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IN THE SUPREME COURT OF THE UNITED STATES

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MAYO COLLABORATIVE SERVICES, DBA :

MAYO MEDICAL LABORATORIES, ET AL., :

Petitioners :

v. : No. 10-1150

PROMETHEUS LABORATORIES, INC. :

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Washington, D.C.

Wednesday, December 7, 2011

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 10:05 a.m.

APPEARANCES:

STEPHEN M. SHAPIRO, ESQ., Chicago, Illinois; on behalf of Petitioners.

DONALD B. VERRILLI, JR. , ESQ., Solicitor General, Department of Justice, Washington, D.C.; for United States, as amicus curiae.

RICHARD P. BRESS, ESQ., Washington, D.C.; on behalf of Respondent.

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P R O C E E D I N G S

(10:05 a.m.)

CHIEF JUSTICE ROBERTS: We will hear argument first this morning in Case 10-1150, Mayo Collaborative Services v. Prometheus Laboratories.

Mr. Shapiro.

ORAL ARGUMENT OF STEPHEN M. SHAPIRO

ON BEHALF OF THE PETITIONERS

MR. SHAPIRO: Thank you, Mr. Chief Justice, and may it please the Court:

We're here today to urge the Court to reinstate the district court's decision, which faithfully applied this Court's precedents under section 101 of the Patent Act. The problem with the Prometheus patent is its broad preemption of a physical phenomenon, which prevents others like Mayo Clinic from offering a better metabolite test with more accurate numbers. And this is a huge practical problem for patients.

These thiopurine drugs are strong medicine. Too much of this can be fatal; too little can leave -- leave a chronic lingering disease in the patient.

JUSTICE SOTOMAYOR: I'm sorry. I didn't think that this patent covered the actual machine. Mayo is free to develop a new machine.

MR. SHAPIRO: Well, what it can't do is use

1 any number from 400 up until infinity, and it believes
2 that's the wrong number. And it can't have a -- a
3 different standard for a legion of autoimmune diseases,
4 and there are dozens and dozens of them. And that's a
5 broad field to preempt the natural phenomenon.

6 JUSTICE SOTOMAYOR: It -- it actually is
7 much narrower than that. It's within a range, two
8 ranges actually. And so it has already changed one
9 range, and that's not the subject of the district
10 court's finding that the lower number it's proposing is
11 infringing.

12 So it's not as broad as you are stating.

13 MR. SHAPIRO: Well, you -- you see, Your
14 Honor, we believe the correct number is 450 to 700. And
15 that's necessary to cure various autoimmune diseases.
16 And Prometheus took the position that its patent
17 preempts everything above 400, all the way up to
18 infinity, it said, for all autoimmune diseases, dozens
19 and dozens of them.

20 JUSTICE SOTOMAYOR: Well, it took that
21 position, but the district court narrowed it to 15
22 percent, to 15 --

23 MR. SHAPIRO: Well, you know, actually it
24 didn't, Your Honor. You will see in that opinion, there
25 are two rulings: one is the 15 percent ruling, which

1 lowers the number; but it said 400 and above all the way
2 to infinity. There's no upper limit on this.

3 So as a practical matter, there's no room
4 for anybody else to offer a metabolite test. And what
5 this means for patients is one opinion in the United
6 States. If you have one of these life-threatening
7 diseases --

8 JUSTICE SOTOMAYOR: It can offer the test.

9 MR. SHAPIRO: -- you get one opinion.

10 Pardon me?

11 JUSTICE SOTOMAYOR: It can offer the test.
12 It just can't recommend the dosage to the doctor.

13 MR. SHAPIRO: Well, it -- it can't have a
14 test that has a different therapeutic range, because
15 that's a preemption. They take the position --

16 JUSTICE SOTOMAYOR: Tests do two things:
17 they measure something --

18 MR. SHAPIRO: Yes.

19 JUSTICE SOTOMAYOR: And therapeutic range
20 does something else. The tests can happen. The doctor
21 gets a number. What the doctor does with that number is
22 a different issue.

23 MR. SHAPIRO: And -- and what -- what
24 Prometheus submitted and the court agreed is if you are
25 notified, if you are aware of their range when you're

1 drawing blood, that's an infringement right then and
2 there, if -- if you're aware or warned by their number.

