor.

The National Institute of Health, for example, has applied for genomics patents in the past and has obtained them. They've made a policy decision to change that since the last few years.

People, let's go to the specific question of how can genes be patented, particularly human genes, which is what we're talking about today. And from a patent lawyer's perspective, and a patent practitioner's perspective, it's a fairly straightforward question. Genes basically are chemicals. They're very complex chemicals to be sure, but they are themselves chemical compositions. And chemical compositions as a category, like pharmaceuticals and other chemicals that are discovered or invented, have been patented since the very earliest stages of the system.

Well but people say, I walk around, I'm carrying my genes around with me today. The products of nature exception that was just referenced a minute ago. How can you patent something that's just found in nature? Well the answer is, we don't. The patent doesn't, a patent cannot issue to something that is found in nature in its naturally occurring form.

What the patent does issue on in the genomics area and in other areas, is on the isolated and purified form of that genome. It has to be the chemical composition has to be discovered, it has to be isolated and purified, and it has to be put and alleged

to be put forward for a use that hasn't been known before. And that, in that case, the gene is patented, not in its necessarily in its naturally-occurring form.

So well I sort of get that. But give me some other examples. I said, fine, we've patented for example, it's a classic story of Penicillin where mold was found in a petri dish to have anti-bacterial capabilities. And Doctor Flemming, what he did was isolate from that mold, the active ingredient, namely the Penicillin. And a patent issued on to that drug, Penicillin.

Well it's a human though, we're talking about humans, aren't we? We issued a patent to human insulin when insulin was isolated and purified from the human pancreas. And it was discovered that it was the active component in regulating sugar metabolism, in preventing diabetes. We issued patents to naturally occurring insulin as well.

Taxol, a cancer-inhibiting drug, isolated from yew trees in the United States. Once the drug is isolated from those trees and purified, we issue patents. As a matter of fact, many, many, many pharmaceutical patents in particular are naturally occurring substances which have been discovered and isolated from those sources.

What are the big issues? First of all the issue of utility, which I'm going to go into in just a little bit more. Secondly a novelty which I mentioned and thirdly, this issue of non-obviousness. People say, well, and we're going to talk about it

I'm sure in a little bit, there's nothing really inventive going on here. These are just being produced by these sequencing machines, which are churning out all this data and all this information.

That's not a bad argument. The challenge is, it runs afoul of a very specific provision in the law, in section 103 it's called, which says that the way we come by the invention, does not negative whether or not you get a patent. And it was intended to overturn a Supreme Court decision on the so-called flash of genius test, where [inaudible] come see you when you're asleep, like the inventor of Benzene or the inventor of the [pulmorized] chain reaction who was driving up the Mendocino coast. Or it takes you 30 years to figure it out, you're still entitled to a patent.

Another thing I want to highlight a little bit because we'll talk about this, is the fact that we're going to talk about the questions of access to this technology. It's a very important issue. Licensing and access is key to this discussion. It is different, it is distinct from whether or not you get a patent in the first place, and whether you should get a patent in the first place. They are very related, we'll talk about the [narrow] relationship, but they are distinct things.

This issue of whether genes should be patented has been studied extensively. There have been extensive public hearings. The United States Patent Trademark Office has had a number of

hearings on them, Congress has held a number of hearings. I've testified three or four times before Congress on this topic. It is one of ongoing debate, but is certainly one that's been discussed thoroughly.

Let me talk a little bit about how the U.S.P.T.O. deals with these questions. First, as was suggested, when the first genes first came along, when the first applications were filed, the office was fairly restrictive about it. They were new, they were moving in a very step-wise fashion. There were quite a lot of what's called wet biology in the disclosure.

They really required, because there wasn't a lot of backup, the utility was very sketchy, there were a lot of questions and the Patent Office was very restrictive. The courts basically overturned that. The courts basically said, "Nope, they're meeting the requirements, they're entitled to the patent."

So they went back to the drawing board and they crafted in particular a set of guidelines for examiners around this utility requirement. Because that's where the rubber's meeting the road. What use are you actually discovering for these inventions?

And we published a set of utility guidelines. A lot of feedback was gotten, particularly from the public sector, particularly from the NIH, National Institute of Health, and it was good and valuable feedback. In the meantime, one of the courts decided a case called [Eli Lilly] which concerns both this

issue and the other disclosure issue. And we revised the again, and took additional testimony.

And in this case, because of the testimony we heard, we raised the bar. The Patent and Trademark Office now requires a three-part test of utility. You have to show specific utility, substantial utility and credible utility. For example credible utility, if you're going to claim to cure a disease that hasn't been cured in the past, you're going to have to show the patent office a lot of evidence to support that.

We met with a lot of folks, the director of NIH and others, and I think most observers believe that we hit that mark pretty well. At the conference at the White House or at the announcement at the White House that Justin referenced, both Craig Vetter who is the private sector representative from Celera and Francis Collins, representing the public funded Human Genome Project, both mentioned in their remarks and mentioned to me that they felt we'd hit those guidelines pretty well.

Utility is a tough standard. Traditionally it's been very low. You had to show very little utility. And that's an issue that's, I think going to be, continue to be discussed here today.

Another key issue is what about fragments of genes? I sort of get the whole gene, that's a lot of work that goes into discovering that whole gene? What about what are called express sequence tags, little fragments of genes, they've been called the

filet mignon of the gene. What about snips [inaudible], filet mignon to the cow I think is probably the analogy.

M: At least the burnt ends or something.

TODD: So [inaudible] polymorphs which are mutations basically, of a gene which you discovered. The examination of those is more controversial. What's happened I think over time in the office is that the office has gotten much more rigorous about that and frankly the disclosures that the inventors and their companies have brought forward to the office, have been much more complete. And I think the more complete those disclosures are, the more likely you're going to get a patent.

Those early-generation ESTs, those aren't going to get through. The later generations are.

