In The Matter Of:

ASSOCIATION FOR MOLECULAR v.
UNITED STATES PATENT AND

February 2, 2010

CONFERENCE
SOUTHERN DISTRICT REPORTERS
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NEW YORK., NY 10007
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Original File 022SASSOCIATION.txt, Pages 1-81

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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ASSOCIATION FOR MOLECULAR PATHOLOGY, et al.,

Plaintiffs,

v. 09 Civ. 4515

UNITED STATES PATENT AND TRADEMARK OFFICE, et al.,

Defendants.

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February 2, 2010
10 a.m.

Before:

HON. ROBERT W. SWEET,

District Judge

APPEARANCES

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(Case called)

THE COURT: Let me ask if there are lawyers who are seated in the audience section, so to speak, may I suggest that you come up and use the jury box and that will perhaps free up some seats for those who are standing.

Okay, we are here on the Association's case, the motions against the Patent Office and Myriad. I am sure you are all familiar with that.

Counsel, have you all worked out how you are going to proceed?

MR. HANSEN: Your Honor, we haven't discussed it but we have been assuming plaintiffs would present all of their arguments on all the motions and then defendants would present all of their arguments on the motions, and I don't know, and if your Honor wanted rebuttal we could allow for rebuttal.

THE COURT: How is that?

MR. POISSANT: I was proceeding on that assumption.

MR. MORRISON: That is fine for the government.

THE COURT: Okay.

I will hear from the plaintiffs.

MR. HANSEN: Good morning.

Chris Hansen, one of the lawyers representing the plaintiffs in this case.

I am going to discuss the facts of the case, the claim construction issues and the constitutional claims. My co-counsel, Ms. Park, is going to discuss the law relative to Section 101 of the Patent Act governing what is eligible patentable subject matter.

This case has produced an enormous volume of paper. It's an understatement to say that we have submitted voluminous papers. But this case really matters to individual women and individual Americans. It involves two human genes, which the Patent Office has granted a patent on. These human genes correlate with an increased risk of breast and ovarian cancer particularly among women. And it is because of the authority granted under the Patent Act that allows the patent holder to prohibit all research on these genes and allows the patent holder to bar or monopolize clinical testing of these genes that we are here.

The plaintiffs include four major associations of physicians, researchers, clinicians and pathologists and among our amici include the American Medical Association and other major national organizations of physicians and clinicians. It may be an exaggeration at all to say that the plaintiffs are supported by essentially the entire American medical establishment that believes that the patents in this case are harmful for women's health.

There are a lot of disagreements represented in the papers that the parties have submitted and the parties have spent a great deal of time trying to explain the nature of DNA

and the nature of the complexities of this case. But when all of that is stripped away, this case comes down to two very fundamental and very simple questions: First, is isolated DNA markedly different than DNA? Markedly different is the standard set by the United States Supreme Court in Chakrabarty, and all of the patent claims in this case that deal with the DNA themselves are premised on the notion that isolated DNA is, in fact, markedly different.

The second critical question is with respect to the method claims that are being challenged, which involve comparing two forms of DNA, can you read into those method claims language that isn't there, and by doing so somehow save the claims?

I would like to talk first about the composition claims and then about the method claims.

The composition claims are claims over "isolated DNA." DNA is a molecule that appears in the body. It's very fundamental to life. It provides the information our body uses to create proteins. It also passes down the information about us to our children.

DNA is composed of chemicals called bases or nucleotides and these bases or nucleotides are strung together in long segments. A long segment of DNA that does something in the body that creates a protein is called a gene. And what defendants have patented is what they have called the BRCA1 and

the BRCA2 genes. They have patented a large number of forms of the BRCA1 and BRCA2 genes but the court actually need not go into most of those forms of the gene because so long as any one of the things that is encompassed by the claim is a product of nature or a law of nature, the claim must fall. And so I am only going to really discuss one of the forms of the composition claims that are encompassed by these patents.

One thing we are clear on is that Myriad does claim BRCA1 and BRCA2 genes that are taken out of the body and taken out of the cell and cut down to the length that the BRCA1 and BRCA2 gene is. They may claim a lot more things than that. In fact, they may claim the entire DNA so long as the BRCA1 gene is in there somewhere, but we don't really know. They have been somewhat vague in their papers about that. But we know it covers the isolated BRCA1 and BRCA2 genes. And we also know that it covers those genes, including the parts of the gene that actually function, which are called exons, and the part of the genes that actually don't provide much function, which are called introns.

Now, let's think for just a second about whether the isolated DNA is markedly different than DNA. The parties have cast that argument in terms of structure and function -- the structure of the DNA in the body, the structure of the DNA isolated, the function of the DNA in the body, and function isolated.

Those are really surrogate ways of getting at the question whether it's markedly different or not. And the bottom line is DNA in its isolated form is not markedly different than DNA in the body. There are of course differences. It's not when it's isolated it's not surrounded by the body. It's not surrounded by the other things in the cell. It's not surrounded by other things that sort of attach to the DNA that are called by scientists chromatin. But the DNA itself is fundamentally the same.

And here is the best evidence for how we know that: What Myriad does for a living is it has you send a sample of blood or saliva, something that has DNA in it, and they will, then, isolate your DNA from the blood or saliva. They will sequence it so as to get a long string of letters that represent the nucleotides or bases that I was talking about. And then they look along the string of letters and they say is this string of letters the way it's supposed to be or is it different than it's supposed to be, and they write back to the woman involved and they say, your DNA is exactly the way it's supposed to be, don't worry about it; or, they say, your DNA has mutations and the mutations have the following significance. They don't say the DNA in our test tube has mutations or has variations.

But we have no idea what the DNA in your body looks like. That would be useless to the women involved and it would

be a useless form of business. What they say is the DNA in your body has mutations. If the DNA that is isolated were different than the DNA in the body they couldn't say that. By definition the informational content, the structure of the DNA isolated has to be the same as the DNA in the body or they can't draw the conclusions that they draw.

We have used a couple of metaphors in our briefs to sort of discuss the nature of isolation and whether isolation makes any difference or not.

THE COURT: I would like the gold one.

MR. HANSEN: As do I, although there is a question as to whether the gold one works.

Let me try a couple of others because this is the crux of the case.

As I am standing here right now and I pricked my finger and let the drop fall on the podium, the blood on the podium would be isolated from my body. It would still be blood. It would not be an invention of any kind in the same way that the isolated DNA is not an invention.

THE COURT: But Myriad takes the position that there is a chemical change and that is accurate. There is a chemical change.

MR. HANSEN: I am not sure it's accurate because the chemical change has to do with the non-DNA parts.

THE COURT: But it is a chemical change. Submitted to

analysis the chemistry is different from the isolated DNA and the DNA -- and correct me if I am wrong.

Listen, I am wearing my DNA tie but I certainly don't want to indicate that I have the strength and the familiarity with these concepts as you do. So if I am wrong correct me.

MR. HANSEN: It's certainly true that the chemical structure is not markedly different but more essentially it's not really different in any meaningful way. So DNA, as I said, consists of these nucleotides or bases, which are chemicals, and these chemicals are linked together one right after the other represented by the four letters -- the nucleotides in the body, the nucleotides isolated, the chemical structure, claimed chemical structure. The sequence of the nucleotides in the body and the sequence of the nucleotides isolated, identical. Otherwise it doesn't make any sense.

Now, it is true that in the body sometimes the DNA has things attached to it. Sometimes it has metulation attached to it. Sometimes it has protein attached to it. There are things attached to it and that is what the scientists call chromatins but what we call DNA doesn't include those things. And so the DNA itself, whether it's in the body or whether it's isolated, is certainly not markedly different and, in fact, virtually identical.

And the other metaphor I would use, one other metaphor I would use for you is to take this out of the context of

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products of nature and laws of nature and think of it in ordinary context. And the example we keep using in our briefs is the carburetor. Everyone knows a carburetor is patentable. But taking the carburetor out of the body of the car, out of the engine, and holding it in your hand -- in other words, isolating it from the engine -- doesn't make it a different carburetor. There are a little bit of structural differences. You have unscrewed the screws and taken the screws out of the carburetor so maybe it has screws in it when it's in the engine and not when it's out of the engine. But to talk about an isolated carburetor or isolated blood or isolated gold is different than the carburetor in the car or the gold in the stream or the blood in my veins. It's just simply incorrect.

Myriad also claims with respect to its composition claims the mutations on the gene. Now, they don't, of course, claim they invented the mutations on the gene and they don't claim that they caused the mutations in the gene. But they claim a patent over the mutations on the gene. The mutations, the place where the -- a mutation in the gene means the nucleotide, the sequence is wrong somewhere and where there was supposed to be a C there is now a T or maybe there is whole big segment missing or a big whole segment that is in there that doesn't belong in there.

Those are things that occur in the body and in nature but Myriad has claimed a patent over those mutations. It's the

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same DNA in the same way that the non-mutated DNA is the same in the body. Similarly, the DNA that contains mutations is the same as it is in the body. The same nucleotides, the same sequences. Mutations are caused by nature not by the scientists. And the significance of the mutations is caused by nature not by the scientists.

The significance of the mutation, is this going to create an increased risk of breast or ovarian cancer or is it not?

THE COURT: Isn't that the result of their research, that knowledge?

MR. HANSEN: With that knowledge they uncovered a law of nature. There is no question that they did that and it is very much to their credit and they deserve praise for having done so. Einstein uncovered a law of nature when he uncovered E equals MC squared and he also deserves praise for that discovery, but uncovering a law of nature is not creating an invention. Uncovering a law of nature is not patentable. Laws of nature are not patentable.

THE COURT: Excuse me, but the law of nature is that a given mutation, whatever it is, may have a result with respect to breast cancer.

MR. HANSEN: That is right, your Honor. And that was true before Myriad figured it out and it's true after Myriad figured it out. It has to do with what nature has figured out

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and, again, Myriad deserves credit for having uncovered that and it has advanced women's health that Myriad discovered that. But it doesn't mean they have done anything that is patentable and so that is really about all the composition claims come down to. There is a lot of discussion in the papers about probes and primers and DNA. You don't actually have to reach any of those questions. In fact, if you are convinced that the DNA BRCA1 in the body and the DNA BRCA1 in the test tube are not markedly different, then you must strike down all of the composition claims in this case.

Let me talk just for a second about the method claims. The method claims quite clearly involve comparing two segments of DNA. In fact, they involve comparing two DNA sequences is the precise language of the claims.

This is a simple thing. You look at one string of letters. You look at a second string of letters and you look to see if they are the same or if they are different. And you think to yourself, aha, they are the same or, aha, they are different. That is what they have patented, is the process of looking at two things and having the thought they are the same or they are different. That is not patentable.

