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Laura Pedraza-Fariña

Northwestern University Pritzker School of Law

Rod Passman

Northwestern University Feinberg School of Medicine

Ann Marie Wahls

Latham & Watkins LLP, Litigation & Trial Department

Hari Santhanam

Kirkland & Ellis LLP, Intellectual Property Group

Valerie Eaton

Northwestern University Pritzker School of Law

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**13TH ANNUAL NORTHWESTERN JOURNAL
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TECHNOLOGY**

*Laura Pedraza-Fariña, Rod Passman, Ann Marie Wahls,
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PANEL DISCUSSION: MEDICAL TECHNOLOGY

Laura Pedraza-Fariña,^{} Rod Passman,[†] Ann Marie Wahls,[‡] Hari
Santhanam,[§] & Valerie Eaton^{**}*

LAURA PEDRAZA-FARIÑA: I'm really excited to moderate this discussion, which is going to center mainly around Section 101 (35 U.S.C. § 101) kinds of legal issues, and if we have time we can branch out to talk about inter partes review. So, let me start by introducing the members of the panel, and I'll give a few introductory comments to sort of frame the issues that we will talk about. Then we'll turn it over to the panelists to give some more specific answers to the big issues that I'm going to frame.

My name is Laura Pedraza-Fariña, and I am an associate professor here at Northwestern where I specialize in patent law. I also teach the intellectual property survey course and seminars on innovation and technology. Let me introduce our speakers. We have Ann Marie Wahls, who is a partner in the litigation and trial department at Latham & Watkins. She has lots of trial experience, experience in complex litigation matters, and also experience in biotechnology, which is very relevant to this discussion that we're going to be having here.

And then, let me introduce Hari Santhanam, who is a partner in the IP group of Kirkland & Ellis. Again, a trial lawyer with lots of experience, and experience in particular in the biotechnology area, which is so relevant for the conversation that we're going to have today.

We have Rod Passman, who is actually an MD, so he's going to give us a perspective on practicing physicians. He also has some experience in innovation and trying to figure out how patents impact his day-to-day activities.

And finally, we have Valerie Eaton, who works at Northwestern in the immunology department and is currently pursuing an MSL degree.

^{*} Associate Professor of Law, Northwestern University Pritzker School of Law.

[†] Professor of Medicine (Cardiology) and Preventative Medicine, Northwestern University Feinberg School of Medicine.

[‡] Partner, Latham & Watkins LLP.

[§] Partner, Kirkland & Ellis LLP.

^{**} MSL candidate '18, Northwestern University Pritzker School of Law.

So let me just frame what we want to talk about today. We want to talk about Section 101 and the challenges that recent jurisprudence in Section 101 has caused for diagnostic methods and also, more broadly, methods of treatment. So a brief overview for those of you who may not know what Section 101 is about and how it is framed. In a series of decisions, and the most recent decision is most on point, the Supreme Court has reshaped a lot of patents based on the subject matter. In one particular decision made over Prometheus (*Mayo Collaborative Servs. v. Prometheus Labs., Inc.*), which is the one that is going to impact diagnostic technologies the most, the Supreme Court basically set out what's called a two-step framework to figure out if a diagnostic method or a method of treatment is patentable.

The first step is to figure out if that treatment is directed to a law of nature. The way that *Mayo* set out that test, basically most diagnostics—although this would be something for the panel to talk about—end up being directed to a law of nature, because a lot of diagnostic technology is about finding a clinical relation between a particular marker and a disease.

Then step two is where the Court in *Mayo* introduced this idea of the inventive concept. If a method of treatment is directed to a law of nature, and if you have an inventive concept, then that method of treatment is still patentable. But, what constitutes an inventive concept is something that's been kind of hard to pin down; there are a couple of recent decisions that suggest two different ways of looking at the concept. And so I'll briefly summarize what those positions are, and then we're going to turn it over to the panel with the questions of how the idea of the inventive concept evolved in diagnostic technologies, and is that something that you see in your practice a lot.