3 So any doctor in the United States that
4 draws blood and is aware of this range of theirs is
5 preempting. And the practical result is we haven't been
6 able to offer this competing test now for 7 years.

7 JUSTICE KENNEDY: When -- when the
8 Respondent addresses this, will they take issue with the
9 way you describe what has been preempted, or as you
10 read their -- we'll ask them -- but as you read their
11 brief, is this crystal-clear?

12 MR. SHAPIRO: Well, you'll see,
13 Justice Kennedy, in the district court, they argued for
14 any number above 400. That's -- it's 400 and above is
15 what it says. And they said there's no upper limit on
16 that. The district court found that. That was their
17 position that was accepted.

18 JUSTICE KENNEDY: In thinking about what's
19 preempted, I looked at the Diehr case involving the
20 rubber molding and the constant monitoring. And if you
21 could take an analogy from that: let's -- let's suppose
22 that there was a system of measurements that you take
23 every half-hour which constantly monitor how a drug is
24 being retained in the tissues, and that there is a
25 protocol for the admission of some two or three

1 different drugs to get the balance right. In other
2 words, it's much more complicated.

3 Is there some point at which that is
4 patentable, even though this preempts a -- a whole range
5 of -- of different choices?

6 MR. SHAPIRO: Well, it may be patentable.

7 JUSTICE KENNEDY: And it's hard for you to
8 answer -- you know, there's a million hypotheticals.
9 But I'm just trying to --

10 MR. SHAPIRO: The -- the key is --

11 JUSTICE KENNEDY: -- see what the process
12 is.

13 MR. SHAPIRO: -- the specificity. If it
14 leaves room for others to have their own tests with
15 different numbers and different procedures so that it
16 isn't just one test for the whole country, then yes, if
17 it's specific enough. The specificity is the key.

18 What -- what the Court said in *Bilski*, of
19 course, is that you can't preempt a whole field, a broad
20 field with -- with your -- your patent, which this one
21 does. And if you look at the diseases that are
22 covered --

23 JUSTICE SCALIA: I'm -- I'm not
24 comfortable with that. I mean, it depends on how -- how
25 broad it is?

1 MR. SHAPIRO: Yes. If -- if you -- if you
2 preempt all the numbers up to infinity and all
3 autoimmune diseases, that's a vast field. It's much
4 bigger than -- than the field --

5 JUSTICE SCALIA: What about up to 700? Is
6 that okay?

7 MR. SHAPIRO: Well, no. I -- I think --

8 JUSTICE SCALIA: 550?

9 MR. SHAPIRO: No. I -- I think --

10 JUSTICE SCALIA: 830?

11 MR. SHAPIRO: No.

12 JUSTICE SCALIA: How are we supposed to
13 apply that kind of a rule?

14 MR. SHAPIRO: I think doctors have to have
15 freedom to make their own judgments about these natural
16 phenomena.

17 JUSTICE SCALIA: Above 830 or below 830?
18 Which?

19 MR. SHAPIRO: Well, I -- no. I think --

20 JUSTICE SCALIA: It just seems to me not
21 a -- not a patent rule that we could possibly apply.

22 MR. SHAPIRO: Well, it's the rule I believe
23 adopted in *Bilski* and in *Flook*, that you can't wipe out
24 a whole field so no one else can have a competing test.
25 The result for the public is that these numbers would be

1 frozen for 20 years and a very serious person couldn't
2 get a second opinion from Mayo Clinic, which uses
3 different numbers. That's why we think --

4 JUSTICE SCALIA: But doesn't -- doesn't
5 any -- any medical patent rely on natural processes? I
6 mean, even if you invent a new drug, what that new drug
7 does is -- is natural. It affects the -- the human
8 physiognomy in a certain natural way.

9 MR. SHAPIRO: Oh, yes.

10 JUSTICE SCALIA: Is it -- is it therefore
11 precluded from patentability?

12 MR. SHAPIRO: No, it's not. And in fact,
13 this drug was patented.

14 JUSTICE SCALIA: What is different here?

15 MR. SHAPIRO: The difference is the
16 specificity. If you invent a drug which has a
17 particular chemical formula, others can invent other
18 drugs. There's room for competing drugs in the medical
19 world. And you'll -- many, many patented drugs --

20 JUSTICE KENNEDY: I thought your answer to
21 Justice Scalia would be -- and please correct me -- the
22 difference is, is that what the Respondent is claiming
23 is a -- a patent on the measurement of the result.