And they almost concede that that is not patentable because they don't really attempt to defend the patenting of that. Instead they say no, no, you don't understand our claims are entirely different we patented much more than that. We

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patented a lot of other things. Inherent they say in comparing is the notion that we isolated the DNA, we sequenced the DNA. There are a whole lot of steps you need to engage in before you can look at the two strings of letters. And you should read into our claims all of those prior steps.

Now, they very carefully don't precisely identify what those prior steps are so I am not entirely sure what you are supposed to read into their claims, but their essential argument is even if the claim as written is illegal you should read stuff into it.

Well, there is an inherent problem in that not only are there patent law problems with that, as Ms. Park will discuss, but there is just a logical problem with that. Almost anything that is constructed has prior predicate steps. If I am proofreading a book somebody has to have written the book, somebody has to have bound the book, somebody has to have published the book in order for me to look at the two copies of the books, but you certainly wouldn't say that all of those steps were inherently necessary as part of what I am doing when I am proofreading a book. And there are thousands of other examples, similarly, where reading in constituent steps that are necessary doesn't make any sense and if it does, then everything becomes patentable because everything at the end has to have been preceded by prior events.

And the method claims, plaintiffs' argument with

respect to the method claims is really that simple. It is that you can't read into the method claims all of these prior steps that they don't identify but that they want you to try and read in.

Now, I want to talk for just a second about the constitutional claims the plaintiffs have brought in this case. We have raised two constitutional claims, one with respect to the First Amendment and one with with respect to Article 1.

With respect to the First Amendment, it is accurate to say there is very little case law applying the First Amendment in the context of patent law. That is because until recently it wasn't necessary. A patent on a carburetor raises no First Amendment problems of any kind and so no one has complained about the First Amendment application. But recently the Patent Office has begun patenting things that, in fact, do raise First Amendment problems.

One of those is with respect to the Bilski case, which the Supreme Court has heard argument on and is expected to decide soon, which has to do with business patents. Indeed, one of the judges in the Federal Circuit in writing an opinion in the Bilski case indicated he thought there were First Amendment problems with respect to the patents granted in Bilski.

And there seems to be considerable confusion about what our First Amendment claim is. And I will try to make it

as clear as I possibly can.

Let's talk about this comparison claim, the method claims the defendants have, comparing one piece of DNA to another piece of DNA and thinking to yourself these are different or these are the same. The essence of that claim is thought. The essence of that claim is thinking the thought they are the same or they are different. I would have thought notwithstanding the limited case law that it would be relatively self-evident that the First Amendment prohibited the government from giving exclusive control over a thought to a private company. But that is precisely what the federal government has done in this case. That is precisely what the Patent Office has done. If you accept our notion that the comparison claims are to be interpreted the way I have described them, then this is a patent on thought and not only is it invalid under 101, it's also invalid under the First Amendment.

With respect to the DNA composition claims, they also violate the First Amendment but in a different way. One of the primary virtuous of the patent system is that you have to describe your invention in great detail. And part of the reason for that requirement is so that other people can come along and see what you have invented and make it better by inventing something different.

So to belabor my carburetor example, you can take the

patented carburetor and put the screws on the other side and maybe it's a better carburetor. It's called in patent law the ability to invent around the patent, and it is one of the great virtues of our patent system. The problem with the composition claims, the claims over the isolated DNA in this case, is that you can't invent around them. The gene is a product of nature. It was made by nature. We must look at it in the form nature made it in order to know what information it conveys, in order to know its significance, in order to advise women of the significance of the DNA. Therefore, you can't invent around it. What that means is that the patent in this case is not over DNA, it's over all the knowledge of the BRCA1 and BRCA2 gene. Remember, the patent in this case allows Myriad to prohibit everyone in the country from engaging in any research on the BRCA1 or BRCA2 gene.

They haven't chosen to enforce the patent as vigorously as their authority is but that is not the relevant question. The relevant question is have they been given exclusive control over all the knowledge over BRCA1 and BRCA2, and the answer is yes. It ought to be I would think relatively simple to conclude that that is not good for women's health and it's not required by the patent system, by patent statutes, and if it were it would be unconstitutional because giving a private company control over an entire body of knowledge is unconstitutional.

Finally, I want to briefly address the Article 1 claims. We claim that this violates Article 1 of the constitution which sets up the patent system. Article 1 says that we have a patent system in order to advance the useful arts. It is our allegation, and our belief, that this does not advance the useful arts.

The primary question that everyone has been debating in the papers is whether the patent system provides a necessary incentive for people to either discover the law of nature, namely that BRCA1 and BRCA2 genes relate to breast and ovarian cancer or that certain mutations relate to breast and ovarian cancer. Did we need the incentive of the patent system in order to get people to find that law of nature? And, therefore, isn't it a useful price to pay that if we lock up that law of nature it's still a useful price to pay because we wouldn't have gotten that information otherwise?

Well, we know as a matter of fact in this case that that is not true with respect to these genes. There were other labs -- and this is a completely undisputed -- there were other labs looking for the BRCA1 and BRCA2 gene at same time. They were looking just as hard. They had already -- some of them had already announced they were not going to patent the discovery if they were the first to uncover it because they thought this was a kind of knowledge that should be available to all scientists. It's true Myriad found it first with

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respect to BRCA1. They found it virtually simultaneously with a lab in England with respect to BRCA2. But we know there were labs all over the country looking just as hard as Myriad was and they would would have found the BRCA1 and BRCA2 genes and their significance, even if it had not been for the incentive of the patent system. So then the defendants' fall-back is, well, you need the incentive of the patent system to commercialize the invention. Nobody is going to start doing all the BRCA1 and BRCA2 testing if they don't know that they are going to make money off of it.

Well, we know that in this case that is just simply false. There were people doing BRCA1 and BRCA2 testing prior to Myriad's enforcement of its patents. It was already being commercialized and Myriad shut that down because Myriad has insisted that it must maintain exclusive control over the commercialization of this gene.

We know that research has been inhibited by the existence of the gene. We know that clinical testing has been inhibited by the existence of this patent. We know that new forms of testing and methods of using the gene have been inhibited. And all of that means that we have not advanced the useful arts. In fact, we have impeded them.

I think it is most helpful to talk about what Myriad has not invented in this case. Myriad has not invented a method of taking a gene out of the body. Myriad has not

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invented a method of sequencing or analyzing or amplifying the gene. Myriad has not invented DNA. Myriad has not invented the nucleotides that form the structure of the DNA. Myriad has not invented the sequence of nucleotides that comprise DNA. Myriad has not invented the genes BRCA1 and BRCA2. Myriad has not invented the structure of the nucleotides of isolated DNA because the structure of the nucleotides in isolation is the same in the body. Myriad has not invented the sequence or order of nucleotides in isolated DNA, again identical to what it is in the body. And maybe, most importantly, Myriad has not invented the informational content of DNA, either in the body or isolated.

Myriad has not invented the significance of that information and DNA is fundamentally an informational molecule. Myriad has not invented the significance. They have not invented the mutations, or the location of the mutations, or the structure of the mutations, or the sequence of the mutations, or the informational content of the mutations, or the effect of the mutations. And they have not invented the idea that looking at two sets of letters and seeing if they are the same or they are different, they haven't invented that either.

A patent is not a reward for effort and there is no question that Myriad has engaged in effort in order to uncover the significance of the BRCA1 and BRCA2 gene. It's also not a

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reward for uncovering nature. To use the language of the United States Supreme Court in Funk Brothers, you cannot patent an ancient secret of nature now disclosed. That is what Myriad has done and that is all Myriad has done, and that is why these claims were not properly granted patents and your Honor should find the claims invalid.

Now Ms. Park will address specifically the case law with respect to Section 101.

MS. PARK: Sandra Park for the plaintiffs, your Honor.

So the 15 patent claims relating to BRCA1 and 2 genes that we have challenged in this case are invalid and not patentable subject matter under Section 101 of the Patent Act and in granting these patents claims the U.S. Patent and Trademark Office violated long-standing Supreme Court precedent that has held that Section 101 does not allow for the patenting of natural phenomena, products of nature, laws of nature, and abstract ideas.

Now, the two questions that are raised under 101 in this case is, one, with respect to the DNA claims are these patentable compositions of matter and, number 2, with respect to the method claims are these patentable processes. And the Supreme Court has said, yes, sometimes you can call natural phenomena compositions or processes but that still does not make them patentable.

And in Parker v. Flook what the court said was the

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rule that the discovery of a law of nature cannot be patented rests not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of discoveries the statute was enacted to protect. So this is exactly the situation we have in this case, where under Section 101 of the Patent Act these composition claims are not patentable compositions of matter and the method claims are not patentable processes.

And with respect to the composition claims the legal test that I want to point your Honor to is the one set out in Chakrabarty v. Dike, which is the Supreme Court case from 1980, and in that case the court was looking at a general ethically engineered bacterium and so basically what Chakrabarty had done was insert new genetic material into the bacterium and now this bacterium could eat oil, so it's extremely useful for oil clean-up purposes.

The court was looking at that bacterium and in doing so they looked back at an older Supreme Court case, the 1948 case of Funk Brothers, and that dealt with a different sort of bacterium where there is a combination of six bacteria species that the patentee has identified to fix nitrogen from the air for plant photo growth but also not inhibit each other, so that is beginnings of 6 bacteria species that had not existed before together in nature. In looking at these two situations of Chakrabarty and Funk Brothers bacterium, the court noted the

question was does a product have markedly different characteristics from any found in nature?

And with respect to the Chakrabarty bacterium the court concluded, yes, it does. This is a genetically engineered bacterium. It cannot eat oil normally and it now performs this distinctive function.

The second question that the court asked in that case is whether the patentee had discovered only some of the handiwork of nature and there they were also looking at the language of the Funk Brothers. That is the quote from Funk, the handiwork of nature. What the court concluded there is that with respect to the Funk Brothers bacterium, that was just a happy work of nature because the quality of the bacteria that the patentee had patented was simply the quality it could fix nitrogen and not inhibit each other. That was a natural quality. That was not something the patentee had invented. He had certainly identified it but he had not invented it.

Now when you apply these principles of Chakrabarty to the isolated DNA in this case what we see here is that the DNA here is not engineered for all the reasons Mr. Hansen described. Really all we are doing in the isolation process is elucidate the nucleotide sequence that exists in the body. The genetic information remains the same. It stores the same information for the creation of proteins and the regulation of cells in our our bodies. And we also know that this isolated

DNA contains all the genetic information necessary to transmit a certain trait, and so one declaration I would point your Honor to is the declaration of our expert Dr. Robert Nussbaum, who talks about the classic experiments that show that isolated DNA once introduced into a new environment will transmit the same original traits that it contains.