Let me set out two cases that seem to be somewhat irreconcilable. There's one particular case that's called *Ariosa* (*Ariosa Diagnostics, Inc. v. Sequenom, Inc.*) which had to do with fetal diagnostic technology. The court basically said, well, this is a law of nature, because all you're finding is that there are some cells of the mother and there are some cells of the fetus that you can find in the mother as well. This was a huge discovery at the time, because it allows non-invasive testing of pregnant mothers. But that was a law of nature, because it existed before it was actually found.

And then the court says once you know that law of nature, then taking those cells out of the mother's blood and testing them for abnormalities is a routine procedure. Those are methods that we know how to do. And so this routine procedure is not enough to make something an entirely inventive concept.

Then there's this other case that's called *CellzDirect* (*Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*) that seems to suggest the court taking a

different tack. In *CellzDirect*, it's a method for basically preserving cells by freezing them twice, when people thought that it would only work by freezing them once. It turns out you can freeze them twice and the cells survive. So potentially that's a law of nature: You find that the cells can survive two freezings. And here, the Federal Circuit said something quite interesting. The Federal Circuit says, yes, but freezing it twice is not a routine step, because people weren't doing that in the real world before. So there's a contrast between the two cases: When we talk about routine steps that are not part of any inventive concept, are those routine steps things that in fact were happening in the real world, or are they things that anybody would know how to do once you actually know the law of nature? So the *CellzDirect* case maybe provided hope for people who are doing diagnostics, but maybe that hope has been shattered by subsequent decisions. So that would be one question to the panel: There are these two cases that are similarly irreconcilable, but we have had later cases since then, so what do we think about that dynamic?

And then I'm going to ask some broader questions about whether the panelists think that the Supreme Court got it right. The broader question of whether patents promote innovation or access to diagnosis, and the even broader question of—and somebody who is involved in medicine might be able to contribute to this—do we even need patents in this technology? Are there other alternatives that will give us those diagnostics?

So did the Supreme Court get it right in basically eliminating a lot of diagnostics in method of treatment and patent protection? I will now open it up for a lively discussion.

HARI SANTHANAM: I don't know how many of you have a background in patent law, but the number one issue is a recent issue that's coming up more and more in a lot of cases. And a lot of times, when you think of patents, you think about: Did somebody do it before? Is this obvious? Is this otherwise valid? And the question here on Section 101 is: Is it actually eligible for a patent in the first place? And the Supreme Court has said, well, it used to be all the way back to the 1980s, because of a case called *Diamond v. Chakrabarty*. Anything under the sun made by man could be patent-eligible, so long as it meets some other requirements. And the issue here is, well, okay, are our diagnostics tools patentable? And as was pointed out, there are a number of conflicting cases that have now come up, and this is an evolving area of law. So the *CellzDirect* cases are on one end, the *Ariosa* case is on the other end. There's a host of other cases that are pending before the Federal Circuit.

And this is a unique area of patent law, because there's been patent cases here before just one circuit. It's not the Seventh Circuit versus the

Federal Circuit. These are cases that one panel decides that might be conflicting with a case in another panel, within the same circuit. But to address this issue, at least from my perspective, of the patentability of diagnostics, I think it goes back to when *Mayo* came down. All these cases were just trying to say, okay, well, how similar is this diagnostic tool to *Mayo*, and if it looks like it, smells like it, walks like it, it's the same thing and it invalidates it.

And in *CellzDirect*, it was somewhat different in that it wasn't really a diagnostic tool. It was more of a laboratory technique, and what was specifically an issue there was hepatocytes—these liver cells—and they were using hepatocytes, culturing them to run experiments. And they came up with the way of being able to preserve these liver cells so that you can use them in research in a way that others had not done in the past. So it wasn't so much as detecting something in the body that's naturally occurring. They focused on the fact that there was an actual improvement to a method that people were using.

