IN THE SUPREME COURT OF THE UNITED STATES

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ASSOCIATION FOR MOLECULAR :

PATHOLOGY, ET AL., :

Petitioners : No. 12-398

v. :

MYRIAD GENETICS, INC., ET AL. :

- x

Washington, D.C.

Monday, April 15, 2013

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 10:04 a.m.

APPEARANCES:

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DONALD B. VERRILLI, JR., ESQ., Solicitor General, Department of Justice, Washington, D.C.; for United States, as amicus curiae, supporting neither party.

GREGORY A. CASTANIAS, ESQ., Washington, D.C.; on behalf of Respondents.

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P R O C E E D I N G S

(10:04 a.m.)

CHIEF JUSTICE ROBERTS: We'll hear argument first this morning in Case 12-398, Association for Molecular Pathology v. Myriad Genetics.

Mr. Hansen?

ORAL ARGUMENT OF CHRISTOPHER A. HANSEN

ON BEHALF OF THE PETITIONERS

MR. HANSEN: Mr. Chief Justice, and may it please the Court:

One way to address the question presented by this case is what exactly did Myriad invent? And the answer is nothing.

Myriad unlocked the secrets of two human genes. These are genes that correlate with an increased risk of breast or ovarian cancer. But the genes themselves, their -- where they start and stop, what they do, what they are made of, and what happens when they go wrong are all decisions that were made by nature, not by Myriad.

Now, Myriad deserves credit for having unlocked these secrets. Myriad does not deserve a patent for it.

JUSTICE GINSBURG: Mr. Hansen, Respondents say that isolating or extracting natural products, that

has long been considered patentable, and give -- examples were aspirin and whooping cough vaccine. How is this different from -- those start with natural -- natural products.

MR. HANSEN: Well, in -- in essence, Your Honor, everything starts with a natural product. And this Court has said repeatedly that just extracting a natural product is insufficient. For example, this Court has used the example of gold. You can't patent gold because it's a natural product.

The examples that you cite all involve further manipulation of a product of nature, so that the product of nature is no longer what it was in nature; it's become something different. And in many instances has taken on a new function.

But --

CHIEF JUSTICE ROBERTS: Do you dispute that you can patent, however, a process for extracting naturally-occurring things?

MR. HANSEN: Of course. I think that is totally acceptable. And what's interesting in this case is, the process that Myriad uses to extract the genes is not at issue in this case. It's a process that's used by geneticists every day all over this country. It is routine, conventional science.

CHIEF JUSTICE ROBERTS: So isn't that -- why isn't that a way to, in effect, have patent protection for the product? Does somebody who wants to use the product, the DNA -- extracted DNA in this case, have to find a new process from -- to extract it if they want to have it available?

MR. HANSEN: Well, the -- the process by which it's extracted is now very routine.

CHIEF JUSTICE ROBERTS: Oh, no -- yes, I know. I'm assuming it isn't, that they discover this process and it leads to a -- a particular product. Does anybody who wants to use the product either have to get a license for the process or find a different way of extracting it?

MR. HANSEN: I think they have to find a different way of extracting it, in the same way that finding a method of extracting gold does entitle you to a patent on the method of extracting gold, it may also entitle you to a patent on the use of gold. For example, if you find a new way of using gold to make earrings, or if you find a new way of using DNA to do something, you may be entitled to a patent on that because --

JUSTICE SOTOMAYOR: Can you tell me why their test wasn't given a patent? I know the method of

extraction wasn't, and why. Why would the tests -- would the tests be subject to a patent?

MR. HANSEN: The tests are also routine and conventional science, but in this particular case, there were some method claims that we challenged. The method claims in this case involved taking the genes that you extracted from the woman and the gene that you -- the way you think it should be, and simply looking back and forth to see if they're the same or different. And the Federal Circuit that -- found that that was an abstract idea and not patentable.

And, in fact, that's --

JUSTICE SCALIA: Well, I'm curious as to why the methodology of extracting the gene has not been patented. You say everybody -- everybody uses it. Why wasn't that patented?

MR. HANSEN: The original -- the original methodology was patented, and is -- is patentable. In fact, if they came up with a new process, it would be patentable. But it has -- but that -- it has been very freely licensed. In fact, the patent may now have expired. And so it's used all over the country every day.

JUSTICE ALITO: Can I take you back to -- to Justice Ginsburg's question because I'm -- I don't --

I'm not sure you got at what troubles me about that.

Suppose there is a substance, a -- a chemical, a molecule in the -- the leaf -- the leaves of a plant that grows in the Amazon, and it's discovered that this has tremendous medicinal purposes. Let's say it -- it treats breast cancer.

A new discovery, a new way -- a way is found, previously unknown, to extract that. You make a drug out of that. Your answer is that cannot be patent -- patented, it's not eligible for patenting because the chemical composition of the -- of the drug is the same as the chemical that exists in the leaves of the plant.

MR. HANSEN: If there is no alteration, if we simply pick the leaf off of the tree and swallow it and it has some additional value, then I think it is not patentable. You might be able to get a method patent on it, you might be able to get a use patent on it, but you can't get a composition patent.

But as --

JUSTICE ALITO: But you're making -- you keep making the hypotheticals easier than they're intended to be. It's not just the case of taking the leaf off the tree and chewing it. Let's say if you do that, you'd have to eat a whole forest to get the -- the

value of this. But it's extracted and -- and reduced to a concentrated form. That's not patent -- that's not eligible?

MR. HANSEN: No, that may well be eligible because you have now taken what was in nature and you've transformed it in two ways. First of all, you've made it substantially more concentrated than it was in nature; and second, you've given it a function. If it doesn't work in the diluted form but does work in a concentrated form, you've given it a new function. And the -- by both changing its nature and by giving it a new function, you may well have patent --

JUSTICE ALITO: Well, when you concede that, then I'm not sure how you distinguish the isolated DNA here because it has a different function. Will you dispute that? Isolated DNA has a very different function from the DNA as it exists in nature. And although the chemical composition may not be different, it -- it certainly is in a different form. So what is the distinction?

MR. HANSEN: Well, I don't think it has a new function, Your Honor, with respect. I believe that what -- Myriad has proffered essentially three functions for the DNA outside the body as opposed to inside the body. The first is we can look at it. And that's true,

but that's not really a new function. That's simply the nature of when you extract something you can look at it better.

The second two rationales that Myriad has proffered are that it can be used as probes and primers. Three of the -- three of lower court judges found that full-length DNA, which all of these patent claims include, cannot be used as probes and primers. But more important, finding a new use for a product of nature, if you don't change the product of nature, is not patentable. If I find a new way of taking gold and making earrings out of it, that doesn't entitle me to a patent on gold. If I find a new way of using lead, it doesn't entitle me to a new -- to a patent on lead.

JUSTICE KENNEDY: From what you know and from what the record shows, would the process of tagging the isolated DNA be patentable? The process of tagging, we just don't know about that or is there a patent on that?

MR. HANSEN: The very patents in this case include claims on -- on DNA that is tagged so that it can be used as a probe. We have not challenged that. We are not asking the Court to strike down that.

JUSTICE KENNEDY: Under our -- our law, is a patent ever divisible so that if it's valid in part but

invalid in another part, it can still stand as to the part?

MR. HANSEN: No, it is not permissible under patent law to do essentially a narrowing -- narrowing construction of the -- of the claim.

JUSTICE KENNEDY: But if you haven't challenged this, then -- then where are we with respect to the tagging? I don't quite understand. Because the -- the entire patent, which includes tagging, would fail under your argument.