Briefly talking about access. We hear a lot of war stories, we're going to hear them tonight about this company being too hard there, that hospital cracking down too hard. One of the things I did a lot of was jaw bone and work with the genomics companies to make sure they don't, if you will, kill the goose that lays the golden egg. We'll have an issue though of patent pooling or patent layering, which I'm sure we'll get into.

We commissioned a white paper at the PTO to deal with the question of what if you have to go to too many people to get a license? Too many entities to get licenses for patents? And I

think the patent pooling, which we can talk about, is one good solution.

How many patents are we talking about? That's a question that was asked. At the moment there are about 6500 patents that are to genes themselves or to open reading frames. About 1300 of those are to the human genes, there are patents on [rice] gene and mouse gene and all sorts of other organism genes. About 1300 at the moment are to humans.

There are about 20,000 all into genes themselves, fragments, snips, ESTs, that sort of thing. There are about 20,000 that are pending that claim genes fragments, snips and other things. And there's also a category that gets mixed in here a little bit that I want to make sure we understand, called provisional applications. These are basically place-holding applications.

Many of those never ripen into full patent applications and then into patents themselves. But as you evolve your technology, you will occasionally file what is called a provisional application. It's a much less disclosure, much cheaper, and there are about 30,000 that are currently on file.

To give you an example, Celera announced that they would file 6000 applications to genes that they discovered. What they meant were provisional applications, they then clarified later and said we'll only really file about 300 applications on actual gene sequence. That's about where we stand, Justin.

JUSTIN: So I heard you describing the legal history, I kind of heard a series of pendulum swings in there, and tell me if this is right, from extremely restrictive when genetic patenting first came along, to somewhat looser. Some people might say promiscuous even. And that initial swing, if I'm hearing your right, was somewhat driven by the courts and the patent office losing its position in court. And then so what we've had most recently in response to the political controversy to some criticism is a bit of a pulling back.

So we've got the pendulum swinging back a little bit the other way toward a more restrictive set of guidelines on what you can patent. Is that about right?

TODD: I don't think to say it pulled back a bit is accurate. I think it pulled back much more toward the middle and I think that that was where it probably should reside.

One thing I also want to clarify, when the initial restriction period was on, there were not a lot of patents coming out. But those individuals or companies who wanted those patents, took them to court, took the PTO to court and that's what caused the swing back. There was not a swing where suddenly the flood gates opened. I think the PTO basically said, "Well, let's see if we, before the flood gates to get too far, let's test these rules, let's create new guidelines." And that's what we did.

JUSTIN: Right. Todd mentioned that private interests are not the only ones filing patents, in fact last time I looked, the biggest file of genetic patents, or one of the biggest may have been the Regents of the University of California system, where a huge amount of genetic research -- that's the birthplace really of biotechnology and genomics. And they own and license then to private interests a whole lot of patents.

We would like to ask though why private interests are so concerned about this? Why is there such an effort to file patents on genes, given that the public sort of hears it and goes, "What are they doing?" You'd like to know why the companies feel that it's so important.

So we'll ask now Scott Brown to talk to us. He does this for a living. He runs a shop that I would bet, as a matter of fact, I pulled his company's list of issued patents and it ran to 16 pages of very close small type just to give a one-line description of each patent they've got. And I'm sure they have a lot more pending.

So tell us why you're doing that and why private industry cares so much about getting these things through.

SCOTT: Well obviously the promise of the human genome project both the private aspects and the public aspects that have done, is to decipher as much as we can about our knowledge of human

disease and to find cures and therapies and diagnostic tests to better the existence of all of us. To find drugs, find tests, to help cure human disease.

And that's what companies like Millennium, all major pharmaceutical companies, and biotech companies, that's what we're in the business to do is to find those cures, find those tests. And as much as we might wish it were otherwise, doing so requires lots and lots of money. There are many statistics that you hear thrown around.

To develop a drug, one drug that successfully gets to the market through the FDA and into the hands of patients, costs anywhere from $500 million to $800 million of investment by a company. $500 to $800 million to get one successful drug to the market.

And again, we'd wish it were otherwise perhaps, as a matter of public policy, but that kind of investment isn't made by public interests. It can only be made in the private sector. And the way the system works, private sector investment isn't going to occur unless there's some return on that investment.

So patents play a huge role in getting that investment made by investors to start companies, by companies to get the return that's promised by some type of a patent, [that's stayed] on a particular drug or a test, to recoup the investment they've made of their own dollars and their shareholders' dollars with respect to that.

So the patent system has played a huge role, particularly in the biotech industry, but also in the traditional pharma industry in getting that investment made. And it takes really, it's taken three forms over time. With the biotech industry, getting that initial venture capital money to get the company started, you've got a great idea that's come out of some very basic research that has promise to some, to cure some disease or to find some particular test. Getting that initial venture capital money, the first question the venture capitalist asks you is, "Well, do you have a patent?"

What are the patents? How long are the patents going to be? How broad is the protection you're going to get? Without patents, basically venture capitalists aren't going to knock on your door.

So early company startups that have great ideas that want to try to get into commercialization so you can actually help patients, require that type of investment, and without patents, the VCs aren't going to be there.

The other type of investment you get are [for/from?] companies like Millennium. Millennium obviously started way back when as a venture capital entity, but as time goes on we've taken a [patent to state] that covers mainly targets that could be used to find small molecule drugs. Not drugs that are genomic themselves in the fact that they're based on DNA or protein, but looking at the targets, the genetic targets, the proteins in the

body that those drugs act on in order to affect human disease. And taking our patent to state that's based on those types of genomic properties and getting investment from larger entities, larger pharmaceutical companies, to partner with us and to give us, invest in us, from that perspective, to help them develop drugs. And now we've moved into relationships that actually ourselves, developing drugs in conjunction with those partnerships.

