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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:

CHRISTOPHER A. HANSEN, ESQ., New York, New York; on behalf of Petitioners.

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, Inc.

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

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

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

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

16 But --

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

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

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

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

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

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

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

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

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

12 And, in fact, that's --

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

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

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

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

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

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

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

20 But as --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 JUSTICE SOTOMAYOR: All right, that

1 individual claim is invalid.

2 MR. HANSEN: That individual claim.

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

6 MR. HANSEN: That is correct, Your Honor.

7 JUSTICE SOTOMAYOR: The primers and probes
8 stand.

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

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

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

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

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

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

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

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

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

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

3 JUSTICE SCALIA: Curiosity is your answer.

4 JUSTICE KAGAN: I thought you were going
5 to --

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

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

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

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

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

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

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

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

23 MR. HANSEN: Well --

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

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

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

6 JUSTICE SCALIA: Well, that's lovely.

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

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

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

21 MR. HANSEN: And that's certainly true.

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

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

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

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

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

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

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

25 JUSTICE SOTOMAYOR: That's a failure of the

1 patent law. It doesn't patent ideas.

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

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

7 MR. HANSEN: Sure.

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

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

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

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

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

9 MR. HANSEN: Yes.

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

15 MR. HANSEN: Yes.

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

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

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

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

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

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

16 MR. HANSEN: It is true --

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

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

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

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

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

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

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

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

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

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

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

19 MR. HANSEN: No --

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

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

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

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

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

10 MR. HANSEN: Sure, of course.

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

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

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

24 MR. HANSEN: No --

25 JUSTICE BREYER: Because of the word

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

7 MR. HANSEN: Yes, Your Honor.

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

10 MR. HANSEN: There --

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

13 MR. HANSEN: Well, that certainly --

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

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

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

23 CHIEF JUSTICE ROBERTS: Thank you, counsel.

24 MR. HANSEN: Thank you, Your Honor.

25 CHIEF JUSTICE ROBERTS: General Verrilli?

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

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

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

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

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

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

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

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

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

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

22 GENERAL VERRILLI: Our position, though, is
23 that cDNA is patent eligible because we think, unlike
24 the isolated DNA which is just taken from your body,
25 cDNA is an artificial creation in the laboratory that

1 doesn't correspond to anything in your body.

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

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

11 JUSTICE SOTOMAYOR: I understand --

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

19 GENERAL VERRILLI: That's a little --

20 CHIEF JUSTICE ROBERTS: If you got something
21 that's big, it seems to me pretty obvious that you could
22 take a smaller part of it; that the idea -- a smaller
23 part of something that's bigger is obvious. Now, yes,
24 you can have a patent on the process of extracting that
25 small part, but I don't understand how a small part of

1 something bigger isn't obvious. And if it is, I don't
2 understand why this -- these issues aren't addressed at
3 that stage.

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

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

23 CHIEF JUSTICE ROBERTS: I'm -- I'm not sure
24 that's responsive to my concern. Your answer said well,
25 here are a lot of reasons why this shouldn't have patent

1 protection. My question goes to whether we ought to
2 focus on those reasons at the eligibility stage or at
3 the obviousness stage.

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

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

13 GENERAL VERRILLI: Yes, Your Honor.

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

20 Why -- why should we -- why should we do
21 that? We have claims that if patent eligibility is
22 denied here it will prevent investments that are
23 necessary for the development of new drugs or it will
24 lead those who develop the new drugs, new diagnostic
25 techniques, to keep those secret, not disclose them to

1 the public. Why -- why should we jump in and -- and
2 decide the broadest possible question?

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

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

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

21 GENERAL VERRILLI: Yes, and that --

22 JUSTICE GINSBURG: Is that so?

23 GENERAL VERRILLI: No. I think the picture
24 is much more complicated than that. In many other
25 nations it wouldn't be patentable and the patent law is

1 different from nation to nation.