MR. HANSEN: Oh, I'm sorry, no. I misunderstood. The claims that we are challenging do not -- are not limited to tagging, are not limited to use as probes. There are other claims that we are not challenging that are limited to probes. Those would remain, but the -- but the claims that we're challenging would in fact be struck down because they're not so limited. In fact --

JUSTICE SOTOMAYOR: Then -- then explain when you said you can't narrow. You said earlier you can't narrow.

MR. HANSEN: Yes. If a claim reaches something that is both impermissible and permissible, it -- the claim is invalid, period.

JUSTICE SOTOMAYOR: All right, that

individual claim is invalid.

MR. HANSEN: That individual claim.

JUSTICE SOTOMAYOR: But the patent with respect to claims that are not invalid would still stand.

MR. HANSEN: That is correct, Your Honor.

JUSTICE SOTOMAYOR: The primers and probes stand.

MR. HANSEN: Would -- would still remain. Even if you were to rule for Petitioners, you would not have to rule concerning the use of DNA as a probe or a primer.

JUSTICE KAGAN: Mr. Hansen, could you tell me what you think the incentives are for a company to do what Myriad did? If you assume that it takes a lot of work and takes a lot of investment to identify this gene, but the gene is not changed in composition, and what you just said is that discovering uses for that gene would not be patentable, even if those new -- even if those uses are new, what does Myriad get out of this deal? Why shouldn't we worry that Myriad or companies like it will just say, well, you know, we're not going to do this work anymore?

MR. HANSEN: Well, we know that would not have happened in this particular case, Your Honor. We

know that there were other labs looking for the BRCA genes and they had announced that they would not patent them if they were the first to find it. We also know that prior to the patent actually being issued, there were other labs doing BRCA testing and Myriad shut all that testing down. So we know in this particular case that problem would not have arisen.

But the point of the whole -- the whole point of the product of nature doctrine is that when you lock up a product of nature, it prevents industry from innovating and -- and making new discoveries. It -- that's the reason we have the product of nature doctrine, is because there may be a million things you can do with the BRCA gene, but nobody but Myriad is allowed to look at it and that is impeding science rather than advancing science.

JUSTICE SCALIA: But you still haven't answered her question. Why? Why would a company incur massive investment if it -- if it cannot patent?

MR. HANSEN: Well, taxpayers paid for much of the investment in Myriad's work, but --

JUSTICE SCALIA: You're still not answering the question.

MR. HANSEN: But -- yeah. But I think scientists look for things for a whole variety of

reasons, sometimes because they're curious about the world as a whole, sometimes because --

JUSTICE SCALIA: Curiosity is your answer.

JUSTICE KAGAN: I thought you were going to --

MR. HANSEN: Sometimes because they want a Nobel Prize. Sometimes --

JUSTICE KAGAN: I thought you were going to say something else, Mr. Hansen, and I guess I -- I hoped you were going to say something else, which is that, notwithstanding that you can't get a patent on this gene, that -- that there are still, you know, various things that you could get a patent on that would make this kind of investment worthwhile, in the usual case. But if that's the case, I want to know what those things are rather than you're just saying, you know, we're supposed to leave it to scientists who want Nobel Prizes.

And I agree that there are those scientists, but there are also, you know, companies that do investments in these kinds of things that you hope won't just shut them down.

MR. HANSEN: Let me give a specific example that may be helpful in doing a better job of answering the question. One of the -- one of the amici has

worried a lot about whether a decision for the Petitioners in this case would invalidate recombinant DNA. Recombinant DNA is in fact what all the major innovations in industry are doing these days. It's DNA where the scientist decides the sequence rather than nature deciding the sequence.

There is nothing in our position that would prevent recombinant DNA from being patented, but there is -- it is the cases that if the patents are upheld, recombinant DNA is frustrated.

People can't use pieces of the BRCA gene to recombine them and find new treatments and find new diagnoses and find new things that will advance medicine and science as a result of these patents. It's a perfect example of what the point of the product of nature doctrine is.

JUSTICE SCALIA: Yes. But, of course, to profit from -- from that recombinant DNA, you have to not just isolate the gene, but then you have to do something with it afterwards. So you really haven't given us a reason why somebody would try to isolate the gene.

MR. HANSEN: Well --

JUSTICE SCALIA: I mean, sure, yes, I can do stuff with it afterwards, but so can everybody else.

What advantage do I get from being the person that or the company that isolated that -- that gene. You say none at all.

MR. HANSEN: No, I think you get enormous recognition, but I don't think --

JUSTICE SCALIA: Well, that's lovely.

MR. HANSEN: But I think that we know that that's sufficient. We know it's sufficient with respect to these two genes. We also know it's sufficient with respect to the human genome project.

JUSTICE KENNEDY: Well, I'm not sure the Court can decide the case on -- on that basis. I'm sure that there are substantial arguments in the amicus brief that this investment is necessary and that -- and that makes sense. To say, oh, well, the taxpayers will do it, don't worry, is, I think, an insufficient answer.

As Justice Kagan's follow-up questions indicated, I thought you might say, well, there are process patents that they can have, that this is sufficient.

MR. HANSEN: And that's certainly true.

JUSTICE KENNEDY: But I -- I just don't think we can decide the case on the ground, oh, don't worry about investment, it'll come. I -- I just don't think we can do that. It may be that the law allows you

to prevail on the fact that this is -- occurs in nature and there's nothing new here, but that's quite different.

MR. HANSEN: And it is certainly true, as Your Honor suggests, that one of the incentives here is a process patent or a development patent. If you -- if you've isolated the gene and you find a new use for it, you could get a patent on the new use for the patent.

JUSTICE SOTOMAYOR: That's the whole point, isn't it? The isolation itself is not valuable, it's the use you put the isolation to. That's the answer, isn't it?

MR. HANSEN: That's exactly correct. Thank you. Yes, that is the answer.

JUSTICE SOTOMAYOR: And so that is the answer, which is in isolation it has no value. It's just nature sitting there.

MR. HANSEN: Interestingly, it has one value. And that is you can look at it to see if there's a mutation in it. And when you find a mutation in the isolated gene, you write back to the woman who provided the sample and you say to her because the isolated gene is the same as the gene in your body, I can tell you that there's a mutation in your body.

JUSTICE SOTOMAYOR: That's a failure of the

patent law. It doesn't patent ideas.

MR. HANSEN: And it shouldn't patent ideas, and -- but it also makes the point that isolated gene and the gene in the body are the same.

JUSTICE SOTOMAYOR: Can we go to -- can we go to cDNA a moment?

MR. HANSEN: Sure.

JUSTICE SOTOMAYOR: That is artificially created in the laboratory, so it's not bound in nature. It's not taking a gene and snipping something that's in nature. And yet you claim that can't be patented. The introns are taken out, the exons are left in, and they're sequenced together. Give me your argument on that. I read your brief, but it is not a product of nature, it's a product of human invention.

MR. HANSEN: There are two big differences between cDNA and DNA. The first is exactly the one Your Honor just discussed, which is that the introns, the noncoding regions, have been removed. That is done in the body, by the body. That's done in the process of DNA going to mRNA.

What the scientist does who's creating the cDNA is they take the mRNA out of the body and then they simply have the natural nature-driven nucleotide binding processes complement the mRNA. So that if the mRNA has

a C, the scientist just puts a -- the corresponding nucleotide in there and nature causes them to bind up. The scientist does not decide --

JUSTICE BREYER: I know, but I don't see the answer because I gather, if I -- if I've read it correctly, that when you have an R -- the messenger RNA does not have the same base pairs. There's a U or something instead of an A or whatever it is.

MR. HANSEN: Yes.