But bottom line is, they do seem conflicting, and that's one of the issues that we have to deal with. I'll stop talking and send it over to some other folks, but it all depends, at least from my perspective, on when a judge takes a look at the case and says, well, how close is it to *Mayo*? Does it smell like *Mayo*? Does it walk and talk like *Mayo*? And if it is, then I think that really just colors the analysis going forward.

ROD PASSMAN: So I'm not a lawyer, and I will tell you as I hear you speak, what interests me is that every day, every medical journal in the world, people describe a better way to do something. And no one thinks that I want to patent this idea, right? I'm a cardiac electrophysiologist; I do procedures on people's hearts with catheters and pacemakers and defibrillators. We're always tweaking what's out there to make it better. But hardly any of us would say those tweaks are worthy of patents.

So in the case you're describing, it seems to me, you're using well-defined techniques to sort of push the boundaries a little. But it doesn't sound terribly original to me. So as a layperson, in the medical community, could you explain to me why something like that is patentable? And why every article that I write that takes existing technologies and maybe finds a better way to do it, why isn't that patentable?

HARI SANTHANAM: Well, I'd say that there are two issues here, right? One is, okay, is it patent-eligible? That is, does it fall within the categories of what could be potentially patented? And with the second, it's how knowledgeable or nonobvious is this? And there's some overlap between these positions, the way that the Supreme Court is defining the standards. But the question I think is: Is this a natural phenomenon? Is this a law of

nature that we're just trying to usurp and patent? But at the same time, you also have to look at how have other people looked at this. Is this a common research technique? Is it just a basic laboratory principle that you're applying? And so I think the questions are a little bit different.

But I think the answer to your question—how people are going about having small advancements—I'm not necessarily an advocate of it. But I think that how it's justified is that everything that you patent is really just an incremental change from what somebody else has done. You're always taking a body of law, of art that's out there, combining things and putting together and ultimately coming up with something that you can say wasn't in the patent a priori—what came before. And we put some inventive thought into it, so it's not obvious. And so most things are incremental improvements. So that's how they justify you getting the patents.

Ann Marie Wahls: And I'll add to your point, Doctor, about when to patent versus when not to patent. I think a lot of it also depends on who's doing the discovering, and what kind of motivation is behind it. So for research institutions, perhaps there isn't as much of a motivation to go and get a patent because they're not necessarily commercializing anything. It's more just to advance science and continue on with new discoveries. But for diagnostic startups that perhaps are looking to commercialize their discoveries and invest millions and millions of dollars into discovering these new diagnostics, and meeting with venture capitalists to come and back them up, patents are much more important to them because if they don't have that patent protection—or at least they say they can't have patent protection—it's going to be more difficult for them to get the funding that they need.

At the same time, I think for companies that do patent these diagnostics, they're also more willing to go out there and educate the public and educate the physicians about these diagnostics. They're more willing to work with insurance companies to help get them on board to pay for these things. So, overall, I really think it does benefit the patient in the end. I think with this recent line of cases, *Mayo* and the Federal Circuit project that comes after it, it's going to be more difficult, for sure, to get those kinds of patents going forward. That may have an effect on the introduction and the commercialization of that practice.

Hari Santhanam: And one thing I would add to what Ann Marie said is, yeah, I do think a lot of universities take that approach. That is, we're doing basic research, we shouldn't have to get a patent. That was the mentality all the way through I think the early 2000s, but more and more we're seeing in litigation that universities are becoming involved. The Wisconsin Alumni Research Foundation is probably into the licensing arm of the University of Wisconsin, and a lot of universities now are also doing

the same approach. They're taking all the patents that they've accumulated, and then they're creating a licensing arm that goes out and tries to monetize those patents. It's a shift in the paradigm.

ROD PASSMAN: Well I'll tell you, I've had some experiences where some of the research that I'm doing has some potential intellectual property involved. But the companies that I am working with basically would say, we don't think that you do. You could fight us, you could get your lawyers, and this could take years, and what is that going to do to your research, right? I'm more interested in getting my research out there; the potential benefit of a patent may be there, but it's not what my motivations are. So how does Northwestern go against a very, very large company willing to fight you tooth and nail every day, and what does that do to the progress of your work? Most of us would throw our hands up and say, "I give up," right? "I care about doing my research, that's why I'm here." We wouldn't even pursue that line of thinking.