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

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

19 JUSTICE SOTOMAYOR: I understand why you are
20 saying cDNA is patentable as a subject matter. I am
21 looking at the way the claim is phrased, however, and it
22 says that it's patenting a DNA segment 15 nucleotides
23 long or longer. The reality is that 15 nucleotides
24 doesn't necessarily bridge a sequence that goes between
25 exons. It -- it can -- one exon can be 15 or more

1 sequences long. So are you arguing that this claim as
2 written is sustainable?

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

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

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

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

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

20 But if I -- just to return to the point that
21 Justice Alito made, the Court really was faced with a
22 similar situation in Mayo. On the one side you had
23 the -- the industry coming in and saying: Look, we have
24 got a lot of reliance issue, PTO has issued more than
25 150,000 patents here. You are going to really disrupt

1 those reliance issues. On the other side you had the
2 American Medical Association, as you have here, coming
3 in and saying: Actually, these patents inhibit much
4 more innovation than they incent.

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

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

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

25 CHIEF JUSTICE ROBERTS: Briefly, please.

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

5 Thank you.

6 CHIEF JUSTICE ROBERTS: Thank you, General.

7 Mr. Castanias?

8 ORAL ARGUMENT OF GREGORY A. CASTANIAS

9 ON BEHALF OF THE RESPONDENTS

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

12 It is now 33 years after Chakrabarty,
13 31 years after the first isolated gene molecule patents
14 issued, and 12 years after the Patent and Trademark
15 Office issued its carefully reasoned Utility Guidelines
16 confirming that new isolated gene molecules are eligible
17 for patents, and it's almost 16 years after Myriad's
18 patents began to issue, Patents which -- yes.

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

21 MR. CASTANIAS: On a -- a new extraction
22 process, no. Most of the processes are known. But
23 that's not relevant to patent eligibility or, for that
24 matter, patentability. As the last sentence, Justice
25 Sotomayor, of Section 103A says, "Patentability shall

1 not be negated by the manner in which the invention was
2 created."

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

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

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

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

17 MR. CASTANIAS: Sure. Well, Justice
18 Sotomayor, I guess I'll take issue with the notion that
19 there is nothing additive here. What Myriad inventors
20 created in this circumstance was a new molecule that had
21 never before been known to the world. Now remember,
22 genes are themselves human constructs. And this points
23 up some of the serious analytical problems with the
24 Product of Nature Doctrine as the line-drawing exercise
25 that you've asked General Verrilli and Mr. Hansen to

1 engage in has illustrated.

2 Now, the line-drawing is what is the product
3 of nature to start with? Is it me? Is it the genome?
4 Is it the chromosome? Is it the -- and the gene
5 ultimately --

6 JUSTICE SOTOMAYOR: Look, I can bake --

7 MR. CASTANIAS: -- is what was defined.

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

16 MR. CASTANIAS: And that's --

17 JUSTICE SOTOMAYOR: Explain to me --

18 MR. CASTANIAS: Sure.

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

22 MR. CASTANIAS: Okay. I'll start by -- by
23 showing you how this is actually a different structure.
24 It actually has an entirely different chemical name when
25 you give it the C --

1 JUSTICE SOTOMAYOR: That's the cDNA.

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

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

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

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

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

20 JUSTICE SOTOMAYOR: Well, I guess --

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

23 JUSTICE ALITO: Why is the chemical
24 composition in the isolated DNA different? You were
25 about to explain that.

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

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

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

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

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

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

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

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

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

20 (Laughter.)

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

24 JUSTICE BREYER: Well, which one have I not
25 read --

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

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

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

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

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

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

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

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

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

25 JUSTICE BREYER: As a matter of science.

1 MR. CASTANIAS: As a matter of science with
2 the following -- okay.

3 JUSTICE BREYER: Okay. Very well. If you
4 are saying it is wrong, as a matter of science, since
5 neither of us are scientists, I would like you to tell
6 me what I should read that will, from a scientist, tell
7 me that it's wrong.

8 MR. CASTANIAS: You want me to tell you
9 something from a scientist that you should read that
10 tells you that it is wrong?