To give you an idea of the magnitude of value that's placed in that paradigm and the intellectual property that supports it, Millennium has raised close to $2 billion between stock offerings, bond offerings and then this partner investment. The partner investment alone has been over a billion dollars over the 10-year history of the company. And that's money which is going into making those drugs and allowing us to make the kind of investment of the order for about a billion dollars a year that we make in trying to find drugs and tests that are really going to change people's lives.

So that's the second form, is that type of reinvestment by companies, partnering of companies, in order to do it. The third actually, which mainly applies to big pharma, but as companies get into commercial mode, as opposed to research mode, is simply the commercial return.

Obviously it's good to have patents on drugs, because that allows you to recapture that investment by selling it at a profit

that helps you recoup that investment sooner. When patents run out, generic drugs come on the market, prices go down and then opportunity goes away.

So in order to get that, having patents, particularly in the biotechnology companies, on the proteins that are used to cure things. Things like [arithropoet] and human growth hormone. Human insulin. Having major patents that whole companies have been built on, companies like [AmGen] was built basically on the back of the [arithropoeten] patent and in fact a patent battle that affected a company I used to work for, really was the difference between AmGen being the huge success that they are and able to make even further drugs beyond that, but the huge commercial success versus my former company, Genetics Institute, who has subsequently been bought up by another pharmaceutical company and really doesn't exist in the form that it did before.

JUSTIN: You guys lost then, is that?

SCOTT: Yeah, we lost. I wasn't there then, I came in the aftermath. But they did lose a big patent battle. It was over the patent, and that was the difference between that huge success versus being taken into a larger entity.

So sort of in those three ways, in all those three ways, the patent, the right to exclude others so to have some period in which you can recoup commercial investment, is really at the

heart of all of those things and really is the driver that keeps that investment that allows those drugs, that $500 to $800 million to be spent to get the drugs on the market that help to benefit us all.

One other point that I wanted to sort of make to tie into some of Todd's comments, he said there's 20,000 applications pending. Just to give you an idea of what those numbers really mean, that's 20,000 applications in which there's anywhere from one to 10 to 100 to 10,000 genes covered in each of those applications.

So there's a huge amount of, we're talking about a huge amount of intellectual property that is being discussed as part of this debate and that we are looking, companies like Millennium and other companies in the industry are looking to, to plow that ground, to find the jewels that are in there that are going to turn into real therapies to treat patients.

So, again, the patents are a, I've heard many people call it a necessary evil. I'm not sure I like that word, because it's not an evil, it's a good thing for us all because it drives drug making. But it is the thing that we have to do. And I thin the debate should center on what is the proper scope of those, the standard that, the change in the utility standards that Todd referred to.

Again, it might surprise you to see [I think] is a good thing. He told you it used to be easier to get patents in my

area of the world, it's more difficult now. I think that's a good thing for several reasons which we'll probably get into later. If nothing more, it's a good political compromise, and that's really what it is.

We could talk about those details. It's not based in the patent law, it's a political compromise. But it's a good one because things had gotten perhaps a little too liberal with respect to what we were able to do and get out of the patent office. And now that it's swung back, perhaps at the right place, and we'll talk about that more. But that's the commercial perspective.

JUSTIN: So this is no small point that he's making of course about cures and how the American system works to develop them. In the early '90s, I had friends who were dying all over the place of AIDS and then in about 1995, they stopped dying and the reason they stopped dying was that a bunch of drug companies developed and put on the market drugs that saved their lives.

And all of a sudden all these people with sort of leftist political leanings were saying, "Holy cow, boy we believe in capitalism."

However, we've got a pretty pro-patent kind of vibe going up here and I've been watching you kind of fidget over there

[talkover]

JUSTIN: I've been seeing you kind of moving in your chair. So it's true that a lot of the objection to this evolving law and this evolving system has come from the academic community. There have been a lot of reservations about the way it's going and about boy aren't we creating a lot of problems for ourselves? There have been a lot of examples and maybe we can get into some of them, of specific problems, specific difficulty people have had doing research.

Tell us about that and tell us why the academic world is so worked up about this.

ERIC: Sure. Now before I do it, disclosure. I'm on the Board of Directors [inaudible]

M: Yes he is.

ERIC: And that should be disclosed first. But that doesn't mean we necessarily will agree on

M: And I know we don't, so, [inaudible] here it comes.

ERIC: But what I do agree with, absolutely, the patent system is essential if we're going to get drugs in this country. Investing the $500 to $800 million when someone else can swoop in

afterwards and sell your drug, would absolutely kill innovation of drugs in a bottle of therapies. We have to have that protection. But it doesn't follow for that, that we have to have willy-nilly patenting of all of these very early research tools.

And there we have to back off and ask the line. There's no question that a protein in a bottle, insulin, growth hormone or whatever, is going to be injected into a patient, needs to be protected by a patent, nor to justify the clinical trials, should be protected by a patent, no arguments.

But the academic discussion around this, I think proceeds in the following dialog, which I think started off sort of naïve and went back and forth between academia and the lawyers, and academia and the lawyers.

Let me see if I can try to reconstruct as best I remember the discussions. The naïve academic position: "How can you patent this stuff? It's product of nature." Patenting the Moon, Jupiter, like you were saying, how can you do that? And then the patent lawyers come along and say, "Well you guys don't understand. We're not patenting what's in nature, we're going through sophisticated purification. We're demonstrating utility. We're encouraging innovation."

The academic scratches their head, reads what patent law is about and says, "Give me a break. This is not Penicillin. This is not Taxol. Once you make one DNA library, taken all the fragments out of the human genome, you have unmasked, purified

all of these individual components. This is not some inventive, novel purification of individual distinct molecules, it's all laid out in a library. It was invented by the founders of molecular biology. So don't give me this 'we've really purified it out of nature.' Technically we've put it in a plasma and all that, but isn't that really just a legal fiction?"