The other aspect of Funk Brothers I would like to talk about is that it was a product, so it's a product of a combination of 6 bacteria. And the court there looked at the qualities of the bacteria and they said these qualities are manifestations of laws of nature. And so like heat of the sun, electricity, qualities of metals, these bacterium qualities are not invented by the patentee. If you apply that principle to this case the genetic information stored in the DNA is the most significant characteristic or quality of the isolated DNA that has been patented here and the fact it encodes for protein is a law of nature.

I would also like to point the court to an example of the patent claim defined according to a naturally occurring law of nature and that is Claim 6 of patent '492 which reads, "An isolated DNA molecule coding for a mutated form of the BRCA2 polypeptide in sequence number 2, wherein said mutated form of the BRCA2 polypeptide is associated with a susceptibility to cancer." So just as the Funk Brothers bacteria was patented based on its natural qualities of fixing nitrogen, the DNA in

this claim has been patented according to the fact that there is a naturally occurring relationship between mutations and susceptibility to cancer, and that is a law of nature that the claim preempts.

Now one of the arguments that defendants have made is that there are differences, chemical differences, in isolated DNA and DNA in the body and that alone should be enough for patentability. For the reasons Mr. Hansen described those differences to whatever extent they exist are trivial.

The case I would point the court to is American Fruit Growers, a Supreme Court case from 1931, where there was a fruit that had been impregnated with borax, a chemical that allowed the fruit to be resistant to mold, and in that case the court noted that even though there was a change with the fruit, the borax did not exist in nature and that change was not enough to make it patented. Similarly, isolation does not change the fact the isolated DNA does not contain the sequence. Trivial differences are not suffcient to create patentable subject matter. The other thing to note about American Fruit Growers is it crystallized the principle in Chakrabarty that you need to look at markedly different characteristics to determine whether there is a natural phenomena.

Now, the defendants also rely on lower court cases to rebut these three Supreme Court cases that we have cited in our brief and these cases for the most part do not deal with all

the Section 101. Some of them deal with genetic material but that was looked at in terms of Section 101 patentable section than criteria.

The one case I do want to discuss is the Parke-Davis case from 1911. That is the case the defendants cite as the strongest evidence for their argument and we completely reject the notion that Parke-Davis on any level supports the idea that isolated DNA could be patentable. There are two reasons for this. One is that the compound, the purified adrenalin of Parke-Davis, is a completely different sort of compound from the DNA at issue in this case. And the second reason is that the legal analysis of Parke-Davis has been rejected by the Supreme Court in subsequent years.

So let's talk about the adrenalin in Parke-Davis. One thing to understand about adrenalin is that it's the same compound in all of us, whereas DNA is a very unique compound in that it stores information in its nucleotide basis that is unique in almost all of us. Because of the nucleotide sequence that stores information that makes it a very different compound from adrenalin.

In isolating and purifying the adrenalin what happened there is that the inventor caused a rearrangement of atoms and the resulting product was a super-concentrated form of adrenalin that could be used as therapeutic. That was the final product, unlike here where the isolated DNA is still the

same in terms of its nucleotide sequence.

Furthermore, the patent on the purified adrenalin did not prevent anyone from taking adrenalin out of the body and examining it or measuring it. People were still free to see whether somebody's adrenal glands were functioning properly. Here that really highlights the different between DNA and adrenalin. Once you patent isolated DNA you have patented the nucleotide sequence that each of us has in our body and people are not allowed to look at that sequence.

The second issue with Parke-Davis is that it's a 1911 district court case that was affirmed by the Supreme Court but it was a case that focused on novelty. The court there was basically stressing the fact that the inventor was the first to purify adrenalin in a stable form and the court went so far as to say, and each opined, that even if something extracted without change that that would be patentable if it was the first time for the extraction.

I would point the court to the fact that that was a 1911 case and the cases that followed from the Supreme Court in American Fruit Growers, Funk Brothers, Chakrabarty and Diehr, have overruled this analysis. In Diehr the court said that novelty is a completely different criteria in terms of patentability from subject matter eligibility.

The next thing I would like to address is that defendants argue that prior to Myriad's invention isolated BRCA

DNA molecules did not exist. And the thing I would state there is that the same thing could be said of the fruit in American Fruit Growers and the kinds of bacteria in Funk Brothers. Those fruit and bacteria did not exist prior to the intervention of the person who patented them or who attempted to patent them. Basically the defendants are saying that anything extracted from natural phenomena can be patentable and the test has been that isolation or instruction alone is insufficient to make something patentable.

The Supreme Court case on this point is American Wood Paper from 1874 which looked at refined cellulose that was refined from plants and thus was much more useful in the making of paper. The court there said that differences in degree of purity are insufficient to create a new composition of matter absent substantial differences in the properties the compounds exist. And so, again, we have the court looking at how substantial are the differences and in a way this is the precedent for the Chakrabarty test again of markedly different characteristics.

Unless your Honor has any questions about that I am going to move on to the method claims.

The method claims are governed by three Supreme Court cases that have talked about when laws of nature and abstract ideas are not patentable and those are Benson, Flook, and Diehr. There has also been a federal district court case from

last year called In Ray Bilski that set out a machine or transformation test for all processes.

None of these claims is tied to a particular machine or apparatus and the only question under Bilski here is whether there is a transformation required by the claims. I think the crucial point here to understand is that one can violate these claims without sequencing, without doing any of the things that the defendants would try to read into the claims. One can violate these claims by simple mental thought. And that is because they involve the comparing of genetic sequences.

Genetic sequences can appear as a string of letters of the nucleotide basis and when you have the two sequences you can mentally compare them. It's a totally mental process. There is also a way of doing this as geneticists commonly use with a program developed by the National Center For Bio-Technology Information where again you feed two sequences into the program, the program issues a printout and basically it just shows along those two sequences where the nucleotide bases match or don't match. It's a completely mental process. The claims themselves do not require that there be isolation or sequencing.

I also want to address the Prometheus case which defendants discuss. In Prometheus there are three steps at issue there. The first was the administration of a synthetic drug to the body and there is no step analogous to that in

these method claims we have before us.

The second step involved a determining of metabolyte levels after that drug has been introduced, and the third step was whether the metabolyte level indicates the need to change the dosing of the drugs.

I would argue that the comparing sequences claims of this case are most analogous to that third step of Prometheus, not the second step as defendants urge, and that is because there is nothing in these claims that determines the sequences. The determination of levels of metabolites that may have involved transformation in Prometheus but the comparing of sequences is much more akin to that third step where basically what was going on is determining whether or not the level of metabolyte required a change of dosage. Similarly, here you are comparing two sequences and noting whether there is a difference and whether that difference might be significant for cancer.

I would also note that even if you accept their argument that isolating and sequencing are somehow required in their claims we would object to that for the same reasons we talked about with respect to the isolated DNA that isolated DNA does not transform that DNA and so does not make those methods patentable processes.

The last thing I would like to mention is that a lot of what has been animating the court in its concern about

natural phenomena being patented is the concern about natural phenomena being preempted and that is because we want natural phenomena to be free for all for their use and in Diehr the court said, "He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes."

In Benson the court looked at a method of programming a computer to convert signals from one form into another, using a mathematical algorithm, and the court concluded that the formula would have no significant practical application except in connection with the computer, and so even though a computer was involved, the patent claim was invalid.

Similarly, here we have genetic information stored in the BRCA1 and 2 DNA. That information has no practical application unless the DNA is isolated. And so by nature of these claims they have completely preempted access to that information.

The defendants argue that taking down these patents would hinder innovation, but it's exactly the opposite. Because these patent claims give exclusive rights to that information, all the follow-on innovation that we would want to see happen is preempted.

The four national organizations, the 6 geneticists, and two genetic counselors, they are all preempted from engaging in clinical work that involves sequencing of these

genes.

What it all boils down do is the defendants have attempted to minimize the fact that by patenting isolated DNA they have exclusive rights over genetic information. But this case would not be brought if the patents did not give exclusive control over the information stored in all people's BRCA genes. Because of the patents, patients like Lisbeth Ceriani, Runi Limary, Genae Girard, Patrice Fortune, Vicky Thomason, and Kathleen Raker cannot access information about their own BRCA1 and 2 genes without the permission of the patent holder. They need this information to make educated and important health decisions -- decisions about surgery, about treatment, and their lives. And it's this preemption of any examination of any person's BRCA1 and 2 genes that the patents not only tolerate but actually enforce. And it's this preemption of natural phenomena and laws of nature that render these patents invalid under Section 101.

THE COURT: Thank you.

MR. POISSANT: Good morning, your Honor. My name is Brian Poissant from Jones Day.

I will be speaking on behalf of the Myriad defendants.

With me at counsel table is my partner Dr. Coruzzi, Dr. Laura Coruzzi, and Barry Satine.

Well, your Honor, history certainly does have a tendency to repeat itself. 30 years ago, almost 3 years ago to

the day, a young patent applicant by the name of Chakrabarty was seeking to patent a genetically modified bacterium that basically ate oil, a very, very unique invention. This case wound it's way all the way up to the Supreme Court as you heard several times today so far about the infamous Chakrabarty case and at that time there was an impassioned group of scientists, similar to right now, including a lot of normal Nobel Laureates that urged the Supreme Court that if genetic technology is going to be patented there would be a gruesome, gruesome parade of horribles to happen and it could, indeed, pose a serious threat to the entire human race.

What did the Supreme Court do? The Supreme Court said, thank you, and wisely and correctly said, however, issues such as those are public policy issues for the Congress, not for this court. The only mandate of this court is to construe Section 101 as written and passed by Congress. These other issues, public policy issues, those are concerns for Congress.

The Supreme Court in Chakrabarty went onto hold that Section 101 should be expansively construed. The genetic technology there involved was indeed eligible, patent eligible subject matter under 101. 30 years later the gruesome parade of horribles never, never materialized. The bio-technology industry was virtually born on that day and has grown and flourished ever since.

Now, let's fast forward to last May. The ACLU

recruited 20 plaintiffs, filed a complaint challenging basically gene patenting in general. They picked Myriad. They picked 15 claims from Myriad's 7 Myriad patents as a test case. Sounding the same alarms that were sounded in Chakrabarty, this court has been deluged with a huge amount of declarations, and amici briefs on behalf of the plaintiffs claiming the same parade of horribles; that the patents in this case have hindered, will hinder, have hindered and will hinder cancer research, they will hinder the quality of genetic testing and they will hinder access to genetic testing.