11 JUSTICE BREYER: No, I need to know --

12 MR. CASTANIAS: I think you could look at
13 the declaration in the -- the Joint Appendix for
14 Dr. Kay, for example. Dr. Kay's declaration appears
15 at -- starting at page 370. You'll find an extensive
16 discussion in there of the technology here and -- and of
17 the genetics.

18 But, Justice Breyer, just to explain the
19 finishing thought, what -- what Dr. Lander says in his
20 brief is that these pseudogenes, which are un --
21 undifferentiated fragments, exist in the body. What
22 hasn't been brought to the -- to the forefront is
23 something that is new and useful and available to the
24 public for -- for allowing women to determine whether
25 they have breast or ovarian --

1 CHIEF JUSTICE ROBERTS: Can I --

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

4 Yes, Mr. Chief Justice?

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

7 MR. CASTANIAS: Sure.

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

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

21 MR. CASTANIAS: Well, I -- I guess I'll even
22 take issue with that, because the -- the story of how
23 the SEQ ID number 2, the genomic DNA segment came about
24 is exactly the opposite of that. If you look, for
25 example, at page 488 of the Joint Appendix, that's the

1 declaration of one of the inventors, Donna Shaddick, at
2 paragraph 27, what -- what she explains is that the
3 Myriad inventors first created the cDNA, which we agree
4 at least on that score with the Solicitor General, is
5 indeed eligible for patenting. But then -- and by the
6 way, that cDNA was created from hundreds of different
7 patient samples to create what was called a consensus
8 sequence.

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

11 MR. CASTANIAS: And then what the -- what
12 the Myriad inventors then did to create what is called
13 SEQ ID number 2 and what is claimed in claim 1 of the
14 '282 patent is to take -- actually manipulate that
15 further to add in the introns. It was in -- actually,
16 the inventive process was additive.

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

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

25 MR. CASTANIAS: Well, first of all, you

1 wouldn't even know where to snip until the Myriad
2 invention. That's the first problem.

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

6 MR. CASTANIAS: Right.

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

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

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

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

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

25 JUSTICE KAGAN: Well, but can you patent the

1 thing itself?

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

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

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

7 JUSTICE KAGAN: -- from the Amazon forest.

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

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

13 MR. CASTANIAS: Okay.

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

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

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

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

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

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

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

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

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

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

24 MR. CASTANIAS: Well, since this Court --
25 I'm sorry.

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

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

10 JUSTICE GINSBURG: Do you concede --

11 MR. CASTANIAS: I'm sorry.

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

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

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

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

13 Is that --

14 (Laughter.)

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

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

24 JUSTICE BREYER: All right. So, when you
25 are on that, that's good. A more basic question to me

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

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

16 Now, in any individual case that might be
17 unfortunate or fortunate. But consider it in the mine
18 run of things. It's important to keep products of
19 nature free of the restrictions that patents there are,
20 so when Captain Ferno goes to the Amazon and discovers
21 50 new types of plants, saps and medicines, discovers
22 them, although that expedition was expensive, although
23 nobody had found it before, he can't get a patent on the
24 thing itself. He gets a patent on the process, on the
25 use of the thing, but not the thing itself.

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

4 MR. CASTANIAS: Well --

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

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

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

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

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

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

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

19 JUSTICE GINSBURG: Even though -- even
20 though the Government has disavowed it, even though the
21 Government, representing the United States --

22 MR. CASTANIAS: Even so, and -- and the
23 reason for that is --

24 JUSTICE GINSBURG: At least that the
25 strength of the presumption would be diluted.

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

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

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

15 JUSTICE KAGAN: Yes.

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

19 JUSTICE KAGAN: Right.

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

23 JUSTICE KAGAN: But the first --

24 MR. CASTANIAS: -- if it had use. If it had
25 a new utility, then yes.

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

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

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

10 JUSTICE KAGAN: Yes. Chromosomes are very
11 useful.

12 MR. CASTANIAS: -- in any case.

13 (Laughter.)