Utility, isn't it really true that most of the claims in the beginning were that you could use this piece of DNA as a probe to recognize itself by Crick-Watson base pairing? Which is a step above say producing enough of it to use as packing peanuts, but it will offer you the same intellectual content.

And innovation, this is kind of mindless stuff. You do just run it through the sequence or it's the same thing all the time. Of course we've got to protect the stuff where it's really an invention and it's really going to help patients and all that but aren't we by wording limited time monopolies to this mindless generic innovation discouraging the investments in the hard stuff and function. And isn't that a bad social bargain.

We agree there's maybe some little bit of invention there but the really hard work is figuring out how to turn it into a therapy. Now the patent lawyer comes back and says section 103 says it doesn't matter how mindless it was. And the academics scratch their head, section 103, looks up section 103, all right maybe it doesn't matter how mindless it is and the patent says

and we've raised the bar to include substantial and specific incredible evidence of utility and all those sorts of things.

And so the academic backs off and says all right look, maybe the mistake is in discussing the black letter law. Maybe it isn't really an issue of black letter law we should be debating but rather an issue of social and economic policy. This is after all a bargain between society and inventors. Society agrees to grant limited time monopolies, inventors agree to disclose but we've got to set the bar right in order to get the optimal return.

If we were to hand away monopolies for very little work we'd be getting a pretty raw deal. When we had the Homestead Act in the 1800's we didn't hand away land for walking the boundaries and just filing a claim, you had to work the claim and really add value to it. Maybe we ought to just forget about the black letter law and inquire into the true economic and social return that we're getting out of it.

And there if you take pharmaceutical companies into the back room, off the record, not on the Internet, and ask which would you rather have, lots of patent [that] states around the individual genes that are the targets that you'd like to screen for drug discovery or freedom to operate. They'd rather have freedom to operate, they'd rather compete on inventing molecules to tickle receptor Y than try to hold the patent [estate] on

receptor Y to prevent anybody else from making a molecule to tickle it.

And why, because we today have a thicket of problems out there where pharmaceutical companies and biotech companies drop projects because the patent estate is very muddled and patients lose out. If in fact the competition were not over staking this land rush claim to the thing that we barely understand, this receptor which might give rise to a drug, but was in fact over granting a meaningful patent on a molecule in a bottle. Then we might be incenting the better behavior, we might be getting a better deal for society.

That's about where I think the discussion has gotten to so we all agree we need patents. The question is simply should we be giving them away here, here or here and my own personal sense is that there's a tremendous amount we don't know about the human Genome, tremendous amount we don't know about cell biology and I want to see those billions of dollars investments going to that and I think, not withstanding the argument they can all be cross licensed in the secondary market and all that, we will be better served by setting the bar even further than the improved bar that the patent office got.

JUSTIN: So what way they've gone some ways in the right direction.

ERIC: The direction is absolutely right.

JUSTIN: You just want them to go further?

ERIC: I would and we'll get into perhaps in a moment what I think is far more important issues which I'll mention just as a placeholder for the discussion. There are patents now, which folks are filing on, and beginning to issue to grant the monopoly on all possible molecules that affect a receptor to treat a disease. Including molecules you've never described. You've described two molecules in your application and claim all molecules anybody's ever going to think of for affecting this receptor.

Boy is that going to discourage competition. It's going to discourage me to drugs, it's going to discourage precisely the things that makes better second and third generation drugs and we better think carefully. Where we choose to grant the monopolies affects where we will get the investment and in the end the prices will pay.

Anyway, so I think the academic discussion started pretty naïve but it's worked its way [up].

JUSTIN: You know you really have to work to get an opinion out of Eric. [laughter] Thank you.

ERIC: Well you asked me to sort of come out of my shell tonight.

JUSTIN: I did, I did. So there is a whole class of people in the world whose job it is to try to reconcile law and morality. It's a tough job but it has to be done and Pilar is one of them. And what we'll ask her to do now and I'd like the audience to begin thinking about questions you'd like to ask because I'm

going start, as soon as she's finished I'm going to start asking a few questions up here but if I see you folks sort of moving over to those microphones then you're on live. So we'd love to have time to get into as many audience questions as we can.

Pilar, tell us how the community people that you work with, your colleagues, [bioeth??] view this debate. What has been the sort of range of responses to these arguments between the patent lawyers who say chapter 103, here's what it is. And the academics who are sort of asking what is the, how do we get the greatest social utility out of this system.

PILAR: Well you know it's interesting because I think in some ways there's a mirroring of what Eric said about the interaction between academic scientists and the legal community which is that we began the ethics discussion with emphasis being quite naïve about what a patent is, what rights it grants.

The early kinds of concerns about patenting human DNA had to do with things like human dignity and there was a feeling that granting a patent on a human gene somehow gave a property right in the inventor over another person and that this would be some kind of violation of human dignity.

These kinds of arguments were based on the misunderstanding that patents grant ownership for one thing and that patents somehow, people didn't understand that the patent system perceives the DNA that is being patented as something different than the completely natural DNA that's in your body.

So those early arguments I think were based on some misunderstandings. There was a second kind of argument that I think has a lot of resonance, a lot of intuitive appeal but also hasn't gone very far. Has to do with this idea of human DNA as part of the common heritage of humanity. And there's some ideas out, we all have a human Genome and somehow we all have an interest in the human Genome and so how can it be that one or a few, not one obviously, but that a few entities, a few inventive entities can get rights that give them kind of a position staked out on that human Genome that we all ought somehow to have access to because we all possess a human Genome.

So people said, well the human Genome is the common heritage of humanity and therefore we all ought to have rights to it, some kind of common and universal right. There are some real problems with that kind of an argument. For one thing human Genome is an abstract concept. We all have our own human Genome, each of us has a human Genome in our body. It's not the same as other people's unless we're an identical twin.