LAURA PEDRAZA-FARIÑA: I have a follow-up question to continue with that discussion. It's quite interesting to think about who is doing diagnostics. So Hari and Rod, you brought two interesting issues, I think, about who is doing the diagnostic development, and then the commercialization point. Now, one argument that the Court got it right might be that the people that are doing diagnostic development—a lot of them are universities. If you look at *Ariosa*, if you look at all of this stuff, at things that doctors discovered, and potentially then transferred it up—I'm not sure of the backing of the case, but it does seem that potentially it might be a tech transfer out of the university but then maybe was licensed or transferred, right, to a development company, to a for-profit company. And so the question is, number one: Do we need the startups for development diagnostics? Do you know anything about that? What's the balance, right? Is a lot of it done at universities? Many cases including *Myriad (Ass'n for Molecular Pathology v. Myriad Genetics, Inc.)*, which is not about diagnostics but about genes, and the big part of the discoveries were done at universities. So, do you have any sense about what the breakdown is?

And then the second one is: Are diagnostic methods of treatment the type of technology that doesn't require the same amount of huge investment that a drug might? So do you see a difference between drugs and diagnostics? Once you stepped from what the doctor has discovered to the application, it may not be as costly, right? What about the idea that, if you're worried about commercializing diagnostics, diagnostics almost commercialize themselves, once you figure out this stuff?

ANN MARIE WAHLS: I think it probably depends on the type of diagnostics. So, if it's something that's looking for a mutation in a certain

gene, that may be very time-consuming and extremely costly to actually find that mutation across an entire genome. That may require a greater investment in time and resources than some other type of diagnostic that maybe isn't as difficult to develop. I'm not really sure about the breakdown between what's done at the university versus what's done at startups or big corporations. Maybe Valerie might be able to shed more light on that.

VALERIE EATON: One of the projects that I'm working on in the lab is basically biomarker discoveries. So we're also finding a panel of proteins that could be used to screen for multiple sclerosis or track to see the progression. That's been a huge investment of money and time to develop that project. Even though a lot of the diagnostic tests are done by startups, in this case the university would actually have an interest in patenting it, just because it is a huge investment of time. So, I think that kind of factors into it too just because of how much effort goes into it as well.

ROD PASSMAN: But I do think that the bar is somewhat lower than a drug or a device, where you need to show outcomes, right? So, thousands of patients, potentially millions of dollars, lots and lots of time. I think that it's probably easier to do a diagnostic, once you've shown that it's sensitive and specific and all that. I think one of the interesting questions clinically is that when you come up with something—I don't have a lab, my lab is my patients, and then we get into the conflict of interest issue, right? If I'm trying to develop something, and I'm using Northwestern patients to help develop that, and I have a company that's developing that, then what is my role as their treating physician, in terms of my conflict of interest? So, there's another layer of complexity, from my perspective.

So, I'd almost rather not go there; it's easiest to not go there.

HARI SANTHANAM: Yeah, I do think it's not clear where the divide is between a university that originated diagnostic tools versus startups. But we do see a lot of them in these cases that are popping up. *Ariosa* was one of them, *Myriad* was one of them.

Another case that's currently pending is brought up by the Cleveland Clinic (*Cleveland Clinic Found. v. True Health Diagnostics LLC*). It's a similar diagnostic case where what they're looking at is an analyte in the blood and trying to correlate it with cardiovascular disease. And the court just applied *Ariosa* and said, okay, well, this is not eligible for patent-eligible subject matter. And that case went up to the Federal Circuit, and the Federal Circuit said it's invalid. And there's now a cert. petition that's been filed. It's gotten past the typical result of cert. petitions, which is usually getting denied. Now, the court has asked for a response, and then I think what would really be telling is if they asked for the views of the Solicitor General because this area is evolving. There's a lot of money at play, and there is a lot of

research that goes into developing the diagnostic tools. So, do you want a system that possibly just invalidates any diagnostic backing? That's one of the issues that the Supreme Court's being asked to consider right now.