JUSTICE BREYER: So when you actually look, if you could get a super-microscope and look at what they have with the cDNA, with their cDNA, you would discover something with an A, not a U. Is it AU? Is that the one?

MR. HANSEN: Yes.

JUSTICE BREYER: Okay. Okay. So -- so you would discover something with an A there, you see, and you wouldn't discover something with a U there. And there is no such thing in nature as the no-introns AGG, whatever, okay? It's not there. That's not truly isolated DNA. But you can go look up the Amazon, wherever you want. Hence the question. Now, on that one, how? How is that found in nature? The answer is it isn't.

MR. HANSEN: Well, but I would suggest, Your

Honor, that the question is not whether it is identical to something in nature. The question is whether there was a human invention involved, whether it is markedly different from what is found in nature.

JUSTICE SOTOMAYOR: But that goes to obviousness. That does not in my mind go to the issue of whether it's patent eligible. You may have a very strong argument on obviousness, but why does it not -- it's creating something that's not found in nature at all.

MR. HANSEN: The sequence of the nucleotides is dictated by nature. The order that they go in is dictated by nature.

JUSTICE SOTOMAYOR: Well, that's a separate question --

MR. HANSEN: It is true --

JUSTICE SOTOMAYOR: -- about whether this claim is too expansive because it's claiming every 15 nucleotides and nature produces 15 randomly. But assuming the claim was for the entire mutated gene and not the small snippet that they want to capture the whole gene with, that's -- that whole gene without the introns is just not found in nature.

MR. HANSEN: It is not -- the -- the exons with the exact same composition and in the exact same

order are found in nature, and the question is whether when the body removes the introns, has the body made something markedly different than what is in nature, and it is our view --

JUSTICE KENNEDY: When I first looked at this case, I -- I thought that maybe the cDNA was kind of an economy class gene, was -- it wasn't. But my understanding is that it may have a functionality that the -- the DNA isolate does not, easier to tag, et cetera. That may be incorrect for the record, but that was my present understanding.

MR. HANSEN: It is somewhat easier to work with cDNA to make recombinant DNA, and it's recombinant DNA that is the place where all of the innovation and all the efforts are taking place. And if we lock up --

JUSTICE KENNEDY: Is all the tagging done on recombinant DNA?

MR. HANSEN: All of the change -- all of the useful things that we are inventing is done -- is done through the process of recombinant DNA. And if we lock up the cDNA, it makes it harder to do the recombinant DNA. So that if someone owns all the cDNA, I can't do recombinant DNA using what the company owns.

JUSTICE GINSBURG: Mr. Hansen, you answered my initial question by saying they start -- everything

starts with a national -- natural product, but these others, the examples that I gave, you said they involve manipulation. The -- the cDNA can't be characterized as involving manipulation?

MR. HANSEN: It certainly -- there's -- there is some manipulation, although it's -- it's letting nature manipulate, not doing -- not the scientist manipulating. But it -- what the other factor that distinguishes aspirin and the other examples you use from cDNA is that they have -- the alteration of the substance has also altered the function, and cDNA has exactly the same function as DNA with the exception of Justice Kennedy's, that it's easier to use with.

JUSTICE SCALIA: Do you -- you've really lost me when you say that it's nature that does the alteration rather than the scientist. I mean, whenever a scientist does an alteration, he does it, you know, by some force of nature.

MR. HANSEN: No --

JUSTICE SCALIA: I mean, he doesn't do it unnaturally, does he? I mean, there's some --

MR. HANSEN: Well, let me try an analogy, Your Honor, that might be helpful. In our view, it's like Funk Brothers in the sense that the five bacteria in Funk Brothers didn't sit together in nature.

The scientists took them and put them together in nature. Here the scientist takes the exons and lets the natural processes of the body put them together in -- in the laboratory. It's exactly the same as Funk Brothers.

If I could reserve the remainder of my time, Your Honor.

JUSTICE BREYER: Can I ask a question, which I don't think will be taken from your time.

MR. HANSEN: Sure, of course.

JUSTICE BREYER: But I have to ask you this. Look, you say don't reach the cDNA issue and the reason is because of the nature of the claim. Okay, I look at their claim. Their claim says they want, "the isolated DNA of claim 1 wherein said DNA has the nucleotide sequence set forth in SEQ ID No. 1."

Then we turn to that and the first thing it says right there is it says, "The molecule involved is" -- "Molecule type: cDNA." And then it has a long list and that long list is a list of the basis, okay.

So molecule type, cDNA. So they say what do you mean they aren't claiming cDNA? That's what they say they're claiming.

MR. HANSEN: No --

JUSTICE BREYER: Because of the word

"wherein." So I go back to the "wherein" in Prometheus and the "wherein" -- you read "wherein" as in context, and in this context you mean to say that a person who makes isolated DNA that has lots of introns in it as well as the sequence is going to be an infringer under claim 2?

MR. HANSEN: Yes, Your Honor.

JUSTICE BREYER: Is there any support for that other than the treatise that you cited?

MR. HANSEN: There --

JUSTICE BREYER: I mean, I looked at that and it said read the "wherein" depending on context.

MR. HANSEN: Well, that certainly --

JUSTICE BREYER: And then depending on -- okay. Then you got -- you heard what I said, so I want to know is there anything else I should read?

MR. HANSEN: Yes. The other support for it is the definition of the DNA in the patent itself, which we cite, which says that whenever we use the term "DNA" we mean both.

JUSTICE BREYER: Yes, I saw that. I saw that.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

MR. HANSEN: Thank you, Your Honor.

CHIEF JUSTICE ROBERTS: General Verrilli?

ORAL ARGUMENT OF DONALD B. VERRILLI, JR.,
FOR THE UNITED STATES, AS AMICUS CURIAE,
SUPPORTING NEITHER PARTY

GENERAL VERRILLI: Mr. Chief Justice, and may it please the Court:

Enforcing the distinction between human invention and a product of nature preserves a necessary balance in the patent system between encouraging individual inventors and keeping the basic building blocks of innovation free for all to use. Isolated DNA falls on the ineligible side of that divide because it is simply native DNA extracted from the body. The claim that it is a --

JUSTICE SOTOMAYOR: Are we fighting over nothing? Are you fighting over nothing? If -- if they can patent this cDNA in the way they have, what does it matter, since it appears as if research has to rely on the cDNA to be effective?

GENERAL VERRILLI: I actually think that -- I think we're -- we're fighting about something of importance. That question gets right to it. I want to answer the question directly, Your Honor. I'd like to make a prefatory point before doing so.

The claim that isolated DNA is a human invention rests entirely on the fact that it is no

longer connected at the molecular level to what surrounded it in the body. But allowing a patent on that basis would effectively preempt anyone else from using the gene itself for any medical or scientific purpose. That is not true about a patent on cDNA. A patent on cDNA leaves the isolated DNA available for other scientists and other -- and others in the medical profession to try to generate new uses.

JUSTICE KAGAN: Mr. Hansen -- Mr. Hansen just said that to do recombinant technology, you have to use the cDNA rather than the native D -- the isolated DNA. Do you disagree with that?

GENERAL VERRILLI: That's not my understanding, Justice Kagan. My understanding is that you -- that the native DNA can be used for recombinant DNA without the step of cDNA. We do think cDNA is important and the position of the United States is that cDNA is patent eligible. We disagree --

JUSTICE KENNEDY: Well, suppose his understanding is correct. Suppose your misunderstanding -- suppose your understanding is not correct.

GENERAL VERRILLI: Our position, though, is that cDNA is patent eligible because we don't -- we think, unlike the isolated DNA which is just taken from your body,

cDNA is an artificial creation in the laboratory that doesn't correspond to anything in your body.