First and foremost, your Honor, before I go any further, I would like to address those issues because we in turn on behalf of Myriad have put a tremendous amount of evidence in the record to show that these allegations are simply not true. Myriad has, indeed, been a very, very, very fine steward of these patents and as the evidence shows, both from Myriad and from all the amicis that have appeared on behalf of the 7, as the evidence they have put in the record shows that the Myriad gene patents in particular and gene patents in general have not prohibited cancer research. They have not prohibited access to genetic testing and they have not prohibited quality of genetic testing.

In fact, your Honor, if you stop and think about it, you know, we wouldn't be here today if it wasn't for Myriad. They discovered the BRCA1 and BRCA2 gene. They discovered what

it meant. That is the incentive in the patent system. That is what the patent system is all about. You make discoveries and then divulge them and give them to the world. These poor women -- and believe me, I don't minimize anything whatsoever about what has been put in the record here, but think about it -- they wouldn't even know they had a BRCA gene problem if it hadn't been for the inventions and discovery of Myriad disclosed pursuant to the patent system.

More importantly, however, as with Chakrabarty, these policy issues are not relevant to the issue before this court. The only question, the only question before this court is Section 101, the wording of Section 101, and how that wording has to be construed, not what some industry groups think the law should be but what the law is as written.

I was listening and I don't think anybody so far today told the court what the actual wording of Section 101 actually is. That is what you have to look at and that is what you have to consider.

Indeed, to go beyond that, your Honor, and to consider all these other like atmospherics, so to speak, put into the record, indeed as shown by the evidence we put in the record and as done by the amicis, if you were to consider those and give them any kind of weight, which they shouldn't be according to Chakrabarty, those are things for Congress, if you do though that could lead to the invalidity of thousands of gene patents.

I will get to that in a little bit. They seem to downplay it now and say we are only talking about 15 claims and 7 patents. No, no, they are talking about the invalidity of thousands of gene patents. This could unravel the foundation of the entire biotech industry. Numerous therapeutic drugs and diagnostic tests that are now in development will never see the light of day, and the field of personalized medicine, which is now growing where doctors are going to be doing genetic experiments and figuring out what type of drug really works for you rather than just taking drugs in whole, that personalized field -- that field of personalized medicine may never see the light of day.

Your Honor, despite the huge record that has been presented, there is essentially, as I said, only one question for this court, and that question is the scope and application of Section 101. There are no other patent issues. Believe me, I have been doing this for 35 years, the patent law could raise a lot of other issues dealing with validity of the patent, whether anticipation, obviousness, disclosure, and none of those issues are before the court. The only, only issue before this court is Section 101 and whether the claimed subject matter is eligible patent matter under that statute.

Section 101 hasn't changed since Chakrabarty. It still has to be given the expansive reading that the court gave it in Chakrabarty and when that is done, your Honor, I submit

that the undisputed evidence in the record will show that the challenged patent claims in this case are indeed eligible subject matter. The constitutional claims, I consider them frivolous atmospherics. In any event, if you look closely they fall, if the 101 claim falls they completely go by the wayside also. As shown in the record, as shown by the applicable law and the evidence in the record, Myriad is entitled to some summary judgment that the claims, the challenged claims do indeed constitute patentable subject matter. They do not violate the First Amendment and they do not violate Article 1, Section 1, Clause 8.

What I would like to do now, your Honor, is discuss in a little more detail the issues, starting with Section 101 and then I will conclude with the constitutional questions.

Section 101, let's look at the actual words of it for the first time today. Any new and useful process, machine, manufacture or composition of matter is eligible. New and useful, and those four categories, as noted in Chakrabarty this has a very broad scope. Basically it covers anything under the sun that is made by man. There are two types of claims in this case that have been challenged; there is claims to isolated DNA molecular compositions and there is claims to diagnostic tests that utilize those compositions.

I submit, your Honor, when you look at the applicable law and you look at the facts, focusing first on the isolated

DNA compositions, they are clearly compositions of matter within the meaning of 101 and they are new and they are useful as will be shown, end of story. The method claims, they are clearly processes within the meaning of 101. They are new and they are useful, again, end of story.

Let's talk about, first of all, the isolated DNA compositions. I think it's helpful to put this in context, your Honor, to talk briefly about the making of the invention here. And for that I would submit disclosed at length in the patents, the patents are very long and very detailed disclosures of how these inventions were made. It's also discussed in the inventor declarations we submitted of Dr. Shaddick, Dr. Skulnick and Dr. Tavtigian.

Briefly, as your Honor noted, Myriad discovered the BRCA1 and BRCA2 gene. They discovered what it meant. They discovered the mutations on it and that is the gift; that is what they gave to society as a whole. What we are talking about now though is not that discovery that is in the public domain. We are talking about what do the patents actually cover? That is a different issue. Okay?

In any event, what Myriad did was they involved the location and identification of the two genes, BRCA1 and BRCA2, associated with breast and ovarian cancer. These genes are part of a human genome which is very, very, very long. There are over 25,000 genes that they have discovered so far in the

genome and there is countless other DNA included in the genome.

I think to put this in perspective each cell of your body has the human genome on 23 chromosomes and they tell me, and this is anecdotal and hearsay, but they tell me if you stretch it out, if you take out the genome it would stretch from here to the moon and since there are 23 chromosomes, since it's over 23 chromosomes, I will give you it's 1/23rd of that exists in one chromosome so you have 1/23rd of 250,000 miles will give you how long a piece of genomic DNA is in each chromosome where each was discovered. Just figuring out how hard it is to find something that long it boggles the mind. Using the elaborate processes detailed in the patents, in the declarations, they discovered the BRCA1 and BRCA2 genes along that very, very long stream of genomic DNA. They found the location and they found the structure of the BRCA gene. They identified the mutations in the BRCA gene that are basically suggestive of the possibility or predisposition to ovarian and breast cancer. And, most importantly, your Honor, they isolated, they identified and isolated the involved BRCA DNA nucleic compositions on that very, very long strand of nucleic acid. And they isolated it away from the genomic DNA and the rest of the cellular materials that -- and think about a long string, somehow this long, and they found a very, very small piece of it, and that is what they isolated. That is what they identified and that is what they told the public and everybody

this is the part that is implicated in cancer. This is the part that they extracted out and that is the part, your Honor, that became the subject of the families of isolated DNA compositions we are talking about. That is what those claims cover. They cover that family of isolated BRCA DNA molecules.

This is not nature's handiwork. Read the patents. Read the declarations. This is the work of man. This is the ingenuity of man. It's the very hard work of man. True, you don't get patents on hard work, but hard work is certainly suggestive of how difficult it was to find this and what we are really claiming here.

Section 101 specifically provides by its terms literally that compositions of matter are eligible for patent protection, eligible patent subject matter. It is undisputed, and in fact it is undisputable, that the claimed isolated DNA compositions are indeed compositions of matter. They are indeed very, very complex polynucleic acids. That is not the real issue. The next inquiry under Section 101 is they have to be new and they have to be useful.

Let me talk about new. That seems to be the crux of the matter here in this case, are they new.

The claimed isolated DNA compositions covered by these claims do not exist in nature. They are not free floating. They don't float around in the cell. There is some suggestion in the papers you can go in the cell and find these

specifically claimed compositions floating around. No, they are part of that very, very, very long genomic DNA. They are not simply plucked out of the cell. You don't simply go in and pluck it out and say I found it. There is an elaborate thing you have to do to go along the entire genomic composition and find it. They are isolated.

What is meant by the word isolated? I read somewhere in their papers supposedly this is a trick, this is a trick, a clever little trick that patent lawyers use. In that case there are about 50,000 patents out there that use that clever little trick and the Patent Office has been buffaloed 50,000 times. I don't think so.

This is classic patent law 101, using the word isolated, and what does it mean? In this case it's specifically defined in the patents, your Honor. Look to the patents. It's defined. You take the entire native genomic DNA, and remember I told you that very, very, very, very long thing that is in the cells, you take that out. That has to be extracted from the cells first and then all the other materials around it have to be removed.

I was trying to think of an example. We say in our brief analogies, and this case is not subject to analogies but nevertheless I am going to violate my own rule and use one. Think of a large egg with a very, very, very long thread imbedded in it. That is what we are talking about. The egg is

the cell, the thread is the genomic DNA all bundled up and it's thousands of miles long. You have to go in there and find it and unravel it and then you have to look for the part of it you are really interested in. That is what isolated means. Simply by opening up the egg and finding this long gene the battle is just beginning. You have to now go along the DNA and find what part of it is really the interesting part, what part is the critical part you are looking for, and that is what they did. That is what isolated means.

In other words, the claimed DNA, your Honor, is isolated from that very, very long genomic DNA sequence and there are two critical things here. The claimed DNA is an infinitesimally small part of the genomic DNA and, most importantly, the claims in this case do not cover, and I can't emphasize this enough, they do not cover anything in the body. They are making it sound like we have patents on the human body, we have patents on the human gene and patents on the genome. Not true. We have patents on things that have been isolated from it that have very, very, very important utilities which I will come to in a second. These claims do not cover anything in the body.

Let's talk about the applicable law.

I think, your Honor, that it's fairly or very clear, the law is absolutely clear, in fact established for over 100 years, that compositions of matter isolated from natural

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sources are new within the meaning of Section 101. Starting with the seminal case of Parke-Davis by Judge Learned Hand from this court was probably the leading case, or at least the case that started all of this. Here you had animals, you had adrenal glands, super adrenal glands in animals. They knew there was something there that was useful but they didn't know what. The applicant went in and found adrenalin. We know it's in the body, a fight-or-flight phenomena. It does have observational characteristics because if somebody is going to hold you up your adrenaline would kick in and do something about it. They went in and isolated it.

They isolated it away from all the other glandular tissue and they put it in a form that could be used. And that is why Judge Learned Hand said that is, indeed, a patentable subject matter. They put it in a form that made it therapeutically useful. It made it useful in the real world. It wasn't just sitting in some glandular tissue and couldn't be used.

Let me stop right here. Ms. Park talked about Parke-Davis, the Parke-Davis case, indicating that it turned on novelty. No. I submit, your Honor, Judge Learned Hand was an excellent judge. The case, I think at page 110 starts the discussion. He talks about novelty. He talks about how the composition novelty means that the adrenalin as claimed of existed before in the art. There was some other art out there

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dealing with acid-based compositions or something like that. He discusses novelty and says no. He then goes on to talk about three objections.