ANN MARIE WAHLS: I think the Federal Circuit has recognized that, too. So, in the rehearing of the petition en banc in *Ariosa* that went to the Federal Circuit which was denied, two of the judges, Judge Lori and Judge Moore, came out and said, yeah, we agree that it's under the current framework, provided in *Mayo*. We reached the right decision here. But this has huge implications on the diagnostic industry overall. They recognized the significance of these types of decisions to diagnostics and just the medical community in general. But, they also, you could tell from the opinion, it seemed like they felt like their hands were a little tied by *Mayo*, and they had to do it and the court told them.

LAURA PEDRAZA-FARIÑA: And do you agree with that? Is it that the Supreme Court got it wrong in *Mayo* in that there's always just one potential outcome, or is it maybe that the Federal Circuit is applying it in sort of an inflexible way? Is there a way to be more creative about how we interpret *Mayo*?

HARI SANTHANAM: Sure, and I think my perspective on *Mayo* is the two-part test. So, you had to look at whether, first of all, was it directed to a natural phenomenon. Then you'd say, okay, well, is it adding something that makes it inventive? And I think what the Supreme Court didn't do in *Mayo* that's causing all of this confusion is, well, how do you really apply that first step? And depending on what level of abstraction that the judge or the Federal Circuit decides to use, then they can say, well, it's a natural phenomenon or it's not a natural phenomenon. So, in *Ariosa* they said, it's just a relationship between the cffDNA and a particular condition. And they said, well, that's a natural phenomenon. If you attack this cffDNA, it's a diagnostic marker, it's just a natural phenomenon. Whereas if you go to *CellzDirect* they say, well, it's not a natural phenomenon. You're not patenting cells, you're patenting a tool to create those cells. And so I think there's an interesting quote that came out of the *CellzDirect* case that really summarizes what the first step of the *Mayo* test is, and what the problem is, and it's the level of abstraction.

If you look at any patent on a drug, you can say, well, that's a natural phenomenon. It's just showing how the drug interacts with the human body, and so that's a natural phenomenon. But that's not the level of abstraction that most people look at; they look at a drug as a chemical compound that's been synthesized and processed, and it's new and useful and nonobvious. Similarly, if you look at a diagnostic test and you say, well, it's not really the relationship between this analyte in your blood and this medical condition—

if you look at it at the level of a diagnostic tool—then you get past that first *Mayo* step. So I think we need more guidance on *Mayo* step one, and possibly the Supreme Court is going to provide it in some of these cases that are coming up.

ANN MARIE WAHLS: I agree, Hari. I think that step one right now is just so broad. It just covers any kind of what they consider natural phenomena. Anything that's naturally occurring falls under step one. The Federal Circuit and *CellzDirect*, so the liver cell case, try to sort of play with the framework a little bit. So they said no, it's not really directed to these liver cells. It's directed to this method that they discovered to freeze, and then they do this twice-cycling of the cryopreservation of these liver cells. And so that's what is really being patented here, and it's nothing to do with the liver cells themselves. And I think they are trying to find a way to work around it, although in some of the cases they're just so close to *Mayo* that it's hard to pull away from that. I think they feel very much compelled that they have to apply that *Mayo* framework the same way the Supreme Court did in *Mayo*.

HARI SANTHANAM: I think we've got a question.

AUDIENCE MEMBER 1 [KEYNOTE SPEAKER JAMES O. WILSON, MIDWEST REGIONAL OFFICE OF THE U.S. PATENT & TRADEMARK OFFICE]: I have a question. For me, when I think about intellectual property, I think about the inventive concept and the hand of man that goes into the development of that inventive concept. So, in my mind, I see a scientist or someone working in one of these companies that does diagnostics. I see someone coming up with a way of doing something, or a way of putting together a set of steps that would not be naturally occurring, but that would require some thought process or some inventive concept in somebody's mind to put a set of steps together to arrive at something that is patentable, whether it's a diagnostic or whether it's a drug, or whatever.