JUSTICE GINSBURG: But Mister -- General Verrilli, I got the distinct impression from your brief that your view was that, although the cDNA may be patentable, it might very well be rejected as obvious.

GENERAL VERRILLI: That's true now, Justice Ginsburg, but obviousness is determined at the time that the patent is issued, so what may be true now might not have been true at the time the patents were initially issued. And --

JUSTICE SOTOMAYOR: I understand --

CHIEF JUSTICE ROBERTS: But I -- I thought the basic general approach here was we have a very expansive view of what is patent eligible and then we narrow things through things -- issues like obviousness and so on. Why -- wouldn't it make more sense to address the questions at issue here in the obviousness realm?

GENERAL VERRILLI: That's a little --

CHIEF JUSTICE ROBERTS: If you got something that's big, it seems to me pretty obvious that you could take a smaller part of it. That the idea -- a smaller part of something that's bigger is obvious. Now, yes, you can have a patent on the process of extracting that

small part, but I don't understand how a small part of something bigger isn't obvious. And if it is, I don't understand why this -- these issues aren't addressed at that stage.

GENERAL VERRILLI: Well, I think my answer to that, I guess, Your Honor, would -- would point first to Mayo, in which the Court recognized that the threshold test under Section 101 for patent eligibility does do work that the obviousness test and a novelty test and a specification test do not do, and the work that it does here, I would respectfully submit, is to ensure that the natural substance, the product of nature itself, is not subjected effectively to a monopoly because if it can be deemed to be a human invention solely as a result of the change that occurs when you extract it from the body, then that means, as a -- as a practical matter that you have granted a patent on the gene itself because no one else can extract it because extracting it is isolating it, isolating it violates the patent.

And so as a result of that, no one else can try to develop competing tests for breast cancer, no one else can try to use this gene for recombinant DNA.

CHIEF JUSTICE ROBERTS: I'm -- I'm not sure that's responsive to my concern. Your answer said well,

here are a lot of reasons why this shouldn't have patent protection. My question goes to whether we ought to focus on those reasons at the eligibility stage or at the obviousness stage.

GENERAL VERRILLI: Well, the Court identified in Chakrabarty and then reiterated in Mayo that -- that it is -- that the right answer to that question, Your Honor, is to focus on them at the eligibility stage because the -- because getting the balance right is of critical importance.

JUSTICE ALITO: Well, the issue here is a very difficult one. It's one on which the government has changed its position, isn't that correct?

GENERAL VERRILLI: Yes, Your Honor.

JUSTICE ALITO: It seems that there is disagreement within the Executive Branch about it. This case has been structured in an effort to get us to decide this on the broadest possible ground, that there's no argument, that it's just about 101, it's not about any other provision of the Patent Act.

Why -- why should we -- why should we do that? We have claims that if patent eligibility is denied here it will prevent investments that are necessary for the development of new drugs or it will lead those who develop the new drugs to -- new

diagnostic techniques, to keep those secret, not disclose them to the public. Why -- why should we jump in and -- and decide the broadest possible question?

GENERAL VERRILLI: Well, I would -- again, I would point the Court to what the Court said last term in Mayo, which is that the determination of patent eligibility really is a double-edged sword.

And it may be that in a -- in a particular case, maybe this case, although we are not expressing a view on it, you could sort the issue out on some of the other criteria, but that won't generally be true, and the proposition of whether you can patent the gene itself is a question we think of fundamental importance, and it raises exactly the two-edged sword concern that led the Court to conclude what it did in Mayo. And Mayo was a situation very much -- I'm sorry.

JUSTICE GINSBURG: General Verrilli, there's an assertion made in Respondents' brief that the United States would be in a singular position. That is, they suggest that in every other industrialized nation this could be subject -- could be patentable.

GENERAL VERRILLI: Yes, and that --

JUSTICE GINSBURG: Is that so?

GENERAL VERRILLI: No. I think the picture is much more complicated than that. In many other

nations it wouldn't be patentable and the patent law is different from nation to nation.

I'll give one example I think helps illustrate the point. In Germany and France, for example, you can get a patent on isolated genomic DNA, but only for a particular use. So you would get what is the equivalent of a use patent, which is a patent that we would think under our patent laws is acceptable, too.

If you -- just as with the question that Justice Alito asked earlier about identifying a -- a useful substance in a plant in the Amazon, if you isolate that and it proves to have therapeutic effects, you can get a patent on that use of it, but what you can't do is get a patent on the substance itself so that no one else can explore it for different uses and for -- and for different therapeutic purposes or to try to recombine it and turn it into a -- an even more therapeutic -- therapeutically valuable substance. And that's --

JUSTICE SOTOMAYOR: I understand why you are saying cDNA is patentable as a subject matter. I am looking at the way the claim is phrased, however, and it says that it's patenting a DNA segment 15 nucleotides long or longer. The reality is that 15 nucleotides doesn't necessarily bridge a sequence that goes between

exons. It -- it can -- one exon can be 15 or more sequences long. So are you arguing that this claim as written is sustainable?

GENERAL VERRILLI: Your Honor, as a -- I am going to invoke my privilege as an amicus in this situation. I think that's a fight between the parties. The point that we wanted to make is that as a conceptual matter cDNA is patent eligible.

JUSTICE SOTOMAYOR: So you are not taking the position that this claim as written is patentable?

GENERAL VERRILLI: That's right, Your Honor. We're just saying as a conceptual matter that we think cDNA is a creation of the lab, it's an artificial creation, it's as a general matter patent eligible.

JUSTICE SOTOMAYOR: Because as I understand it, 15 nucleotides long exists naturally in nature. They get reproduced in that sequence of 15.

GENERAL VERRILLI: That -- that may well be right, Your Honor. As I said, we're not taking a position on the particulars.

But if I -- just to return to the point that Justice Alito made, the Court really was faced with a similar situation in Mayo. On the one side you had the -- the industry coming in and saying, look, we have got a lot of reliance issue, PTO has issued more than

150,000 patents here. You are going to really disrupt those reliance issues. On the other side you had the American Medical Association, as you have here, coming in and saying, actually, these patents inhibit much more innovation than they incent.

And what the Court said is that -- as Justice Kennedy alluded to earlier, that the Court's not in a position to resolve that dispute conclusively. It doesn't have the institutional wherewithal to do it. But what the Court is in a position to do is to apply the general principles of law as they were articulated in Mayo, and then if there needs to be a particular different set of rules for the biotech industry, Congress can provide that different set of rules.

JUSTICE KAGAN: General Verrilli, could I understand what you said because I think it might be a little bit different from Mr. Hansen and I just want to understand your position. You said that a company can't get a -- a patent on the thing, but can get it on the uses. So if I find this plant, let's say, in the Amazon and I can't get a patent on the thing itself, but can I get a patent when I discover that if you eat this plant it has therapeutic effects?

GENERAL VERRILLI: May I answer briefly, Mr. Chief Justice?

CHIEF JUSTICE ROBERTS: Briefly, please.

GENERAL VERRILLI: Yes, you certainly can, and that illustrates the difference. That patent is just for the use, it doesn't tie up all other potential uses of the substance and that's the key.

Thank you.

CHIEF JUSTICE ROBERTS: Thank you, General.

Mr. Castanias?

ORAL ARGUMENT OF GREGORY A. CASTANIAS

ON BEHALF OF THE RESPONDENTS

MR. CASTANIAS: Mr. Chief Justice, and may it please the Court:

It is now 33 years after Chakrabarty, 31 years after the first isolated gene molecule patents issued, and 12 years after the Patent and Trademark Office issued its carefully reasoned Utility Guidelines confirming that new isolated gene molecules are eligible for patents. And it's almost 16 years after Myriad's patents began to issue, Patents which -- yes?