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

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

20 MR. CASTANIAS: If they -- if --

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

24 MR. CASTANIAS: I think if -- to get through
25 the Section 101 gateway, if that chromosome had a

1 specific substantial and credible utility, in other
2 words, it could be used in some --

3 JUSTICE KAGAN: Yes, of course it does.

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

9 JUSTICE KAGAN: Would -- would -- okay.

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

12 JUSTICE KAGAN: And that's interesting --

13 MR. CASTANIAS: Sure.

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

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

22 MR. CASTANIAS: I -- I think -- I think,
23 Justice Kagan, you're really putting your finger on the
24 problem with this, again, I -- I keep wanting to refer
25 to as the so-called Product of Nature Doctrine because I

1 don't believe that as a separate doctrine it really
2 exists. It's just the flip side of the coin of
3 something that shows a lack of invention.

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

10 JUSTICE BREYER: You are saying it gets past
11 101.

12 MR. CASTANIAS: Even if it gets through the
13 101 --

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

17 MR. CASTANIAS: No.

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

21 MR. CASTANIAS: Okay. So let -- let me try
22 to help you with that. Because -- because the
23 distinction is between the liver or the kidney, which
24 was the one brought up in the federal circuit opinion,
25 but liver, kidney, you know, gallbladder, pick your

1 organ. But it's the same thing. It is the same thing
2 when it's inside the body and it's out. That's where
3 our --

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

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

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

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

24 JUSTICE BREYER: Ah. Then -- then watch
25 what you're doing. That's very, very interesting,

1 because, really, we are reducing, then, 101 to anything
2 under the sun, and -- and that, it seems to me, we've
3 rejected more often than we've followed it.

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

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

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

1 MR. CASTANIAS: Right, but in --

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

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

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

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

23 My friend on the other side used the term,
24 in response to Justice Ginsburg, "further manipulation
25 is required to take it out of the product of nature."

1 He -- he said no alteration, to Justice Alito, would
2 make it a product of nature. But there's no dispute in
3 this case that there has been some alteration of the
4 isolated DNA molecules.

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

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

21 Justice Breyer, a point about no
22 impermissible preemption before I sit down. Your
23 opinion for the Court in Mayo made that very much an
24 important point, but I think what you -- what is
25 important to understand here is that these patent claims

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

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

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

23 CHIEF JUSTICE ROBERTS: Well, I don't
24 understand how this is at all like that, because there
25 you're obviously combining things and getting something

1 new. Here you're just snipping, and you don't have
2 anything new, you have something that is a part of
3 something that has existed previous to your
4 intervention.

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

11 CHIEF JUSTICE ROBERTS: Sure.

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

15 Thank you.

16 CHIEF JUSTICE ROBERTS: Thank you, counsel.

17 Mr. Hansen, you have three minutes
18 remaining.

19 REBUTTAL ARGUMENT OF MR. HANSEN

20 ON BEHALF OF THE PETITIONERS

21 MR. HANSEN: Thank you, Your Honor.

22 JUSTICE SOTOMAYOR: Is there some value to
23 us striking down isolated DNA and upholding the cDNA?
24 If we were to do what the Government is proposing in
25 this case, what's the consequences?

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

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

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

23 JUSTICE SOTOMAYOR: Now, I'm making your job
24 harder. How could they write it to do what he thinks
25 would be patentable?

1 MR. HANSEN: Well, all --

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

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

10 MR. HANSEN: Well --

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

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

18 JUSTICE SOTOMAYOR: I am putting that aside.

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

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

25 MR. HANSEN: Right, right. Now I don't

1 think cDNA is recombinant DNA, that's what we've argued,
2 but that's -- that's at least one plausible way of
3 looking at it.

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

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

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

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

1 the plant itself just because you pulled it out of the
2 ground and took it to the United States.

3 CHIEF JUSTICE ROBERTS: Thank you, counsel.

4 The case is submitted.

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

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