That, to me, seems like it should be the standard, and it should be where we attack. I'm from the patent office [laughter] and where the lawyers and the patent office attack the position in *Mayo* is a clearer understanding and definition of the inventive concept and the hand of man, being involved in that thought process. Nobody said that the Court got it wrong. None of them ventured forth to say that the Court got it wrong. I work for the patent office, and I think they got it wrong. I think that they threw a monkey wrench into the system, that they didn't have enough understanding of the specifics and the particular nuances, and—I'm not going to try to work with your Ferrari, you know? I might work with your garbage disposal, but I'm not going to work with your Ferrari.

So there's some aspects and some types of law that you might need a little more assistance from the experts.

ANN MARIE WAHLS: I do, I see what you're saying. And yeah, you look at these opinions, and there isn't much discussion about all of the time, the effort, the research, how complex these issues were, to make these discoveries, right? There just isn't that discussion in the opinions, and so it really seems like something that the court really hasn't talked about. They're looking at it more from an elevated level and saying, well, it's naturally occurring. It's a natural phenomenon that you discovered, and while that discovery is substantial and significant, it doesn't rise to the level of patentability because there wasn't that additional inventive step that was added to transform it into something that was patentable.

VALERIE EATON: I agree with that, especially in my case with my discovery project that I'm working on. I think the process should be, even if the thing that you are trying to patent is a natural phenomenon, how you're using it or how you're applying it should be the questions. Because if you're looking at nervous system proteins, of course they're going to change during the course of a disease like multiple sclerosis. But if you're thinking about applying it to actually tracking the course of the disease, that wouldn't necessarily be something that's obvious to look at. So, if you're taking that phenomenon and applying it in that way, I think that sounds like it should be patentable.

JAMES O. WILSON: The patent office is replete with examples of something we know works this way, but they're taking it and applying it another way. For example, Viagra. Viagra was a high blood pressure medicine. It just happened to have this secondary impact and effect that now you have patentability in another aspect, in another way. So, I agree with you. You still have to say they got it wrong, though.

LAURA PEDRAZA-FARIÑA: Well, I'm not sure they got it, so I think in some ways they got it wrong. This is how I think *Ariosa* in particular got it wrong, and the whole inventive concept idea is quite problematic. If what you're trying to say is that there's a law of nature, and it could be a narrow law of nature, one of my thoughts is that that's where you could try to fix this. There's an older case in which the court says, if it's a narrow technical environment, we don't care. If it's a law of nature, it's a law of nature, but it doesn't make sense, in my opinion, because you care about scope. And if it's a small law of nature, it's not the same thing as $E = mc^2$.

So the court case that I'm talking about, you can't patent $E = mc^2$ and then they sort of pair it, therefore you can't patent anything that has a whiff of being in nature. $E = mc^2$, of course, is a huge scope, whereas the relationship between two proteins in particular, you could make it even

narrower. That could be really narrow in scope. So that is one thing where I think the courts are getting it wrong, and maybe one way to fix it is to say, actually, the scope of the law of nature might matter. You're talking about do we care about the big contribution, and I think the court knows that it takes a lot. I mean, the Supreme Court is saying we know this is an enormous amount of time and commitment, but there's this line that basic research should never be patentable. But then that line is really hard to draw. In terms of the inventive concept, if you look at *Mayo* as saying you take out the law of nature, you can't use that to figure if you were inventive. That's often what is inventive about many diagnostic technologies, right?

In *Ariosa*, what was inventive was we discovered there are fetal cells in the mother's blood. That's huge. But that's a law of nature, so that's not part of the inventive concept. And you have to add something else, and that other stuff is often stuff you would routinely do.