JUSTICE SOTOMAYOR: Is that on the basis of a new extraction process?

MR. CASTANIAS: On a -- a new extraction process, no. Most of the processes are known. But that's not relevant to patent eligibility or, for that matter, patentability. As the last sentence, Justice

Sotomayor, of Section 103A says, "Patentability shall not be negated by the manner in which the invention was created."

JUSTICE SOTOMAYOR: I -- I have a sort of analytical problem. I find it very, very difficult to conceive how you can patent a sequential numbering system by nature, in the same way that I have a problem in thinking that someone could get a patent on the computer binary code merely because they throw a certain number of things on a piece of paper in a certain order.

I always thought that to have a patent you had to take something and add to what nature does. So how do you add to nature when all you are doing is copying its sequence?

MR. CASTANIAS: Well, I guess I'll --

JUSTICE SOTOMAYOR: How do you add to it besides process or use?

MR. CASTANIAS: Sure. Well, Justice Sotomayor, I guess I'll take issue with the notion that there is nothing additive here. What Myriad inventors created in this circumstance was a new molecule that had never before been known to the world. Now remember, genes are themselves human constructs. And this points up some of the serious analytical problems with the Product of Nature Doctrine as the line-drawing exercise

that you've asked General Verrilli and Mr. Hansen to engage in has illustrated.

The line-drawing is what is the product of nature to start with? Is it me? Is it the genome? Is it the chromosome? Is it the -- and the gene ultimately --

JUSTICE SOTOMAYOR: Look, I can bake --

MR. CASTANIAS: -- is what was defined.

JUSTICE SOTOMAYOR: I can bake a chocolate chip cookie using natural ingredients -- salt, flour, eggs, butter -- and I create my chocolate chip cookie. And if I combust those in some new way, I can get a patent on that. But I can't imagine getting a patent simply on the basic items of salt, flour and eggs, simply because I've created a new use or a new product from those ingredients.

MR. CASTANIAS: And that's --

JUSTICE SOTOMAYOR: Explain to me --

MR. CASTANIAS: Sure.

JUSTICE SOTOMAYOR: -- why gene sequences, whether in the actual numbers, why gene sequences are not those basic products that you can't patent.

MR. CASTANIAS: Okay. I'll start by -- by showing you how this is actually a different structure. It actually has an entirely different chemical name when

you give it the C --

JUSTICE SOTOMAYOR: That's the cDNA.

MR. CASTANIAS: No, no, no. That's absolutely true with regard to the isolated molecule as well. Because if you were to write it out in those -- those interminable chemical equations that we had to do in high school, it's a "C" very different, "H" very different.

JUSTICE SOTOMAYOR: So I put salt and flour, and that's different?

MR. CASTANIAS: Well, that is -- that is the combination, yes, of two different things, and that's sort of like -- that's sort of like --

JUSTICE SOTOMAYOR: So if I take them apart, now you can get a patent on the salt and now you can get a patent on the flour?

MR. CASTANIAS: Well, they were apart before, but they were both old. That's the problem with using the really simplistic analogies, with all due respect, Your Honor, about you know, like coal --

JUSTICE SOTOMAYOR: Well, I guess --

MR. CASTANIAS: -- like leaves and that sort of thing.

JUSTICE ALITO: Why is the chemical composition in the isolated DNA different? You were

about to explain that.

MR. CASTANIAS: Yes, thank you, Justice Alito. It -- it's got 5,914 nucleotides. The genome itself has over 3 billion. It's arranged in the way set forth -- as set forth in the SEQ IDs number 1 and 2. Number 2 is the so-called genomic DNA, SEQ ID number 1 is the, as Justice Breyer understood, the cDNA molecule.

When you look at those particular sequences, there was invention in the decision of where to begin the gene and where to end the gene. That was not given by nature. In fact --

JUSTICE SCALIA: Well, well, well, well, this is something I was going to ask you. I -- I assume that it's true that -- that those abridged genes, whatever you want to call them, do exist in the body. That they do exist. You -- you haven't created a type of gene that does -- does not exist in the body naturally.

MR. CASTANIAS: But we've -- I'll -- I'll use my own simplistic analogy which we offered in our brief and which we offered to the lower court. A baseball bat doesn't exist until it's isolated from a tree. But that's still the product of human invention to decide where to begin the bat and where to end the

bat.

JUSTICE BREYER: Well, that's true, but then you were saying something that I just didn't understand because I thought the -- the scientists who had filed briefs here, as I read it, said it's quite true that the chromosome has the BRCA gene in the middle of it and it's attached to two ends.

But also in the body, perhaps because cells die, there is isolated DNA. And that means that the DNA strand, the chromosome strand is cut when a cell dies, and then isolated bits get around, and there may be very few of them in the world, but there are some, by the laws of probability, that will in fact match precisely the BRCA1 gene.

Now, have I misread what the scientists told us, or are you saying that the scientists are wrong?

MR. CASTANIAS: Well, I will tell you that --

JUSTICE BREYER: I probably misread it. There's a better chance that I've misread it.

(Laughter.)

MR. CASTANIAS: Well, no, I think -- I think you may have read some of the submissions correctly, Justice Breyer. I think that's a question --

JUSTICE BREYER: Well, which one have I not

read --

MR. CASTANIAS: I think that's a question of some dispute in this record.

JUSTICE BREYER: So in other words, you're saying that the Lander brief is wrong.

MR. CASTANIAS: Well, what I will tell you --

JUSTICE BREYER: I want to know because I have to admit that I read it and I did assume that as a matter of science it was correct. So I would like to know whether you agree, as a matter of science, that it is correct, not of law, but of science, or if you are disagreeing with it, as a matter of science.

MR. CASTANIAS: What I will tell you is that what are called pseudogenes --

JUSTICE BREYER: I'd like a yes or no answer.

MR. CASTANIAS: Yes. So the answer -- I would say the answer is no because there is no evidence --

JUSTICE BREYER: Was the answer no, you do not disagree with it? I wonder, I disagree or I do disagree?

MR. CASTANIAS: I do disagree with it with the following --

JUSTICE BREYER: As a matter of science.
MR. CASTANIAS: As a matter of science with the following -- okay.
JUSTICE BREYER: Okay. Very well. If you are saying it is wrong, as a matter of science, since neither of us are scientists, I would like you to tell me what I should read that will, from a scientist, tell me that it's wrong.
MR. CASTANIAS: You want me to tell you something from a scientist that you should read that tells you that it is wrong?
JUSTICE BREYER: No -- yes -- I need to know --
MR. CASTANIAS: I think you could look at the declaration in the -- the Joint Appendix for Dr. Kay, for example. Dr. Kay's declaration appears at -- starting at page 370. You'll find an extensive discussion in there of the technology here and -- and of the genetics.
But, Justice Breyer, just to explain the finishing thought, what -- what Dr. Lander says in his brief is that these pseudogenes, which are un -- undifferentiated fragments, exist in the body. What hasn't been brought to the -- to the forefront is something that is new and useful and available to the public for -- for allowing women to determine whether

they have breast or ovarian --

CHIEF JUSTICE ROBERTS: Can I --

MR. CASTANIAS: -- mutations that are likely to result in cancer.

Yes, Mr. Chief Justice?

CHIEF JUSTICE ROBERTS: Can I get back to your baseball bat example?

MR. CASTANIAS: Sure.