The second objection that the defendant was making in that case dealt with patentable eligible subject matter under 101. And that is when Judge Learned Hand said this purified and extracted compound from nature is patentable because it has new therapeutic qualities. It had nothing to do with novelty. That was the specific part of his decision that dealt with eligible subject matter. I think it's page 103 or 104.

There are several cases after Parke-Davis. The Merck case, vitamin B12 patentable extracted from nature. In fact, the quote -- that was the Fourth Circuit following Judge Learned Hand -- specifically said "Nothing in Section 101 precludes the issuance of a patent on a product of nature when it is a new and useful composition," which, by the way, is the exact words of the statute you have to construe.

THE COURT: But all this entire body of knowledge is new obviously since Watson. I mean, it's developed as an entirely new body of knowledge and the whole idea of the genome is a new idea, so in that sense everything is new but does that make a difference, that we are dealing in an area that is really quite unique?

MR. POISSANT: I am not sure I follow your question, your Honor, but it's certainly a unique area. But I think your

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question I would suggest --

THE COURT: What I am really saying is we are talking about information.

MR. POISSANT: No.

THE COURT: Well, you are not. They are. And it is information.

MR. POISSANT: It's information. The discovery is information. The claimed subject matter is not information. That is the distinction. I am going to come to that. Believe me, we vehemently disagree. This is not a patent on information. This is a patent on chemical information that had real utility in the real world.

THE COURT: The essential element of the chemical composition is not new.

MR. POISSANT: It's new because it's isolated. Adrenalin wasn't new. The compound adrenalin is in our body. That is what makes you get excited if someone pulls a gun on you. That was in your body but by isolating it, extracting it, and putting it in an isolated and purified form is what made it patentable. That is what we are dealing with today, your Honor.

I would submit you raised a good question. I think the concurrence in Funk is a very good place to read because it goes to the exact problem we are dealing with here of mixing up this concept of works of nature, products of nature, things of

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nature. Every invention in the history of man involves some phenomena of nature. When Henry Ford invented the combustion engine if we were here today they would be arguing the concept of gasoline exploding is a phenomenon of nature and that is not patentable. Every product involves nature.

THE COURT: Doesn't that go a little too far, then, everything is patentable?

MR. POISSANT: Absolutely not. I am saying the exact opposite, your Honor. Every invention is based on some law of nature but go back to Section 101. Go back to the statute. Is it a composition of matter? Is it a manufacture? Is it a process? Is it an art, and is it new and useful? That is the only question, not whether it has something to do with nature because every invention has something to do with nature. That is the world we live in.

Onward. There are other cases.

I get excited.

THE COURT: You have affected my adrenalin.

MR. POISSANT: Mr. Hansen -- my blood dropping here, I am sure there is adrenalin in it. We have the Bergstrom case where they patented prostaglandin from prostate glands. You have the Kratz case where they patent strawberry essence isolated from strawberries, and you have Bergie where the patentee purified biological cultures, and then we have the Patent Office guidelines.

Your Honor, I submit take a good look at the declaration of Dr. Link that we submitted. She was the author. She was the primary author, mover, shaker, whatever you word you want to choose, with regard to those Patent Office guidelines. You know, she told us about it. It's described in her declaration. They went and they were asked this very question by the then Commissioner of Patents: Are these isolated DNA molecules patentable? Go find out, and make a judgment and find out. Thus, the guidelines in 2001.

What is it all about? She did an extensive -- her and her staff did an extensive review of all the judicial precedent, including the cases I just talked about, including the cases they talked about. They looked at everything. They asked for notice and comment. They can't pass a guideline without asking the world to comment on it. They got notice. They got comment. And they concluded that isolated DNA molecules, exactly what we are claiming here, are indeed patentable subject matter under Section 101.

Let me stop and discuss a Supreme Court case that I haven't heard about today yet called JEG Supply v. Pioneer. This is back in 2001, the turn of the century. The issue came up, I think it started out summary judgment very similar to what we are talking about here where the plaintiff in that case had a patent on plants, had a patent on corn seed and corn plants. The defendant Pioneer in that case was arguing this is

not patentable subject matter under 101. He said these plants are covered by something else but, in any event, they are not patentable subject matter under 101. The court concluded that they were but what is very relevant to the discussion here is in that case the Patent Office had done a study. They had done a study of the applicable law to figure out whether plant patents were, indeed, patentable under Section 101, could they issue a utility patent on a plant. They did the study. They came up with similar guidelines. They concluded that they could and they issued thousands of plant patents over a 16-year period. And over that period there was no congressional action. There was no congressional intervention by Congress or any other agency whatsoever.

The Supreme Court in that case, your Honor, made a very, very important note in a very important point that you are now asking us to conclude 16 years later that plant patents are not covered by Section 101 when the Patent Office has done a study to conclude they are, has issued thousands of patents and Congress has not intervened.

Fast forward to today, what do we have today? We have the guidelines that have been issued by the Patent Office concluding that these isolated DNA compositions are patentable. We have thousands and thousands of patents that have been issued by the Patent Office. We have no congressional interventional action by Congress or anybody else to say it to

the contrary other than this case filed ten years later, ten years after the patents issued. I submit, your Honor, that is dispositive. How the court handled the case in JEG Supply v. Pioneer is dispositive of what should happen in this case.

Well, what do the plaintiffs have to say about all of this? Well, in the first brief they said that all the cases we cited, including the decision by Judge Learned Hand from this court, and the policy guidelines were wrong, hardly a credible argument. Next, they cite a string of cases, some of which were discussed by Ms. Park, purportedly showing instances where products from nature were found not patentable.

I submit, your Honor, take a close look at those cases because if you really read them and you take a good look at them you will see what really happened in those cases was they said was subject matter, the claim subject matter was not patentable because what they were claiming already existed in the prior art. It was what we call a 102 or a 103 case, anticipation or obviousness, issues not before this court. These cases did not turn on eligible subject matter. They turned on the fact of what was claimed was old. You see the word it's patentable and it's being bandied about really loosely in this case because when they say the court said it wasn't patentable are they talking about 101 or talking about 102, 103, 112 or something else? Read those cases and I submit they are talking about something other than 101.

Let's talk about Funk.

Funk is exactly the same thing. If you look at Funk you will see it's actually a 103 case depending on obviousness. They found the compositions had already been sold.

American Box -- there is a good case. Take a look at American box, what they were talking about in American box, a very unique, strange case actually if you think about it. They took an orange and they covered it in boric acid and apparently it lasted longer and didn't get decayed and mold, et cetera. The issue before the court was whether it was an article of manufacture, not whether it was a composition of matter, whether it was an article of manufacture. The court in turn went back to the tariff statutes and they said, well, for something to be an article of manufacture within the meaning of tariff status you really have to manufacture something. You have to make it different. Simply adding a coating to an orange doesn't make it different enough to invoke the tariff statutes and, therefore, it's not an article of manufacture. That case has nothing to do with this case, your Honor. Read it closely. It's an article of manufacture case, frankly, based on the tariff laws.

What is next? Well, now in the reply brief they have a new argument. Now they have come up with this argument that it has to be markedly different I think were the words they used. They say Chakrabarty overruled Parke-Davis so

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Chakrabarty, without even mentioning they overruled Judge Learned Hand. I think if they are going to overrule Learned Hand they would have mentioned it. They says nevertheless the isolated claim composition now has to be markedly different from the phenomena or product of nature. But this is not some new test. If you read Chakrabarty closely all they say, Chakrabarty genetic, remember what is being claimed, the genetically engineered microbe that ate oil. The issue before the court in Chakrabarty -- really the issue before the court was whether living things constituted eligible subject matter under 101 so basically a lot of this is dicta but put that aside. From Chakrabarty went on to say it's okay, it took the right approach. They said under 101 we have to determine whether this genetically engineered bug is, indeed, either an article of manufacture or a composition of matter or is it just something that occurs in nature. And in discussing whether it was not something that occurs in nature, that is when they mention Funk. They mentioned Funk and they said Funk was basically claiming things not only sold but it was claiming things no different than nature. It's like me going outside and trying to claim a tulip and they said that is not what Chakrabarty is doing.

Chakrabarty was markedly different and it had a potential for many new utilities, the potential. So markedly different, the language from Chakrabarty that they are relying

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on for a markedly different test was really nothing, nothing, nothing more than the Supreme Court saying that this thing was new within the meaning of Section 101. That is all they were saying. But, in any event, let's take that on. We will take them on. We will take them on on that challenge whether this claimed isolated DNA compositions are markedly different.

Let's take a look at it.

Your Honor, we are talking now about even assuming arguendo that there is this markedly different test out there let's take a look at the isolated composition claims and address that issue, okay? Isolated. Remember, that is a very important word in these claims. What does it mean? It means they have been isolated not only away from all the other cellular material but they have been isolated from the very, very long native genomic DNA to get to the small pieces that are being claimed. Now, those new claimed tacit compositions being claimed, your Honor, have substantially new utilities. This is not disputed in the record. They have utilities as molecular diagnostic tests. They can be used as sequencing templates. They can be used as probes. They can be used as primers. This is not just words, your Honor. This is how the BRCA -- and you read a lot. There has been a lot submitted about the Myriad BRCA analysis test. That is what it's all about. That is how the test really works. They make it sound like you send the sample into Myriad and they send you back

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letters of the alphabet. You have to see what goes on in order to get there. That is what the BRCA analysis test is all about and I will talk about about it in a second.

The isolated nucleic acids, not only can they be used in diagnostic tests though. You can put them in transgenic animals, transform cells and little manufacturing plants to make the BRCA proteins. You can use them potentially in gene therapy. Remember, I said Chakrabarty talked about market, even their own markedly new, markedly improved test, it's still, as Chakrabarty talked about, new potential utilities. These are all potential utilities. These are actual utilities and some of them are potential utilities but the important point for this court's consideration is that none, none, none of these utilities are possessed by the BRCA DNA in the body, in the native genome. They can't be used. Even they admit you can't sequence DNA in the body. They postulate maybe some day in the future I will be able to walk through a detector like down below and my DNA be will be spit out, but not now. You have to isolate it and get it into the claim form in ordinary for it to have any of these utilities.

So very similar to the adrenalin in Parke-Davis and once it was isolated because these are isolated genes they are isolated away from all the other genomic material and all the other things. In the cells they have the utilities markedly different in structure and markedly different in utilities. By

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contrast, as I just said, none of the nature DNA can do that, none of these utilities.

What is their response? The response is they concede, as they must, that these claimed isolated DNAs have many utilities not possessed by the native DNA but they posit three largely irrelevant arguments. Let me go through them. Not largely irrelevant, irrelevant.