That doesn't mean that we can't have some kind of common interest in an abstract concept like the human Genome but it's not clear what it would mean to treat the human Genome as a common heritage. After all it's not as though it's being depleted by somebody doing research on it. It's not as though somebody doing research on the human Genome takes my human Genome away from me in some way.

So other things that we treat as common heritage of humanity like forests or certain kinds of natural resources, those are often things that could be depleted and the human Genome is not really depleted by most of the research we're doing. Some people also felt that well common heritage of humanity means we shouldn't change the human Genome inside of people's bodies. Yes, maybe, maybe not.

You know human Genome is changing all the time. Where our human Genome's are changing with each generation and it's not clear what patents have to do with whether or not people make transgenic humans. In other words, part of the confusion had to do with the fact that people felt that once somebody had a patent on some technology it gave them the right to do, to perform that technology.

And patents don't actually give you that right. Patents only give you the right to exclude other people from doing what you have patented. So that means even if somebody has a patent on biotechnology, we might still regulate it in ways that prevent them from doing A, B or C with that technology.

So I think some of the early debate had to do with genuine ethical concerns about the human Genome but concerns that probably are not to be played out through the patent system. More recently I think there has been a real concern about access to medication and patenting of human DNA as being part of a larger question of patenting in the medical profession, the

medical fields, and how patents may inhibit access in various ways.

Also I think the interest of ethicist has moved much closer to the interest of academic scientists so that there are real concerns about our patents on biological materials in general, our patents on publicly funded science which is a lot of what DNA patents are or at least a lot of the DNA sequences produced with public funding. Are such patents undermining the values of academia? Do they constitute or create a double dipping situation where the public pays once to have the initial research done and then pays again higher prices on some final product that incorporates that patented item.

So those are some of the newer issues that we've come to and I think one of these sort of points that should be made here is that the patent law is a very kind of instrumental consequential sort of law. All law is but laws and areas of law tend to have, often will have numerous goals that we are trying to achieve. The patent law in a sense is very straightforward in it's goals. It's trying to achieve a public good by getting the most stuff to the public.

So when Eric talks about academic saying well where do we set this bar about when a patent should be granted. In fact that's what a patent policy person should be thinking about. Because the patent law is not just there to give rewards to inventors, it's there, it gives rewards to inventors to create

the most public good. And so the questions that the academic, particularly the legal academics are asking are, where should we be setting these bars to create this public good because for something like access to medicine or access to research tools, the question really isn't the public's right against this private right of the inventor but rather the public's short term interest in access now versus a longer term interest in access to perhaps more things if there's a stronger patent.

So I don't think that the debate should be setup as the public interest versus the private reward. Let's see there was one more point I was going to make before I stopped because I have a feeling a lot of people have questions about the ethical issues so I'd rather kind of pull your questions in than me sit here and just discuss.

Well I guess one of the things I would say is that with respect to creating disincentive, so one of the concerns about academia and patenting things that are produced in academia is a question of whether we will [inaudible] patent system, create incentives that actually undermine invention and innovation rather than provide, rather than increase invention and innovation.

This could happen when we get too many patents or when we have too much difficulty licensing patents in and out between companies and academia. It can happen just in general when we have patents on these very early technologies, we might get

what's called rights stacking. That means that in order to produce some final end product down there, we have to use so many patented things, we have to make so many independent negotiations that we would never get to this end product.

It would either be too expensive or just we would never get through the negotiations. And this is why we start talking about things like patent pooling or we start talking about things like raising the bar on when you give a patent so that we don't have so many little, teeny tiny very early stage patents. Because it is possible that the patent law if sort of pitrated incorrectly, if the bar is set in the wrong place could undermine innovation rather than incentivize it. And I think I'll stop with that.

JUSTIN: Thank you. Folks our program ends in 25 minutes exactly so if you have questions begin thinking of them now and people will be passing around microphones. You can also lineup at the microphones.

I want to ask my panel, who is most familiar with the [Canavan] case and we might use that as a little bit of a case study of this whole debate. I could quickly layout the facts or somebody else could.

So [Canavan] disease is a terrible genetic disorder in which a child who has it never develops properly, never learns to speak, never learns to walk or talk, dies in childhood. Some people, parents of children with [Canavan] disease dismayed at the lack of research into the ailment, 10 or 15 years ago got

organized and starting pressing. Recruited a scientist to work with them, gave the very flesh and blood of their children to do this research.

As a matter of fact one couple that I have interviewed took up, frozen autopsy samples from their child Australia and sort of flew them under the airline seat to the United States to hand them over to the researchers and said please help us. Never knowing, never knowing that the research might become, were never told, never informed that the research might become the basis for a patent application.

Well the Miami Children's Hospital, a researcher who was doing this work ultimately discovered the gene whose defect causes Canavan disease, patented that gene and antibodies to the gene and all associated, very long patent application. And then a company that licensed that patent proceeded to shutdown genetic testing for Canavan disease in hospitals all over the country saying, we own this now.

And the parents were outraged, are currently suing the parents and the University, the Miami Children's Hospital have split up, the parents are suing Miami Children's, it's very ugly. Todd you want to talk about this one and sort of [laughter]

TODD: Well I had the pleasant experience of talking about this on 60 Minutes and, once with Morley Safer boring in, so you're doing a good job, you're as good as Morley I think.

The lawyers take a little bit of bashing but let me use a lawyer's clique. Bad cases make bad law. And this I think is a little bit of the tail wagging the dog. This is one of those exceptions where I think there's a lot of issues here that are very difficult particularly in terms of how the licensing program played out and the actions, which the patent holder took.

It informs the discussion I think we're having but I think merely that. I don't think it necessarily should be used as an example that would drive a change in the law because it can be taken care of and likely will be taken care of through these kinds of processes we're talking about.