CHIEF JUSTICE ROBERTS: My understanding -- my understanding is that here, what's involved, obviously through scientific processes, but we're not talking about process. Here, what's involved is snipping. You've got the thing there and you snip -- snip off the top and you snip off the bottom and there you've got it.

The baseball bat is quite different. You don't look at a tree and say, well, I've cut the branch here and cut it here and all of a sudden I've got a baseball bat. You have to invent it, if you will. You don't have to invent the particular segment of the -- of the strand, you just have to cut it off.

MR. CASTANIAS: Well, I -- I guess I'll even take issue with that because the -- the story of how the SEQ ID number 2, the genomic DNA segment came about is exactly the opposite of that. If you look, for example,

at page 488 of the Joint Appendix, that's the declaration of one of the inventors, Donna Shattuck, at paragraph 27, what -- what she explains is that the Myriad inventors first created the cDNA, which we agree at least on that score with the Solicitor General, is indeed eligible for patenting. But then -- and by the way, that cDNA was created from hundreds of different patient samples to create what was called a consensus sequence.

CHIEF JUSTICE ROBERTS: Okay. You've got the cDNA.

MR. CASTANIAS: And then what the -- what the Myriad inventors then did to create what is called SEQ ID number 2 and what is claimed in claim 1 of the '282 patent is to take -- actually manipulate that further to add in the introns. It was in -- actually, the inventive process was additive.

Now, ultimately, again, going back to the last sentence of section 103, the patentability should not be negative -- or negated by the manner in which an invention was made, maybe that shouldn't matter. But it is a --

CHIEF JUSTICE ROBERTS: I'm sorry, I still don't understand what -- in what sense it's different than just snipping along -- along the line.

MR. CASTANIAS: Well, first of all, you wouldn't even know where to snip until the Myriad invention. That's the first problem.

CHIEF JUSTICE ROBERTS: Okay. So that's a particular -- where you snip. We're talking about though the patentability of what's left --

MR. CASTANIAS: Right.

CHIEF JUSTICE ROBERTS: -- after you've snipped it.

MR. CASTANIAS: And -- and that is indeed a product of human ingenuity and that has substantial new uses. Now, my friends on the other side have said --

JUSTICE KAGAN: Mr. Castanias, go back to Justice Alito's plant in the Amazon, right because it takes a lot of ingenuity and a lot of effort to actually find that plant, just as it takes a lot of effort and a lot of ingenuity to figure out where to snip on -- on the genetic material.

But are you -- are you saying that you could patent that plant because it takes a lot of effort and a lot of ingenuity to find it?

MR. CASTANIAS: The plant itself, I think not, Justice Kagan, but I think the question that was -- that was posed was whether I could take an extract from that plant.

JUSTICE KAGAN: Well, but can you patent the thing itself?

MR. CASTANIAS: The thing itself I would -- in that hypothetical, I would say the answer is no.

JUSTICE KAGAN: Even though you know you have to extract the plant itself --

MR. CASTANIAS: It's a lot of --

JUSTICE KAGAN: -- from the Amazon forest.

MR. CASTANIAS: Ah, but you see, now you're adding the manipulation --

JUSTICE KAGAN: I'm not -- I mean, I don't know what manipulation means. I mean, you have to take the plant and uproot it, all right?

MR. CASTANIAS: Okay.

JUSTICE KAGAN: And carry it away and isolate it. Can you now patent the thing itself? You've now taken it out of the Amazon forest. Can you now patent it?

MR. CASTANIAS: Well, what I -- what I haven't done is isolated a new thing. All I have done is isolate the plant from the forest. And that's the distinction I think I'm trying to get across to the Court, not particularly well at least in my colloquy with Justice Breyer, but I'll try again. And that is that what -- what was, quote, merely snipped out of the

body here is fundamentally different in kind from what was in -- what is in the body. The most important reason it's different in kind is that it cannot be used in the body to detect the risk of breast and ovarian cancers.

JUSTICE KAGAN: Well, the plant in the forest can't be used for any purpose either. It only has a use when it's taken out -- you know, when it's uprooted and taken out of the forest. But it's still the same thing. And I guess what you haven't gotten me to understand is how this is different than that. It's still the same thing, but now that you've isolated it, it in fact has lots of great uses.

MR. CASTANIAS: Well, I think there are two ways -- two ways to look at that.

First of all, if you want to look at it from the -- the perspective of the so-called product of nature doctrine, which I think has some very dangerous consequences if it's not cabined and understood correctly. But if you look at it strictly from a product of nature doctrine, you could say, well, that's the same plant and it says in the 1930 legislative history of the Plant Patent Act that plants that are unmanipulated by the hand of man are not eligible for patents, and that's fine, in terms of their breeding and

genetics and that sort of thing.

But the product of nature doctrine is troublesome for this reason, modern medicine -- go beyond just the isolated DNA patents here. Modern medicine, particularly the area of personalized medicine, is trying to get to a point where what we are administering to individual patients is giving them the opportunity to mimic the actions of the body. And -- so actually, the goal of medicine is to get closer to nature, rather than farther away. And anything that takes the product of nature doctrine beyond the simple truism that the product of nature is something that is not a human invention, then that's very dangerous, not just for our case --

JUSTICE KENNEDY: But when you -- when you isolate the DNA, that by itself cannot be used as -- as a probe until you add tags and -- and other chemicals that make it probe.

MR. CASTANIAS: As a probe, that's true. As a primer, that wouldn't be required.

JUSTICE KENNEDY: So it seemed to me your -- your answer was not quite accurate when you said, well, it can't be used in the body to detect breast cancer. Neither can the isolate without some additions.

MR. CASTANIAS: Well, since this Court --

I'm sorry.

JUSTICE KENNEDY: Now, if it's -- if it's the process or the additions that make it patentable, fine. But you're say that the moment it's snipped, it's patentable, and that it seems to me was -- was the point of Justice Kagan's question.

MR. CASTANIAS: Well, I -- I will say that that is the final inventive act. It's not the only inventive act. It's the final inventive act. If -- if indeed you were creating it --

JUSTICE GINSBURG: Do you concede -- Do you concede at least that the decision in the Federal Circuit, that Judge Lourie did make an incorrect assumption, or is the Lander brief inaccurate with respect to that, too? That is, Judge Lourie thought that isolated DNA fragments did not exist in the human body and Dr. Lander says that wrong.

MR. CASTANIAS: No, what -- I think Justice -- Judge Lourie was exactly correct to say that there is nothing in this record that says that isolated DNA fragments of BRCA1 exist in the body. Neither does Dr. Lander's brief, for that matter. And for that matter, those isolated fragments that are discussed in Dr. Lander's brief again are -- are what are known not -- not in any way as isolated DNA, but as

pseudogenes. They're typically things that have been killed off or mutated by a virus, but they do not --

JUSTICE ALITO: But isn't this just a question of probability? To get back to your baseball bat example, which at least I -- I can understand better than perhaps some of this biochemistry, I suppose that in, you know, I don't know how many millions of years trees have been around, but in all of that time possibly someplace a branch has fallen off a tree and it's fallen into the ocean and it's been manipulated by the waves, and then something's been washed up on the shore, and what do you know, it's a baseball bat.

Is that --

(Laughter.)

JUSTICE ALITO: -- is that what Dr. Lander is talking about?

MR. CASTANIAS: That's pretty much the same as what he's talking about, is that there might be something that was out there somewhere. But -- but that's really -- the search for this sort of thing that might be very similar to the thing but never was known before. The patent law has taught -- the patent law is all about pushing the frontiers.