HARI SANTHANAM: It is something that came up in the Supreme Court cases, both in *Myriad* and in *Mayo*, this issue of preemption. So, the whole idea of having this 101 law is to say, well, you don't want to take a law of nature and preempt its use for everybody. And if you preempt $E = mc^2$, nobody else following you can practice anything that uses that concept, right? And so, a lot of times, in cases that analyze this 101 issue, they'll say, okay, well what are you preempting? And if you're not preempting very much, that's relevant to the analysis of whether it's patent-eligible. And in *Ariosa*, they said, well, it doesn't matter. Even if you look at how much you're preempting, you just follow the *Mayo* framework, and if the *Mayo* framework tells you it's not patentable, then so be it. And I think one of the things that the Court needs to take a look at is, okay, how do we figure out what role this preemption plays in this analysis, and it may be that step one of *Mayo* at some point in the future is going to have to take a look at preemption.

ROD PASSMAN: So, what about every naturally occurring therapeutic plant? Going back to the 1770s, where digitalis was made from foxglove. Quinine was made from the bark of the cinchona tree. The reason the Wisconsin Alumni Foundation exists is because cattle were eating spoiled cloves that had blood thinner in it, and it isolated that blood thinner, leading to the discovery of warfarin. So, what about all those, right? They had saved hundreds of thousands of lives, over the last 250 years. If I discovered a naturally occurring plant that had a therapeutic benefit to it, is that patentable? I wouldn't even have to do very much to it.

JAMES O. WILSON: Is that for me? [laughter]

LAURA PEDRAZA-FARIÑA: We can probably tackle it. I would say that *Myriad* is in a different position than this. There's some interesting language

in *Myriad* suggesting that what you care about is the structure of the chemical, as long as you purify it and you isolate it.

JAMES O. WILSON: And you would probably get a patent for the isolation compound—not the compound itself—because the compounds naturally occur. But how you go about extracting, obtaining, quantifying, and getting an amount of that compound, that is probably what you can process and get a patent for—the process for isolating this compound.

HARI SANTHANAM: It's important to say that it is a process, not the actual compound. It used to be, before *Myriad*, you could get patents on isolated DNA. It went back to the *Chakrabarty* case that said you could patent anything under the sun made by man. And these were the breast cancer genes that were at issue; they were challenged, and they said you can't patent DNA even if you isolate it into a pure form that doesn't exist in nature.

LAURA PEDRAZA-FARIÑA: But I would quibble with that. I think it depends on how you read *Myriad*, because there was that argument about patenting this DNA structure, and the Court said, eh, but we really care about the information. So, for isolating chemicals, you potentially might be able to make an argument that *Myriad* leaves you the ability so long as it's isolated and purified.

HARI SANTHANAM: It's a tough argument to get through, I'm sure the patent office—

JAMES O. WILSON: You're not talking to me? [laughter]

LAURA PEDRAZA-FARIÑA: He wishes to deny it [laughter]. There's a reading of *Myriad* where [the Court] is dividing DNA from chemicals.

HARI SANTHANAM: Question back there.

AUDIENCE MEMBER 2: In both *Myriad* and *Mayo*, the litigants fastidiously avoided raising issues about an expert coming in. So, in these cases, you had the Supreme Court using their own point of elementary science to say cDNA is one thing, but DNA is another. Now, my clients, who are prizewinners in this area, tell me there is a physical difference. And so part of the problem that the Supreme Court has is that so often they're not given the proper tools. It seems to be that the litigants in these cases want a bright-line test, and so they come in and they get a bright-line test, or they ask for a bright-line test. Then you have the issue of, well, be careful of what you ask for, because if the Supreme Court comes in without benefit of expert testimony, and engages in these questions—so, talk amongst yourselves.

HARI SANTHANAM: At least in recent history, that issue would come up in the early stages of the case, which usually would go to trial [with] expert testimony and the jury would decide it. But nowadays one of the common tactics that you see in cases is that the patent owners, or the accusative infringers, will challenge the patent eligibility right at the

beginning of the case and on the pleadings. And you're getting these [Section] 101 decisions that invalidate patents without any expert testimony or testimony at all on the pleadings, and that's another issue that's being challenged. The Federal Circuit, frankly, is all over the place on it. Some cases will say, yeah, you need some additional factual reference. Some will say no, it's okay. And again, that's another issue that's up on cert. in the *Cleveland Clinic* case.