It is the, the researcher who got the patent was the inventor, he discovered the isolated and purified and took, devoted the innovation to it. The issues around who owned the tissue samples that's an entirely different issue, that's the result of an entirely different matter and we can talk about it but that's a different issue. It's a tough and terrible issue in this case but it's a different issue.

And then the key question is the one I mentioned before about access and how is it being licensed. And when the holders of the gene patents develop their licensing programs they have to be extremely mindful of the kind of public reaction they're going to get and this is a prime example of that public reaction.

Now I'm not going to defend them but the hospital and we could've talked about the myriad sciences example as well. They

have to, they in their, they defend themselves by saying we [sell] a licensing program. We charged X for the test. In the myriad case for example it was about $300. In that case $12 is devoted to the royalty payment. Well that's about 4% royalty payment, that's about a standard royalty in almost any industry for licensing the patent. The rest of it was the cost and test itself.

Did this company, was this company right or was the hospital right in saying only we get to offer the test. Well the patent law says that's right, they invented the test. Is that the smartest thing to do politically or commercially, we wouldn't be talking about it if it was.

__: And let me chime in here. You know, the [M?? and [inaudible] situation in this are the two sort of poster children that are held up as incidents that sort of bring this to fruition.

TODD: Well reporters really [inaudible] by the way.

__: Well of course they do. And these are examples of companies acting poorly. A moral and ethical company, Millennium holds itself as trying out to be one of those companies that thinks about these issues, not only are we very careful about how we're getting tissues from people that they know full well what it's going to be used for. And get proper compensation even when it's appropriate for that but also in deciding how tests are going to

be marketed, how tests are going to be made available. You have to consider these things.

Even if you don't think you should do it as a moral or ethical issue, which we do you got to think of it as, so this doesn't happen to you. I mean a company that, the company that's responsible for this isn't doing too well otherwise because of all the lightening storms. So I think again, I agree with Todd it's an instance of someone acting poorly. It's easy for me to say most companies don't act that way but I think most ethical companies like mine don't do this.

ES: This is such a bad case that it obscures the issue. Because let's take a case where a company acts not poorly, discovers a receptor for something, files a patent on it and now wishes to assert its right to be the only company to screen for a small molecule against that receptor to treat breast cancer.

Now what do you say to the women with breast cancer who argue that why don't we have ten pharmaceutical companies competing with each other to each make the best molecule against that receptor. Economically we in fact are not getting as much innovation at that stage because we've granted the monopoly at this stage. That's not an exceptional case that's the rule.

PILAR: But this is one of the reasons that I said that part of the issue here is the patients and public's short term interest versus their long term interest because this is part of the problem is that the patent law accepts that you will have some

restriction, like you will have higher prices for things while the patent is in place. And the idea is ultimately that will increase what the public has.

ERIC: But we've given the monopoly here for the very cheap innovation of discovering this receptor whereas you've told us it's $500-%800 million to develop that drug. We're in fact going to want to have the competition at that stage. So I agree that you can defend the black letter law the right to have a patent on that but a social policy, it is removed enough from a therapy that matters that I want to see the competition down at that stage.

SCOTT: It's a great argument Eric. It genuinely is. The challenge for public policy makers and for the congress and the courts is where to draw that line and how we make those definitions and it's easy for us to sit here and say that that's the way it ought to be but I talked and he gives a good speech about it, Former Vice President Gore's domestic policy advisor David [Bear], when he was a hill staffer he tried to craft a piece of legislation that would define the research tool exception which we'll probably talk about and he found it impossible to do. He had to drop it because where do you define when research moves from purely academic to commercial.

Universities today derive significant revenue and more and more are doing it every day. I'm going to go address the Autumn conference that is the University of Technology Transport

Administrators later this year and it's a huge organization now. Every University hopes they can exploit their own patent portfolio to try to keep the costs of education down.

JUSTIN: But also I think you're argument is also based on a couple of assumptions that I don't think are really true in the real world.

SCOTT: Okay.

JUSTIN: Number one is the people are running around stopping other people from using the receptors to screen for drugs. I could count on less than one hand the instances where I know that's happened and I think I know them all. I can count, it's going to take many hands for me to count the number of instances where companies have dropped programs because of the clouded patent portfolio.

SCOTT: They're not apparent then the National Academy of Science is studying this issue and their step board. They commissioned a paper, the paper shows in the pharmaceutical industries, the pharmaceutical industry gives a defacto research tool exemption and does not inhibit research. [talkover] no one's sue

__: I can also point to numerous situations where companies have gone forward despite that landscape and continue to develop drugs. So

JUSTIN: And I can point to them where they haven't.

PILAR: You know can I say one thing is that I'm a member of that board actually that is putting out that report. And there is not

nearly the kind of data one would like to have about the influence of, about programs that get dropped for instance. You don't see those and we haven't been able to capture those very well with the data that are out there now. And this is one area where we could really use some good research and we don't have it

ES: How come you don't keep stats. It comes up in priority [talkover] portfolio

__: Exactly. And you have to go out and interview people. You have to go out and interview people to find out. Just like you have to really get into the lab and interview scientists.

Todd?: But they didn't quantify the, they didn't quantify the effort that some may have made to go out and try to attempt to get a license. [talkover]. I think what Scott is saying is that the instances where people have refused to grant licenses are few and far between.

SCOTT: That's right. I mean again don't get me wrong. A company with two projects before it, one of which is a patent mess and one of which is clean, almost being equal, they're going to pursue the clean one but that's because you can only invest in one. That's not to say that if they only had [talkover] that had the patent [challenge]

ERIC: But if the other one's better. You should be investing in it except for the patent mess. Or more important and that's what worries me.

JUSTIN: I thought we'd get some excitement going so I think we have some audience

SCOTT: But again I'm saying, but again all [laws] being equal if, I could tell you companies make this choice all the time. That if they've got two projects and the one that's a patent mess is the one that's more significant either from a what it's going to do for medicine or what potential return there could be on making that, they're still going to make that choice.