First, and this is the heart of this, frankly, the heart of the matter in this case. They first argue, remember, we have claimed DNA compositions that have these utilities as diagnostic agents, as gene therapy, all these other things that simply native DNA in the body can't be used as. What is the response? The response is that the claimed DNA, these isolated segments of nucleic acids and the native DNA as it exists in the body have a single property in common. They have the same DNA sequence. They have the same protein coding capacity and, thus, they both basically provide the same genetic information. Think about it. What you are taking now is an isolated chemical composition. It's undisputed that it's a chemical composition that has all the other utilities but because it also codes for information similar to the body this composition magically somehow becomes a phenomena of nature, like electricity, like gravity. Absolutely not, your Honor. In fact, it is this capacity that the isolated DNA has the same sequence as the body and gives the same information is what the

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beauty of this invention is. That is why it works. That is how it works. That is what they are claiming. That is the beauty of this. If it didn't have the same information we wouldn't be here. It would be meaningless. But that doesn't mean the isolated compositions have other utilities, which we will see in a second are very important in a real world. And it's these differences that make them markedly different than what is in the body, not a single, a single common characteristic. This informational aspect of it, so to speak, is largely irrelevant. It's not irrelevant, it's important to the invention, but it's irrelevant to determine if they are markedly different as a matter of law for Section 101.

The second argument they make is that these different functions, these different utilities are irrelevant since they are not recited in the competition claims. Wrong. Black letter law, black latter patent law, composition claims do not have to recite function and, in fact, there is certainly no case that says that function has to be recited to be considered in a section 101 analysis. But the bottom line is composition claims don't recite function. They don't have to, and you can have method claims that recite function but composition claims don't have to recite function.

The final argument is that its claimed DNAs need to be modified to perform some of these functions, such as the probe, a primer, et cetera. Again, totally irrelevant. The issue

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before the court is that these claimed compositions are capable of being modified to do these things whereas native DNA is simply not, incapable of being any of these utilities.

Finally, your Honor, Section 101, as I said at the top of the program here, requires it to be new and useful. Useful we have already discussed and I am not going to replow this ground. These claims, talking about the isolated DNA compositions, these claimed compositions have many, many utilities that are simply not possessed by native DNA, diagnostic agents, gene therapy, protein manufactured, et cetera. Okay?

Well, that concludes the part of dealing with the isolated DNA composition. I submit, your Honor, I go back to Chakrabarty and the admonition in Chakrabarty, look at the statute. The composition of matter, it's new, because it's isolated. It has many, many different utilities. That makes it new as a matter of law and it's obviously useful. End of story.

Let's go on to the diagnostic claims now.

These diagnostic claims basically use the claimed compositions in the diagnostic setting. What is the test? What is the test? The method claims are a little different than composition claims under 101. The test has been articulated in several cases such as Gotshauk v. Benson, the Bilski and the Prometheus case, which we discuss in our brief

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and I will discuss a little bit in a second. And the test is does the method transform an article into a different state or thing and is that transformation central to the purpose of the claimed invention?

Let me take a look at Claim One, Claim One of the '999 patent. There are five method claims and there is one screening claim that seems to be a weak stepsister nobody talks about but that is covered in the brief.

Let's talk about the diagnostic claims. Claim One, a method of detecting a germ-like alteration in a BRCA gene. That is basically saying you are going in and looking at the gene to see if it has a problem. What does it require? It requires analyzing a sequence of a BRCA gene from a human sample. Analyzing, sequence, BRCA gene, human sample -- those are the key words, your Honor.

If you look at the claim language itself, in doing any kind of claim interpretation the law is well established, you look at intrinsic evidence, primarily look at intrinsic evidence which is the claim language itself, the specification and the prosecution history, and you don't get into what experts think the claim means. That is extrinsic evidence. You don't go there unless it's absolutely necessary. Quite frankly, that is the problem we have with their entire claim interpretation. We have a bunch of experts saying what the claim should mean and what they should be doing is looking at

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the claim language and the specifications and the prosecution history to figure out what the claim means. When you do that I submit that the meaning and scope of this claim is absolutely clear, and its real world significance is very, very apparent. What do I mean by real world significance in the BRCA analysis test? That is what the test is all about, the diagnostic claims. You heard about it. That is what the claims are all about. This is how these claims work. What do I mean by that?

The method is directed at detecting a BRCA1 mutation in an individual. This claim, this method basically takes a gene that is buried deep in the human genome. It's a deleterious gene and it makes it clinical in a setting. The critical thing is you take a patient sample and you have to go into the patient's sample and the BRCA DNA molecule must be obtained from this patient's sample in order to analyze it. You have to go in and you have to find it and you have to get it. You have to excise it and you have to look at it. That is how this works, okay?

This is why there is a transformation step, your Honor. When you think about it, you come in with a sample of blood or a tissue sample, usually a blood sample, and something has to be done to that blood sample. You just don't simply put the blood sample into a meter that finds the BRCA DNA and reads it. There are a lot of things that have to be done to the sample and that is why this is a transformative step within the

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meaning of Prometheus, which I will come to in a second.
What do you do? You come in with a blood sample. Mr. Hansen's blood that dripped on here, take the blood sample and you take the sample and crack open the cells. It's my little egg shell. You crack it open and expose it and you open an egg, you have a gimmish in there. My little egg example with a very, very long DNA all bundled up and packaged in there. How do you find it? How do you find what part of that DNA you have to look at? This is where the invention is, your Honor. This is what is really unique. It's amazing.
What do you do? These claims, these isolated DNA claims, they function as probes. They function as primers. What they do is you make them, you take these claimed fragments, strands of nucleic acids, and you change them into a probe, you change it into a primer, and I don't want to go into too much detail here but what they do is they then use those to target and hybridize it to the DNA, the native DNA that is in the cells, and you have to find what part of it to look at. These probes and primers, this is what is very, very unique about it, these probes and primers are like guided missiles. Believe me, I have no clue how this works but the chemistry of these probes, these isolated DNA claims, the chemistry of these probes and primers is such that they know how, I don't know, but they know how to go along this very, very long piece of DNA and stop where they are supposed to stop because I guess they

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recognize their own chemically or something they recognize as their own. So if you have a claimed composition, a fragment or nucleic acid, and it basically corresponds to the BRCA DNA nucleic acid, that little piece can be formed into a probe. It doesn't have to be all of it, some of it. It goes along the DNA and it finds its relative. It finds its BRCA DNA in the human genome and attaches to it. If it's a probe it has a strobe light on it and says here I am, cut this piece out and look at it. If it's a primer it basically stops there and it allows PCR synthesis to go back and forth and make extremely large amounts of it so it can be analyzed. Either way what these claimed inventions are doing is you are forming probes and primers, guided missiles that go in there and isolate the BRCA DNA from the native DNA and that is what you look at. You pull it out and look at it and you compare that and you say what should this look like? That is how the tests are done and that is why this is very, very important. That is how they commercialized it and how they claimed it. They didn't claim the discovery of DNA. They didn't claim the discovery of any law of nature. They claimed these little compositions are used like guided missiles.
I submit, your Honor, if you look, dealing with the '999 patents now, and if you go to the dependent claims in the '999 patents and you look, they elaborate a lot on the details of how all this takes place. In fact, it's in the patent

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itself. All these diagnostic methods and how they work are in the patent. The dependent claims off of Claim One which I have been referring to, all those claims show how these transformative steps take place and how you actually go into a human sample and how you actually pull out and find the BRCA DNA nucleic acid you have to look at.
Let's stop now and discuss Prometheus.
Prometheus, quite frankly, I think is dispositive of this case, your Honor. Prometheus involved a drug, a pro drug. When you give a pro drug it means it turns into a metabolyte. Part of it is cleaved and its changed to the metabolyte in the body and the bad metabolyte is the bad ingredient. The metabolyte was formed and their discovery, not necessarily the patent but their discovery was the idea that they can measure the blood levels of the metabolyte and if it got too high they knew enough to start reducing the amount of drug. If it was too low they upped the amount of drug. How did they claim it? That was the scientific discovery. That is not how they claimed it. They claimed it with a claim that had a determining step in it, determining the level of the metabolyte from a blood sample. You just couldn't look at the blood sample and figure out how much metabolyte is in there. You have to do various things to it. They looked at the dependent claims. They said you can't do that. That is what they did in Prometheus. They looked at dependent claims and the disclosure

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and they reached the conclusion that this determining step -- and, by the way, their brief talks about a brief that had administering determine but Prometheus was determining the level of the metabolyte in the blood sample and based on that determination adjust the amount of drug that is given. But the court in Prometheus said that you, that determinant, determine the level of the metabolyte in the blood sample is a transformative step because the blood sample is no longer a blood sample when you are done with it. You have changed it. You have gone in and you have spun it down. You broke open the cells. You have done all sorts of things to find that metabolyte and measure it.
Go back to this case, your Honor. Exact same thing. You take the blood sample from a patient. You open it up and you do all sorts of exotic things to go in there with probes and primers and basically change that blood sample. You do all sorts of things to it and go and find the BRCA DNA nucleic acid that has to be analyzed. That is how this works and that is what this is all about and that is why it's a transformative step.
Now, what do they say? Their response to this is that we import limitations under the claim, which is a black letter no-no in patent law. You can't import limitations into the claim. That is what they say we are doing.
I submit, your Honor, it's the exact opposite. They

are ignoring limitations in the claim. What are they ignoring? Read their briefs. Remember, let me go back to the claim, the claim says analyzing a sequence of BRCA DNA from a human sample. The other claims talk about from a tissue sample. They ignore that. That doesn't exist. They pretend that doesn't exist. That wording is in the claim. They can't make it go away. That is how it happens. The whole idea is you go into a patient sample and you have to pull out the BRCA DNA nucleic acid to look at it. That is what this is all about. They ignore that language. Worse yet, and it gets worse, they take the word sequence, remember analyzing a sequence, they say, no, no, sequence is just letters of the alphabet. ATCG, those are the letters that correspond to the nucleic acid that make up DNA. They say, no, that is just letters of the alphabet. A sequence is just a string of letters showing the composition of the DNA and all you are doing here is looking at that string of letters and comparing it to another string of letters. Analyzing a sequence is just analyzing letters of the alphabet. That is what their exerts say.

Let's look at what the patent specification says. What does that say?