JUSTICE BREYER: All right. When you are on that, that's good. A more basic question to me is

when you use the word "dangerous." I had thought -- and you can -- I'd be interested in your view -- that the patent law is filled with uneasy compromises because on the one hand, we do want people to invent. On the other hand, we're very worried about them tying up some kind of whatever it is, particularly a thing that itself could be used for further advance.

And so that the compromise that has been built historically into this area is, of course, if you get a new satisfying process to extract the sap from the plant in the Amazon, patented. Of course, if you get the sap out and you find that you can use it, you manipulate it, you use it, you figure out a way to use it to treat cancer, wonderful, patented. But what you can't patent is the sap itself.

Now, in any individual case that might be unfortunate or fortunate. But consider it in the mine run of things. It's important to keep products of nature free of the restrictions that patents there are, so when Captain Ferno goes to the Amazon and discovers 50 new types of plants, saps and medicines, discovers them, although that expedition was expensive, although nobody had found it before, he can't get a patent on the thing itself. He gets a patent on the process, on the use of the thing, but not the thing itself.

Now, that's my understanding of what I'd call hornbook patent law, which you I confess probably understand better than I.

MR. CASTANIAS: Well --

JUSTICE BREYER: And I would like you to express your view on that because that's the framework that I am bringing to the case.

MR. CASTANIAS: I -- I will offer the view, Justice Breyer.

First of all, in this Court's decision in Brenner v. Manson, followed repeatedly by the Federal Circuit, it has been hornbook patent law, to use your term, that you do not need to -- to call out the utility of an invention in a particular claim. What you do have to do is have utility for the invention itself described in the specification.

And that's what the Patent Office looked to in its Utility Guidelines in 2001. But ultimately, neither -- I think this case is very -- very easily decided on a straightforward ground that does not require the Court to go making fine distinctions between cDNA and DNA.

And that ground is this: The reasoned Utility Guidelines issued in 2001 by the Patent Office, who has not, in a very significant decision, joined the

brief of the Solicitor General in this case -- and which they continue to apply under Section 2107 of the Manual of Patent Examining Procedure, this -- these guidelines not only tell examiners what to do, but in the Federal Register they had notice and comment and 23 specific reasoned, supported by case law, supported by science, responses to the objectors. Almost every objection that is made to our patents here was made there and answered there.

The PTO issued those guidelines to the public. They have been relied on now for 12 years, and they confirm a practice that has been in place much longer than that. And if you take -- whether you can call it Skidmore deference or just giving respect to the agency that sits at the intersection of law and science -- Justice Breyer, as your opinion for the Court in Dickinson v. Zurko pointed out -- those -- that decision by the Patent Office is entitled to respect, the reliance that has been placed --

JUSTICE GINSBURG: Even though -- even though the government has disavowed it, even though the government, representing the United States --

MR. CASTANIAS: Even though, and -- and the reason for that is --

JUSTICE GINSBURG: At least that the

strength of the presumption would be diluted.

MR. CASTANIAS: I think you can dilute it a little bit, but you can't take away the fact that it is a 30-plus year practice that the Patent Office, despite the executive's position in this Court and in the Federal Circuit, continues to follow.

JUSTICE KAGAN: Mr. Castanias, could I take you away from the deference point and just ask again about the -- the kind of law that you would have us make. Do you think that the first person who isolated chromosomes could have gotten a patent on that?

MR. CASTANIAS: I think in theory that is possible, but I should say this because this case is about Section 101, I'm trying -- I'm answering your question as though it's about 101, patent eligibility.

JUSTICE KAGAN: Yes.

MR. CASTANIAS: Would it be obvious, would it be novel? I'm not sure. Those are different -- those are different analytical structures.

JUSTICE KAGAN: Right.

MR. CASTANIAS: But would it -- and I think really, the -- the statute does the work here. It is new and useful composition of matter --

JUSTICE KAGAN: But the first person --

MR. CASTANIAS: -- if it had use. If it had

a new utility, then yes.

JUSTICE KAGAN: I'm sorry, because -- because, like Justice Breyer, I consider uses -- patents on uses in a different category.

So I'm just asking, could you patent the isolated chromosome?

MR. CASTANIAS: Again, I -- I perhaps am not making myself as clear as I should. In Section 101, a patent claim must be shown to be useful. And that -- that is a utility that it has to be shown --

JUSTICE KAGAN: Yes. Chromosomes are very useful.

MR. CASTANIAS: -- in any case.

(Laughter.)

JUSTICE KAGAN: The first person who found a chromosome and isolated it, I think we can all say that that was a very useful discovery.

And the question is, can you then -- can the person who found that chromosome and isolated it from the body, could they have gone to the PTO?

MR. CASTANIAS: If they -- if --

JUSTICE KAGAN: And the PTO seems very patent happy, so could, you know, would -- would they have had a good patentability argument?

MR. CASTANIAS: I think if -- to get through

the Section 101 gateway, if that chromosome had a specific substantial and credible utility, in other words, it could be used in some --

JUSTICE KAGAN: Yes, of course it does.

MR. CASTANIAS: -- diagnostic way in the way that we're talking about here, then yes, it would pass through the Section 101 gate. Whether it would pass through the Section 102 gate or the 103 gate, I don't have any opinion on.

JUSTICE KAGAN: Would -- would -- okay.

MR. CASTANIAS: And then there's the further --

JUSTICE KAGAN: And that's interesting --

MR. CASTANIAS: Sure.

JUSTICE KAGAN: -- because then it's not a question about, you know, breaking these covalent bonds or whatever Judge Lourie thought it was about. Right?

So you know, if -- if not DNA, if -- if not the -- the more smaller unit in the chromosome, you know, we could just go up from there and talk about all kinds of parts of the human body, couldn't we? Couldn't we get to, you know, the first person who found a liver?

MR. CASTANIAS: I -- I think -- I think, Justice Kagan, you're really putting your finger on the problem with this, again, I -- I keep wanting to refer

to as the so-called Product of Nature Doctrine because I don't believe that as a separate doctrine it really exists. It's just the flip side of the coin of something that shows a lack of invention.

And, of course, that's where Section 103 comes into full force as the Chief Justice mentioned earlier in the argument. Section 103 allows you to make comparisons to what was old and what was new. I don't think the organ, the liver, gets past 103 in that circumstance even if you say, well --

JUSTICE BREYER: You are saying it gets past 101.

MR. CASTANIAS: Even if it gets through the 101 --

JUSTICE BREYER: Well, that's -- that's the problem. I mean, all parts of the human body? Anything from inside the body that you snip out and isolate?

MR. CASTANIAS: No.

JUSTICE BREYER: And it gets through 101? Does it have to -- I mean, that's actually what's bothering me.

MR. CASTANIAS: Okay. So let -- let me try to help you with that. Because -- because the distinction is between the liver or the kidney, which was the one brought up in the federal circuit opinion,

but liver, kidney, you know, gallbladder, pick your organ. But it's the same thing. It is the same thing when it's inside the body and it's out. That's where our --

JUSTICE SOTOMAYOR: But you're not suggesting if you cut off a piece of the liver or a piece of the kidney that that somehow makes that piece patentable.

MR. CASTANIAS: No. Absolutely not. It's the same thing.

JUSTICE SOTOMAYOR: So what's the difference? I mean, if you cut off a piece of the whole in the kidney or liver, you're saying that's not patentable, but you take a gene and snip off a piece, that is? What's the difference between the two --

MR. CASTANIAS: I would say that -- I would say that under -- under your existing decisions in Chakrabarty, J.E.M., that set forth a broad understanding of Section 101 and an understanding of what is within the limited exception, then what -- I -- I would -- I mean, honestly, I think that Section 103 does this work better than Section 101, but to the point of Section 101, there's -- there is nothing different about that piece in the body.