LAURA PEDRAZA-FARIÑA: There's this tug of war in some ways between the Supreme Court and the Federal Circuit, and there are different ways to interpret what is going on. Some people might think that the Supreme Court doesn't have enough expertise, and so some of the decisions are sort of inaccurate. For the cDNA case, my guess is that the Supreme Court had all the information. I think they understood the science, but they were trying to create a rule that was maybe sort of reflective of some political economy concerns. We can't get rid of all of biotechnology.

AUDIENCE MEMBER 2: But whether they understood the science or not—it seems to me as a litigator—that's a fact issue and [not] something that the Supreme Court should be ruling on. I was on the board of AIPLA at the time they were preparing our amicus filing, and there was real resistance, and not just amongst us. There was great resistance to sort of going a step back and saying, "Throw this back to the District Court and have some factual issues," because everybody wants a hard and fast ruling. And, in the meantime, you have a Federal Circuit that is fully incapable of providing any meaningful guidance to the Supreme Court, or at least consistent guidance.

HARI SANTHANAM: I think it just goes back to them—some of it might be they didn't want to get rid of this ability to have some information from the genes altogether. And it might have been an amicus brief just like the ones that you filed, that kind of swayed them that way. But for those in the audience who don't quite appreciate what the difference is, in *Myriad*, they addressed whether or not you could take a gene, isolate it, and take the information from that gene and patent it. Whereas cDNA isn't from DNA itself. If you take the mRNA from within the cell, you reverse transcribe it and it's got a lot of the same information, but it takes out what you call these introns that occur naturally in DNA. So, they were trying to make some sort of distinction to say, well, naturally occurring means DNA has all these introns. But cDNA isn't naturally occurring. It's man-made and therefore it might be patentable. In reality, there's really not that much of a difference.

LAURA PEDRAZA-FARIÑA: The information that you care about, right, is there. I think we're being told that we're close to our time. Does anybody have one more question?

AUDIENCE MEMBER 3: I'm not sure this is a question, as much as another observation. I did some research this semester on something akin to what you were saying about this use of natural therapeutics, and the way that plays into the patent process. And I think it's really interesting to bring up this question of the process of discovery versus the process of invention, and who is actually responsible for making those discoveries. Because I think the example of the cows eating a certain substance and it has this effect, and a farmer would see it's having this effect on [their] cows. Or, indigenous populations for centuries have been using certain plants or something for certain medicinal effects. Then that knowledge gets carried over by maybe a research institution, or private developer, and they're able to get it patented. And I'm not saying that's not a separate process, but it takes a lot of work and expertise, and that's certainly important and worthy of protection. But it does feel a little bit undercut by the fact that this is knowledge that existed in the ether for much longer than that process. So, again, not a question, just something for discussion, maybe.

HARI SANTHANAM: You're right, there are a lot of these natural therapeutics that are out there, and it's a tough area where you're trying to patent it, at least at this stage close to *Myriad*. But I think the focus now is starting to go towards the process of patents and method patents where you say, well, we're not claiming the compound in the tree bark, we're claiming the way of extracting it out of the tree bark, putting it into a pharmaceutical composition, and then using it. That's where I see the trend going in this area. Pre-*Myriad*, that might have actually been the patent saying, well, we isolated it. Even though it's existing in nature, we isolated and it's in a purified form, therefore it's patentable. But post-*Myriad*, yeah, I think it's going towards process patents.

ANN MARIE WAHLS: Yeah, and I agree with that. And to your point earlier about preemption, I think that's the reason it is going towards process patents, because you're trying to avoid preempting the entire field from using something that would otherwise be naturally occurring, natural phenomena.

HARI SANTHANAM: Used for hundreds of years.

ANN MARIE WAHLS: Exactly.

LAURA PEDRAZA-FARIÑA: Thank you so much.