You go into the specification, your Honor, and I submit you go into the diagnostic section of it and it talks about exactly what I just said. It talks about how you have to take a blood sample from the patient, a tissue sample from a

patient. You have to open up the cells. You have to use elaborate procedures to go in and find the BRCA nucleic acid to analyze it. Sequence. This is particular. I submit, your Honor, if you look at the '999 patent, column 28, line 35, it says, and this is in the diagnostic section, quoting, it says, "The screening method involves amplification of the relevant BRCA sequence using PCR or non-PCR based chemistries."

Amplification of the sequence. Following on starting at column 28 line 41 it goes on to say, "The most popular method used today is target amplification. Here the target nucleic acid" -- not letters, the nucleic acid -- "sequence is amplified by polymerase."

What are they talking about? Exactly what I just said. You have to open up the cell and go in and find it and when you find the BRCA DNA nucleic acid, you amplify it to make a lot of it so you can look at it. You can't amplify letters of the alphabet. This is PCR. This is classic PCR technology where you take the nucleic acid sequences and you make an awful lot of it. This is all these tests you see in police work all done by PCR amplifying samples of DNA. That is what this is talking about. You can't amplify letters of the alphabet. Their whole premise, the sequence, analyzing the sequence is merely just letters of the alphabet and you are looking at letters of the alphabet is dead, dead wrong when you look at the actual intrinsic evidence you are supposed to look at. If

you look at it you talk about analyzing a sequence of the BRCA nucleic acid, physically looking at something, a BRCA nucleic acid, and that is what you are looking at. You are not simply looking at letters. So this word sequence we are not reading anything into the claim. The word sequence is there. What does it mean? They want to ignore that. They ignore the extrinsic eggs and they have experts saying this is just letters of the alphabet. No, no, no.

I submit, your Honor, as to the other claims they are very similar. All the diagnostic claims regarding analyzing a sequence of a BRCA molecule, a BRCA DNA from a tissue sample, they are all the same. From a sample, sequence, sequence has to be amplified. It has to be detected and amplified. You are dealing with a nucleic acid, not letters of the alphabet.

When you look at it properly construed it's easy to see that this claim involves a transformative step almost identical to what went on in Prometheus. This is patentable subject matter under 101, end of story.

Preemption.

Preemption, your Honor. The concept of preemption has been mentioned today briefly and mentioned in their briefs. Preemption deals with a concept when you have a claim that solely covers a fundamental principle of nature, solely. As I have just gone through, the isolated DNA claims cover compositions of matter, not principles of nature. The

diagnostic method claim I just talked about doesn't -- it has a transformative step where you actually transform a human blood sample or human tissue sample to get at the BRCA DNA. DNA nucleic acid -- it's not simply reading letters of the alphabet. These claims have nothing to do with the fundamental principle. As I said, as in function every claim somehow implicates laws of nature but these things are not solely claiming fundamental principles of nature so this idea of preemption is just a total red herring in this case. And this concept of designing around I have never, in 35 years, I have never seen anybody come into a court and say a claim is invalid because you can't design around it. I never heard of any such thing. The whole idea of the patent system is you have a claim. It's there. People with ingenuity can design around it. These things can be designed around. We put in evidence in the record that says people are starting to design around the patents to get at other ways to find whether a person has a BRCA DNA problem or not. There are things being done now that don't implicate these patents. That is irrelevant. Designing around has nothing to do with patent eligibility.

First Amendment. Let me go on to the constitutional claims for a second. It won't take long.

I believe the legal and factual predicate for the First Amendment claim is that the isolated DNA compositions somehow claim information, that they somehow are limited. They

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are simply informational claims and therefore they inhibit thought or speech. No. These claims, as I have pointed out quite graphically today, they cover compositions of matter. A composition-of-matter claim can only be infringed by making, using or selling that composition. It can't be infringed by simply thinking about it, reading about it, writing about it. You actually have to take the compositions. As I said, you have to use these things as guided missiles. You have got to -- to fringe the composition claim you have to make, use or sell the composition, not think about it or not read about it or write about it. It's bizarre. I have never seen a First Amendment claim against any patent claim for that matter. Similarly, the diagnostic method claims they say implicate the First Amendment because they merely involve thought. If you look at one sequence, the alphabetical sequence, you compare it to another, and we have been through that. These claims do not involve comparing alphabetical sequences. They involve going in and finding the BRCA nucleic acid physically and comparing that to the known structure you are looking for.

Article 1, Section 8, Clause 8 similar, apparently as best I can tell from their first brief the argument goes along the lines the composition claims simply cover information, the method claims simply cover thought, therefore they are not discoveries in invention within the meaning of the clause and, thus, they impede progress of science and useful arts. The

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factual predicate is wrong. The claim does not cover thought. They cover physical composition and transformative diagnostic process. Article 1, Section 8, as I am sure Mr. Morrison will get into more detail than me, is a limitation only on the legislative power of Congress. It's not a limitation on the Patent Office. It's not a limitation on any given patents. They are not challenging Section 101 as unconstitutional. They are not even challenging it unconstitutional as applied generally. They are challenging somehow I believe as unconstitutional as applied by the Patent Office for these particular 15 claims. Article 1, Section 8, Clause 8 does not apply. It simply doesn't apply to the activities of the Patent Office in issuing a given claim. It's totally irrelevant and that should be the end of the story.

In any event, since they have purported to put evidence in the record dealing with the fact that these claims don't promote science, I submit, your Honor, Myriad and all of the amici have put in a tremendous amount of evidence. It certainly has nothing to do with the constitutional claims but, so be it, if they want to put evidence in the record we in turn have put a tremendous amount of evidence in the record that shows that these, not only the Myriad patent claims but gene patents in general, have indeed promoted cancer research. They promoted clinical development and quality assurance of the testing. They have enhanced patient access and affordability

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and, most importantly, your Honor, this concept that none of this could have been done, this all could have been done without the patent system is absolutely bizarre. It would be flying in the face of 200 some odd years of law. Congress, the Constitution says what it says.

Congress has passed patent laws and there is a tremendous amount of evidence that has been presented that none of these things would be done without the incentive of a patent system. The fact that Mr. Hansen said, well, somebody didn't care about a patent. I guarantee you if Myriad hadn't been the first to find it, the first being someone else, they would have gotten a patent. It's because they weren't the first that they say we weren't interested in a patent anyway. That is not the way the patent system works.

In closing, your Honor, I would like to leave you with three thoughts.

First, despite some of the statements that they made that this is a case simply about 15 isolated patent claims -- there is that word again "isolated" -- isolated patent claims and 7 Myriad patents, not a big deal -- no, no, no, this case for whatever reason ten years after these patents issued they have decided to use the Myriad patents as a test case to go after gene patents in general and the biotech industry as a whole.

This is not about 15 simple patent claims or we

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wouldn't have had all these people listening to this. I have done this a long time and if we were talking about isolated patent claims it would be only you and me talking about it.

Secondly, JEG Supply v. Pioneer, keep that case in mind. The Supreme Court of the United States said the Patent Office had looked at the situation. They looked at all the case law. They had determined that plants were, indeed, patentable subject matter. They issued thousands and thousands of patents and Congress had not seen fit to intervene, the exact same situation here. The Patent Office looked at it in detail. They issued the guidelines saying these type of isolated DNA inventions are indeed patentable. They issued thousands and thousands of patents and Congress has not done a thing about it. This is not a subject matter for the this court.

A final thought -- Chakrabarty. In Chakrabarty they correctly noted that all of these atmospherics you have heard about in all the papers are maybe well and good, but go to your congressman and tell them about it. Go to Congress and tell them about it. The issue before the court is they correctly recognized the meaning of Section 101 as written, not how some group of people think it should be written, and in doing so they gave an expansive consideration and determined that the subject matter there was patent eligible subject matter and I submit, your Honor, when you look at the applicable law and you

look at the evidence in this record, the undisputed evidence in the record will clearly tell you under Section 101 as is written that these are, indeed, new and useful compositions of matter and they are new and useful processes.

Thank you, your Honor.

MR. MORRISON: Good morning, your Honor. Ross Morrison from the U.S. Attorney's Office for the United States Patent and Trademark Office.

As your Honor has heard this morning, this case and the issues in this case primarily claim whether the patents at issue were properly patented under 101. There has been voluminous briefing in the case as counsel pointed out earlier. Very little of it, thankfully for me, was devoted to the constitutional issues. Even more significantly, as plaintiffs counsel pointed out, there is not a single case cited by plaintiffs in which the court has considered, let alone upheld, a constitutional claim, be it under the First Amendment or the promote progress clause of the Constitution challenging an individual patent claim. U.S. PTO really doesn't belong in the case and your Honor need not give these constitutional claims very long shrift.

I will address each of these in turn. Before I turn to that I wanted to set the stage for when your Honor should only reach the constitutional issues in this case.

As we pointed out in our brief, under the doctrine of

constitutional avoidance your Honor need not reach these claims if your Honor finds in favor of plaintiff on its statutory claims. If your Honor were to find in favor of the plaintiff on the statutory claims your Honor would presumably invalidate the patents at issue, which is the only relief the plaintiffs are seeking here. So the only time that would be proper to reach the constitutional issues would be in fact if your Honor does not find in favor of plaintiff and finds the U.S. PTO did in fact lawfully issue the patents under Section 101 and then turn to the constitutional issues. The plaintiffs in their opposition to our motion said that in that case that is not the only relief they seek. They also want to invalidate the U.S. PTO's policy pursuant to which the patents were issued. Going back and looking at the complaint, the complaint seeks, as your Honor recognized in the first decision, an invalidation of the patents at issue issued pursuant to a policy about the claims.

I also point out to your Honor that as a matter of law if this court were to invalidate the patents upheld by the Federal Circuit or the Supreme Court, the U.S. PTO is required by law to conform its policy to a binding decision of the Federal Circuit or the Supreme Court, so there would be no problem in case that transpired.

The two claims, your Honor, the IP clause and the First Amendment I will speak about briefly, the IP clause claim, which is essentially the IP clause, authorizes Congress

to set up a patent system to promote the progress of the useful arts. That clause, the basis of the plaintiffs' claim as we point out in our brief, there is no case plaintiff has cited where that clause be can be the basis for a limit congressional power. The D.C. Circuit has held that the preamble to the IP clause does not impose a limit on Congress' power.

In any event, even reaching the merits of the claim, your Honor, there is no disagreement between the parties, between plaintiff and defendants here, that the rational basis standard of review applies to any statute enacted under the IP clause and as I am sure your Honor is aware the rational basis standard is a very deferential standard of review with a strong presumption of constitutionality. The only thing that needs to be established to satisfy rational basis of review is essentially there was a rational reason for Congress' action and what the Supreme Court has explicated is that means all there needs to be is a plausible reason. It doesn't have to be right or wrong; it just needs to be a plausible reason.