JUSTICE BREYER: Ah. Then -- then watch

what you're doing. That's very, very interesting. Because, really, we are reducing, then, 101 to anything under the sun, and -- and that, it seems to me, we've rejected more often than we've followed it.

And particularly with a thing found in nature doctrine because, of course, it doesn't just -- human kidneys and so forth. Everything is inside something else. Plants, rocks, whatever you want. And so everything will involve your vast taking something out of some other thing where it is, if only the environment. And it's at that point that I look for some other test than just that it was found within some other thing.

MR. CASTANIAS: And I think, Justice Breyer, there is where I've -- I've tried to explain to you about the different functions, the different values. If you think about patents as economic instruments, the different economic values that come out of this, the different things that patients now have as a result of this human ingenuity, they didn't have the BRCA1 isolated gene before the Myriad invention.

JUSTICE KENNEDY: Well, we could have said that with atomic energy, with electric, but so far the choice -- electricity -- but so far the choice of the patent was that we have a uniform rule for all

industries.

MR. CASTANIAS: Right, but in --

JUSTICE KENNEDY: And -- and that avoids giving special industries special subsidies, which is very important it seems to me.

Let me ask you this, and it's consistent with my -- my preface. If we were to accept the government's position that the DNA is not patentable but the cDNA is, would that give the industry sufficient protection for innovation and research? And if not, why not?

MR. CASTANIAS: The -- the problem of making that decision now is that so much has happened since these gene patents issued and since the Utility Guidelines. I can't tell you for a certainty whether it will hurt the industry as a general matter to not have isolated gene but only have cDNA patents.

But here's what I think it will hurt, and I think it ultimately will hurt the doctrine that this Court comes out of this case with. Because what you will then be asking litigants to do and courts to do is to draw fine distinctions under Section 101 between, well, how much more manipulation.

My friend on the other side used the term, in response to Justice Ginsburg, "further manipulation

is required to take it out of the product of nature." He -- he said no alteration, to Justice Alito, would make it a product of nature. But there's no dispute in this case that there has been some alteration of the isolated DNA molecules.

And that brings me back to the Utility Guidelines. This line was drawn. It was drawn by an expert agency that sits at the intersection of law and science, and it has said, without any apparent -- other than the declarations and amicus briefs that have been put into this case -- without any apparent effect on the explosion in biotechnology and the successful, economically successful, technologically successful, and life-saving industry that is at the heart of these inventions.

That has not -- those -- that parade of horribles has not happened. And you don't have to hypothesize at this point because you've got all of these years of experience between the time these patents issued and the time that this -- this challenge belatedly came along.

Justice Breyer, a point about no impermissible preemption before I sit down. Your opinion for the Court in Mayo made that very much an important point, but I think what you -- what is

important to understand here is that these patent claims aren't for methods. They don't prevent -- present that problem that the Court identified in that argument and in the argument in Bilski. These are for specific molecules that exist in the physical world. That -- that concern that is present with method claims is not here, these patents cover -- these patent claims cover only what is claimed and no more.

There is no risk of a natural law or a physical phenomenon like energy or electricity, neither of which falls within the statutory categories. There is no risk of anything being preempted other than what the claims properly claim, which are human-made inventions of isolated molecules.

And I think one last point to close on. It's important to note that molecules have been patented for a very long time. That's what drugs are. And drugs are often made by taking one molecule and another molecule, both of which are known, reacting them in a test tube, which is a very common thing, its reactions have been around 100 years just like snipping has been, but they make something new and useful and life saving from that.

CHIEF JUSTICE ROBERTS: I don't understand how this is at all like that because there you're

obviously combining things and getting something new. Here you're just snipping, and you don't have anything new, you have something that is a part of something that has existed previous to your intervention.

MR. CASTANIAS: Well, again, Mr. Chief Justice, I -- I -- the discussion we had earlier, the -- in -- in fact, the sequence that's claimed in Claim 1 of the '282 patent was not created by snipping. If I can just conclude with one more sentence?

CHIEF JUSTICE ROBERTS: Sure.

MR. CASTANIAS: Only once it was created can a scientist ever know how and where to make the decision to snip.

Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Mr. Hansen, you have three minutes remaining.

REBUTTAL ARGUMENT OF MR. HANSEN
ON BEHALF OF THE PETITIONERS

MR. HANSEN: Thank you, Your Honor.

JUSTICE SOTOMAYOR: Is there some value to us striking down isolated DNA and upholding the cDNA? If we were to do what the government is proposing in

this case, what's the consequences?

MR. HANSEN: Of -- of course there would be value in that in the sense that -- that, A, it reinforces the Product of Nature Doctrine, but more importantly, the effect of the patents in this case allows Myriad to stop all research on a part of the human body. If you uphold the patents in this case, Myriad can -- has the authority given it by the government to stop anyone from doing research on a piece of the human body. That would be a significant advance, if you were to -- to make it clear that was impermissible.

JUSTICE SOTOMAYOR: Now, how do you understand Judge Bryson's dissent with respect to cDNA? I think he's saying that a gene created from -- into cDNA as a whole is okay, but that he had a problem with the description of that claim because it included 15 nucleotide long segments or fragments which he says reoccur in nature.

MR. HANSEN: Well, and yes, I -- I agree, Your Honor, that he was focusing on Claims 5 and 6, which are the ones that include 15 nucleotides or -- or longer.

JUSTICE SOTOMAYOR: Now, I'm making your job harder. How could they write it to do what he thinks

would be patentable?

MR. HANSEN: Well, all --

JUSTICE SOTOMAYOR: So assuming we believe that there is some human invention in this process, whether it's obvious or not, separate question. But he's not creating -- the cDNA is not in nature naturally.

So make that assumption. Make the assumption that they can make a claim for it. How do we avoid his problem?

MR. HANSEN: Well --

JUSTICE SOTOMAYOR: I know you are helping your adversary by answering this question.

MR. HANSEN: That's fine, Your Honor. I think that the -- all of the claims in this case, all nine claims that we are challenging include both fragments and the whole gene. So I don't think there is anything you can do with respect to these nine claims.

JUSTICE SOTOMAYOR: I am putting that aside.

MR. HANSEN: I think by saying that when genes are transformed in such a way that the scientist decides their sequence rather than the nature deciding their sequence --

JUSTICE SOTOMAYOR: Only if they do a recombinant DNA, that's what you are saying.

MR. HANSEN: Right, right. Now I don't think cDNA is recombinant DNA, that's what we've argued, but that's -- that's at least one plausible way of looking at it.

The genes in this case, the patents on the genes in this case cover the genes of every man, woman, and child in the United States. And as I just said, it gives the -- the government has given Myriad the authority to stop research on every one of our genes. That simply can't be right.

And I would like to make one other point with respect to Dr. Lander's brief. On page 16 of Dr. Lander's brief he discusses specifically that the BRCA genes appear in the body with covalent bonds in fragments. There isn't any real -- there isn't any scientific dispute about that fact.

CHIEF JUSTICE ROBERTS: Why don't you take another minute. You weren't afforded an opportunity to use the time you were reserved.

MR. HANSEN: Well, I guess the only other thing I would say then, Your Honor, is to respond to what I may have left a misimpression with Justice Kagan's questions. We agree that you could get a patent on a use of the leaf that is pulled out of the Amazon or a plant that is pulled out of the Amazon. We don't

dispute that. We don't think you cannot get a patent on the thing -- the plant itself just because you pulled it out of the ground and took it to the United States.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

The case is submitted.

(Whereupon, at 11:11 a.m., the case in the above-entitled matter was submitted.)

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