ERIC: Okay I make it.

JUSTIN: There's some balance.

__: Let's try a different test case. One that's coming up now. A real live situation. I work with a foundation that has a resource of serum cell lines, DNA of 430 multiplex families who are affected by autism. Complex genetic disorder. We spent $6 million finding these families, training diagnosticians, flying phlebotomists and pediatric neurologists all over the country to give them the best ascertainment there is bar none.

We want desperately for biotech and pharmaceutical companies to come in and work with those samples. But the conversations go like this, we would like to pay you a highly subsidized price by you for these biomaterials and have a 12 month exclusive on them when you can't give them to any academic researcher. We would like to use these samples however we wouldn't possibly consider giving a royalty back to organizations that fund biological

research and autism never mind the fact that with an empty purple top tube there's nothing you can do.

The conversation will go, milestones never heard of it or you know that idea about us agreeing to license and never withhold unilaterally licensing down the road even though you actually are like a fraction of away from joint inventor status. That sounds reasonable for other company but not us.

Now what should we do? How do I get, how do we get 450 or 430 family samples into, into use?

Scott?: Is Sharon Terry in the audience by any wide chance? This has been done and in fact, I mean both Eric and Pilar talked a little bit about this sort of gradual process of education that's happened. Among the people who are getting smarter is the patient groups and they have realized that if we are going to give the flesh and blood of our bodies in our children we are not going to give it for nothing necessarily.

And so one of the answers that sort of beginning to be worked out and I don't, I mean I hope by my panel has some answers for you but Sharon's group, PXE International which deals with the rare genetic disease made an arrangement with researchers, got co-inventor status on the patent. In other words they said to the guy at the University of Hawaii, we ain't giving you this unless you give us some consideration. Not necessarily royalties, I think it was a fairly modest deal.

__: The barrier here is this isn't a rare genetic disease. It affects 1 in 250 people with implications for ADHD, epilepsy and a lot of other things. So actually

SCOTT: The incentives ought to be higher.

__: But there's a lot of money at stake and when there's a lot of money at stake people want to give up even less of it. How do I make sure that the IT goes, remember there's no genes found for autism yet. There's probably enough for everybody in this room to have a patent on a gene for autism.

JUSTIN: Scott how would you solve this problem.

__: [talkover] How do we put that IT in the public

SCOTT: Millennium does many deals with various academic institutions to acquire material of the [inaudible] and we do a wide range of structures. We have done deals of the type that you're saying you would like to see. Obviously companies have to look at the value equation of what they're getting. The rarer the material is, the more unique the material is, the more valuable the material becomes, in two cents, it's not only in what return that you may be able to get as that source but also in the fact it may be the only path to again the drug that's going to get out there, treat patients and make the company some money.

So again, it's sounds like you've been dealing with someone who doesn't have a reasonable sense for what the value of what you're sitting on is. Call another company. If there really is

a market for this thing, if there really is a drug that's going to be viable as a development candidate there's someone who's going to be out there willing to pay you proper value for what you've got.

Again, it's, are you going to get all the bells and whistles, not necessarily but there are people out there that again, deal with sources of tissue in ways that are commensurate with the value of what there, about they're presenting. So you've talked to a cheapskate, call another company. [talkover] Unfortunately [inaudible] doesn't do work in that area or I'd tell you to call my shop after we're done. But we don't do work in that area so it's not something we'd be interested in.

PILAR: And this is also another issue that, this is a licensing, this is a set of licensing problems right? And the point was made earlier that although they're very closely linked, there's a whole, there's a whole world of economic theory and political theory that goes around licensing and how people should be licensing deals, what is reasonable to do, how to structure and incentivize.

That is if you didn't have some kind of property or intellectual property and whether that's a trade secret, whether that's physical property, real property or personal property, if you didn't have something to license it wouldn't be an issue. Sometimes that something is a patent but your problem here is really a licensing problem more than it's a patenting problem.

And this has been, there's learning curve, there's a learning curve that universities [inaudible] offices have gone through in understanding what is even rational for them to do with their patent licensing. So a lot of times perhaps they haven't good patent licensing choices and when you're licensing between public institutions and private, large and small, there is a kind of learning curve that has to happen.

JUSTIN: And they're getting better. Believe me. The academics are getting a lot better.

PILAR: Yeah they are.

SCOTT: School of thought that says the academic community, this is not my opinion but others have voiced it, that the university tech transfer folks and the academic license source are actually worse. They're actually more aggressive, they're more difficult to deal with, they're less understanding of the process

__: Some are

Justin?: They're charging more. I don't think that's necessarily true but it's a, it's a challenging system.

SCOTT: Again it's another [pendulum], this is about the 7th [pendulum] we've [planted] into almost. We're going to be headed by the [pendulums]. But that's another [pendulum] that swung back and forth. Very early on academics were unsophisticated and companies took advantage of them. That day is over. I mean really, I mean probably a good 25% or 30% of the academic institutions we deal with in trying to get and pay them real

value they are as aggressive as any company we deal with in what they're looking for for value.

TODD: There's also an interesting

SCOTT: Just your dollars.

TODD: An interesting irony here a little bit too and it concerns for example the NIH. People worry that commercial entities will get patents and then control the licensing process. The NIH made a conscious decision not to seek, after a brief period where they did seek and obtained for example Francis Collin has several genes patents, Genome patents.

They made a decision, Herald [V??] I think directly did, not to seek particularly EST patents but gene patents perhaps generally. Let's limit it to fragment patents for the discussion. What's intriguing about that of course is that if they had gotten the patents on them, they could've controlled the access there. They could've controlled all the license. They could've set the royalty at zero and prevented the commercial entity from coming and getting a patent on something the same or similar and setting that at something great than zero.

And so by giving up the control, I mean that was a decision they made and I know they made it in good faith but they gave up a significant opportunity for control that the patent system provides.