And in the record, your Honor, there is clearly a plausible reason for the patent system that in general, as well as the patent statutes in particular as applied to these gene patents, that would encompass these gene patents.

As counsel for Myriad has set forth, patents on gene patents, for instance, can be expected to stimulate research and development and innovation. That is the whole purpose of

the patents, to give someone protection over an idea and invention so they will bring it into the public. Whether that is in fact true or it actually happened here is not the issue, your Honor. There is no requirement that the U.S. PTO put forth evidence, by way of affidavit or otherwise, to counteract the plaintiffs' claims that it's not true; that these patents haven't led to innovation or that the gene-related inventions would have been discovered anyway. That is not the issue. The only issue is whether it was plausible for Congress to think so.

Clearly under the record and evidence it's plausible for them to think so. In addition of course there was a plausible basis for Congress to establish the patent system and 101 and to establish broad categories that would include such things as gene patents. Again, the thinking being behind the patent law is that they were enacted by Congress to cover things that could be invented in the future.

The patent law Section 101 has existed in its present form and in almost the same way since 1793. The idea was to establish broad categories of patents that could encompass inventions that might be invented in 1790, 1890, or 2010, and it's certainly a plausible basis in the record to think that the patent system that encompasses gene patents was a rational exercise of Congress' legislative powers in the IP clause. That is all your Honor needs to find if your Honor reaches that

argument; that in fact there was such a plausible basis, not whether it's right or wrong. The Supreme Court has repeatedly cautioned you don't need to weigh whether it's a good idea or not but whether it was plausible.

As to the First Amendment claim, your Honor, as the Supreme Court analysis in Eldred v. Carbrot teaches us, the focus of any First Amendment analysis within the patent laws, a case the plaintiffs have not chosen to address in analysis whatsoever, there are a number of things that come out of that analysis. First, the patent system as a whole is compatible with free speech principles. The Patent Act was adopted very close in time as the Supreme Court said with the First Amendment indicating the Founders were likely thinking that there was no tension between the First Amendment and the Patent Act. And, in fact, as the Supreme Court said, the Patent Act promotes free speech. It requires people to bring to the public ideas and inventions and add to the storehouse of knowledge available to the public. There is no tension between the two, number one. Number 2, what comes out of the Supreme Court Eldred decision is that the Patent Act incorporates First Amendment concerns.

What does that mean, your Honor? What that means is it under Section 101 of the Patent Act as judicially interpreted there are exceptions to 101 which protect and implicate First Amendment interests. Specifically mental

processes and abstract ideas are not patentable under Section 101 and, indeed, what plaintiffs are arguing here is that the patents at issue here shouldn't have been patented under 101 for the same reasons that they violate the First Amendment, which is that they consist of thought or thinking about the genes and the gene patents.

Well, if that is the case, your Honor, your Honor will find that the patents were not properly issued under 101 as abstract ideas or mental process. You need not reach the constitutional issue. But the point is that First Amendment analysis is incorporated within Section 101. And then what Eldred also teaches is that if you, in fact, find the patents properly issued under 101 and consistent with the First Amendment, the only remaining First Amendment scrutiny at that point is to see whether the patent law and Section 101 and its categories properly falls within the traditional contours of patent law. That is what the Supreme Court test is. That is the only remaining inquiry. You take Section 101 and the patent law and you say does traditional contours of patent law include Section 101 as applied to the gene patents and clearly, your Honor, Section 101 is within the traditional contours of the patent law. It has existed unchanged since 1793, and clearly what Congress was thinking when they enacted these broad categories was to encompass anything that might be patentable within those categories that couldn't be envisioned

in 1790 or subsequent years and some of those things now would be the gene patents. So that is the only First Amendment analysis. It's very clear under that analysis in Eldred, which the plaintiff has not challenged, that the patents are consistent with the First Amendment should your Honor even reach the First Amendment analysis.

I would just say one thing briefly, your Honor, not much more has to be said about the First Amendment claims. Plaintiffs' counsel says something about the impossible-to-invent-around argument and I am not sure if something is impossible to invent around why it connects to the First Amendment and free speech principles, but what I will say is, again, the patent statute Section 112 accommodates the impossible to invent around it. So, again, once your Honor concludes a statutory analysis you only get to the constitutional claims in a narrow sense, if at all.

The only final thing I would point out, again mentioned by plaintiffs' counsel at the beginning of his argument, is that plaintiffs' counsel said there aren't any cases where his thinking was there aren't any cases involving constitutional claims challenging patents because only recently has the U.S. PTO began to patent things that implicate First Amendment statutes, and that is absolutely false. As we pointed out, the example used in our papers, Bell telephone, that certainly restricts thought. At the time you could not

use the phone to communicate anything, or any communication without a license from Bell. And there are many patents over the years that have implicated First Amendment concerns.

For these reasons and the reasons set forth in our brief, we request your Honor dismiss the constitutional claims as against the U.S. PTO.

THE COURT: Thank you very much, Mr. Morrison. We will take a short break.

(Recess)

THE COURT: Please be seated, ladies and gentlemen. Yes, sir.

MR. HANSEN: It is my hope I can do this in 5 minutes or less.

THE COURT: Take all the time you need.

MR. HANSEN: Thank you.

I think even if you accept the defendant's version of their method claims, namely, that it incorporates all of the prior steps, even under those circumstances this case turns on whether isolated DNA is different than DNA, whether it is either markedly different under the language of Chakrabarty for the composition claims or whether it's transformative even on the method claims. Of course, we don't agree that you can read in those things. But either way this case turns ultimately on are DNA and isolated DNA different, and I would like to address that by taking Myriad's metaphor of the egg.

Cracking open the egg and separating out the yolk does not make the yolk an invention. I would have thought it would have been clear to all of us that the yolk was the invention of the chicken, not of the cook. And yet that is essentially Myriad's position, is that that they invented the yolk. Now, they want to make it sound more difficult than cracking the egg. They want to say there is this little string hidden somewhere deep in the yolk and they had to dig really deep. If the string is in the yolk the chicken put it there, the cook didn't put it there, and no matter how hard it was for the cook to find it within the yolk it's still an invention of nature. It's not the invention of the cook.

The fact that the yolk can be used in baking once it has been separated from the egg and it can't be used for baking while it's still inside the egg is irrelevant. The question here is is the yolk outside the egg markedly different from inside the egg, is it transformative by the fact that it has been taken out of the egg, and the answer in both instances is no, it's still a product of nature and it's still not a patentable subject matter.

Myriad discusses at great length the process in which you isolate and sequence DNA and they make it sound really complicated and really hard and really innovative. Well, it's none of those things in fact. There were literally thousands of geneticists doing isolating of DNA prior to Myriad's

invention, if Myriad had an invention, and there are literally tens of thousands of geneticists that today are isolating and sequencing DNA. It's a standard garden variety by this stage laboratory methodology and labs do it every day on genes, lots of our genes, all the genes unpatented.

Myriad didn't invent those processes. Myriad has no exclusive control over those processes. Those processes are not part of Myriad's invention. They are, in fact, used by everybody all the time. So even if you accept that it's a really hard process, it's still irrelevant because that is not part of Myriad's patents. Myriad isn't claiming the process, they are claiming the composition.

I would like to make two other additional points. First to the notion that it's up to Congress to change the law here if we don't like the law we should go to Congress. Well, the Supreme Court decided a century ago that products of nature and laws of nature and abstract ideas are not patentable. Congress could have changed that law if it wanted to. Congress didn't. That has been black letter law from the Supreme Court for a century and Congress hasn't changed it and it's now the law of the land.

Finally, I would like to remind us once again what DNA is and what the BRCA1 and BRCA2 genes are. They are informational molecules that provide vital information about women's health that are essential for women to find out whether

they are at risk of hereditary breast or ovarian cancer. Myriad has locked up all the information about that. The medical associations and the physicians in this case object to the negative effect that has had on women's health and that is why we ask your Honor to grant summary judgment to the plaintiffs.

MR. POISSANT: Three quick points, your Honor. Mr. Hansen started out by indicating that markedly different was the real issue in this case and he implicated the method claims at the same time. I submit, your Honor, first of all, that markedly different is the test they are proposing that has something to do with the isolated DNA compositions. It has nothing, nothing whatsoever to do with the diagnostic method claims. That test is the Bilski/Prometheus test. Does a transformation occur as we have shown in the Prometheus determining the levels of metabolyte. Finding, locating, isolating and analyzing the BRCA DNA nucleic acid in a sample is a transformative step. Markedly different has nothing to do with that whatsoever. He was trying to lump them together and you can't do that.

The second point, something about the complicated process for isolating -- a very complicated process we talked about but all this was known in the art, how to go about doing this. That is not the point. The point is the end product. The end product is the isolated DNA composition. That is the

end product. That is the end game. We are not claiming how he got there. It's the end game and we have shown these products are new. They are composition of the matter. They are new under the statute and they are useful. They are new and this concept that they are not new because they are informational, that somehow this isolated DNA is informational in the same way that DNA in the body is informational, that somehow that takes a chemical composition and turns it into a phenomena of nature like electricity is bizarre. The fact it's informational does not in any way, shape or form negate the fact that it is an isolated composition of matter that has new and different utilities that makes it markedly different from DNA in the body, and that is the issue before this court.

Thank you, your Honor.

THE COURT: Mr. Morrison?

MR. MORRISON: Nothing, your Honor.

THE COURT: Thank you all very much.

Obviously I am grateful to counsel for the very clear and effective way that they have presented their positions. The briefing in this, as everybody knows that has had anything to do with this, has been extensive. There is a great deal of material here but it's in the finest traditions of the bar that these issues have been clarified and are articulated so well this morning. So I am very grateful to all of you.

Obviously this is an issue of very real concern

obviously to anyone who is involved in the scientific process, anyone who in the business community is considering the way in which new products come to market, and this entire new area of molecular biology and all the gene processes is very challenging. And it's particularly obviously important to anyone who is concerned with the problems, very real, serious personal problems of breast cancer, and I wouldn't be surprised if everyone in this room hasn't been touched by that problem one way or another.

So these are very serious concerns not only to those people who have been affected by breast cancer but the people who are concerned about providing care, analysis, diagnosis, and on many of these issues, if not all of them, as we have heard for the last 2-1/2 hours, there is a very sharp difference of opinion.

So I am not going to decide this issue from the bench today. I am going to reserve decision and I want to thank you all again for the very skillful way in which you have assisted me and in a sense, not totally, but in a sense I am grateful to you for bringing this issue before me because it certainly is a fascinating and challenging one.

Thank you all very much.

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