JUSTIN: And the disease groups have sometimes inadvertently done that same thing. But the point where they have some leverage

they don't know and they sort of hand it over to the researchers. We have a gentlemen who's been waiting very patiently, please.

__: Hi. [Loren Sung] from University of Maryland School of Law. Dr. Lander certainly talked about the fact that the debate seems to be a lot more [forc ous] when you get into very nascent stage technology including the uncovering of Genomic information and part of it is that in terms of the response we've seen this being the case probably because a defacto industry standard that we're talking about here. You can't go out tomorrow and say we won't follow the genetic code here, we're going do our own thing, we're going to have research fall in different lines or approaches.

So that what you have here is the potential bottleneck at a very upstream portion of the technology for all the downstream applications. And one of the things I think the patent attorneys have gotten into and the patent office included is to look at this from the statutory requirements of utility, written description and indeed going back to the obviousness question about saying that we can't look at how routine a particular methodology is to undercover the technology, that once that occurs that that's a fact.

My question deals more with whether or not it's truly an inventive act even beginning. Let's take us away from section 101, 103, 112. Certainly as Mr. Dickinson knows the Federal courts have wrestled with the concept of invention, what's the conception of a piece of DNA or a genetic sequence or a genetic

molecule. The conception really doesn't occur until the sequence information actually comes out because you don't know what the structure of that chemical molecule is. So who's the inventor there? Is it the machine that you put the genetic sample into or is it somebody who visualizes, perhaps it isn't even [talkover]

ERIC: Nobody's visualizing. You put it into the sequencer and you get out the letters. The letters are piped in into the computer, the computer tells you this is similar to a protein kinase and that's what you file. So we can debate whether the inventor is the sequencing machine or the sequence matching computer but it's very rarely in those cases the human who's doing a lot more looking pass there.

__: And that's really my point is that it's less about who we ascribe the invention to but the conundrum that exists there I think drives the question as to whether or not something like this should even be considered an inventive act.

SCOTT: Let me take off my Millennium hat for a minute and put on my metaphysical patent law hat. I think the battle lines is, as we've referred to you several times, over this patent ability issue of genetic information which started with EST example which is really what you're talking about, is the [peristic] example where all you do is throw some hamburger in one end, turn on the machine and you spit out information.

And actually in many companies it goes from that, it looks like a kinase directly into a work processing machine and spits

out the patent application before a human being even sees it. So to take it to the sort of extreme, I think the battleground on utility was the wrong way for that to be fought. I think it should've been fought on whether it really is an invention or not.

You know again, EST is in their pure form, just throw it in, crank it out, it kind of looks like it might be kinase like, I don't think that should be patentable under the system. I think that's an abuse of the system.

__: 103 notwithstanding

SCOTT: 103 notwithstanding [talkover]

PILAR: And in fact though I do think that there are 103 issues.

TODD: 103 is an act of congress. If congress, I'm not defending it one way or another, they responded to a particular supreme court case and particular set of facts as to how one inventor in a very traditional, almost American like way suddenly had this flash of genius.

SCOTT: If it was up to you. But there's not even a flash here.

TODD: Yeah let's give them a chance. [talkover]

SCOTT: Well I'll give you another example that could be analogized to it. The supreme decided a few years ago that a certain level of creativity was necessary to obtain copyright protection. So called [F ??] decision, that the white pages could not be, a standard set of white pages couldn't be

copyrighted. And copywriters that are now I guess intellectual property.

I suppose the opportunity exists for someone to challenge whether there is enough creativity, enough inventorship in this to qualify in an analogous way to the creativity and copyright. Supreme Court may be open to that kind of an argument. The PTO took hearings on that issue and a lot of other issues and we got back, the range of opinion that we got and we made a policy decision at the PTO level. The courts and congress are free to over turn that.

PILAR: Can I just say, I just want to say one [talkover] I want to say 103 here.

JUSTIN: We're running out of time. I think we have one more question from

__: Actually we're web casting this so we have someone on the Internet who has asked question. His name is Michael [Sholman]. He's a medical doctor. He's with Biomedical Consultant to the drug development industry from San Francisco, California. His question, distinguished panelists, can an entity that discovers and patents a gene sequence and function also patent the regulation of its expression without first discovering a means to do so. Must an entity that discovers a way to regulate the expression of gene that has been patented by another entity license the right to regulate that gene's expression from that other entity before commercializing its discovery.

SCOTT: Wow. You want that one or you want me to take it.

TODD: I think the answer to the first is yes and I'm not sure

SCOTT: Well again, one of the requirements of the patent we haven't talked about is the need to enable. In order to get the patent part of the quid pro quo, part of the bargain for getting the monopoly is disclosure of not only what you think you've done but enough information about it to tell someone how to use it, to make and use the invention. That's another statutory requirement and when all [inaudible] property [inaudible] patent with all the time.

So again if they're saying that they've come up with an idea to do it but the question is have they told us enough about how to do it to pull it off. Now technically you can be a disembodied head sitting on a table and never have done anything in order to get a patent. If what you've thought about and described is sufficient to do what you're saying to do. So if this person had that blinding flash, never touched a lab and said you know I would take this kind of a construct and make this type of a molecule and do it this way and I would do this test to see if it was doing what I though it would do and this is how I would get a readout, the answer is yes.

So if they've fallen short of that standard though then they're not going to get something just for having the idea of something you'd like to achieve. That's not good enough, an objective isn't good enough. So there's that fine line between

no do I have to have done eight years of experimentation, no but I better have been a pretty smart head sitting on that table and told enough to really teach people what to do or I haven't kept up my part of the bargain.

JUSTIN: Folks we are out of time now. We would welcome you coming up and sort of continuing to interrogate our panelists. As you can see they're all shy and sort of but we need to finish and I would like to ask you to thank them for coming out and we appreciate it.

[end of recording]