24 MR. SHAPIRO: Yes, it -- it is a patent --

25 JUSTICE KENNEDY: But a measurement in a

1 different answer. I mean, that's how I would have
2 answered the question. But -- but that's obviously not
3 the right way to do it.

4 MR. SHAPIRO: I think that's -- that's
5 one -- one part of it.

6 JUSTICE SCALIA: Well, that's another one of
7 your arguments, but one of your arguments says you can't
8 patent nature.

9 MR. SHAPIRO: You can't patent nature,
10 that's correct.

11 JUSTICE SCALIA: Right, and that relates to
12 the question that I asked.

13 MR. SHAPIRO: But --

14 JUSTICE SCALIA: Now, tell me why you can't
15 patent nature, then?

16 MR. SHAPIRO: Because -- because of the law
17 of nature doctrine that has existed for 150 years in
18 this Court. Congress has never disagreed with that.
19 Pieces of nature can't be monopolized. Neither can
20 formulas.

21 JUSTICE BREYER: Nature --

22 JUSTICE KENNEDY: But nature always has a
23 reaction to the drug.

24 MR. SHAPIRO: Pardon me?

25 JUSTICE KENNEDY: Nature always has a

1 reaction to the drug.

2 MR. SHAPIRO: Yes. So all doctors -- that's
3 part of the storehouse of information. All doctors can
4 look at that reaction. They can calibrate it the way
5 they see fit. They have different opinions. And it's
6 important for all of us that they have those different
7 opinions. We found that the numbers that they were
8 using were way off for skin disorders, dangerously high.
9 400 is the wrong number. The correct number is 150 to
10 300.

11 Now, it's very important for patients to
12 be -- with life-threatening conditions, to be able to
13 get that information.

14 JUSTICE BREYER: All right. So how do
15 you -- that's -- I see that. I will spare you the
16 reasons why I think the law of nature doctrine exists,
17 because they are not relevant to my question.

18 My question is, I think it's hornbook law
19 that the law of nature cannot be patented.

20 MR. SHAPIRO: Yes.

21 JUSTICE BREYER: It is also hornbook law
22 that the application of a law of nature can be patented.

23 MR. SHAPIRO: Right.

24 JUSTICE BREYER: All right.

25 So in this case, what I think the claim is

1 is that we are applying a law of nature. Now, we read
2 the words of applying it: Administer a drug, determine
3 the level. And then it uses the word "wherein," which I
4 will ask them what that means. But -- but -- so they
5 say those two words, administer the drug, determine the
6 level, are the application of the law of nature that
7 they found.

8 Now, there's something odd about that in
9 your view --

10 MR. SHAPIRO: Yes.

11 JUSTICE BREYER: -- at least. And I want to
12 know what.

13 MR. SHAPIRO: For us, the real oddity is
14 that this numerical calibration that they've given
15 extends up to infinity, and it precludes every other
16 blood test.

17 JUSTICE BREYER: All right. Suppose it
18 didn't. Suppose I discover that if I take aspirin,
19 someone takes aspirin, I discover they have to take
20 aspirin for a headache and, you know, I see an amazing
21 thing: if you look at a person's little finger, and you
22 notice the color of -- it shows the aspirin, you need a
23 little more, unless it's a different color, you need a
24 little less. Now, I've discovered a law of nature and I
25 may have spent millions on that. And I can't patent

1 that law of nature, but I say: I didn't; I said apply
2 it. I said: Look at his little finger.

3 MR. SHAPIRO: Sure.

4 JUSTICE BREYER: Okay? Is that a good
5 patent or isn't it?

6 MR. SHAPIRO: No, it's not.

7 JUSTICE BREYER: Why not?

8 MR. SHAPIRO: It's not a good patent.

9 JUSTICE BREYER: If you can tell me why not,
10 I'll have an understanding of where you are coming from.

11 MR. SHAPIRO: Well, because you -- you've
12 added to a law of nature just -- just a simple
13 observation of the man's little finger.

14 JUSTICE BREYER: Ah. Now, we're into the
15 problem. And that is the problem of how much you have
16 to add.

17 MR. SHAPIRO: Yes.

18 JUSTICE BREYER: If you look at the Court's
19 cases, they seem to say Flook, one thing, and Diehr
20 another thing.

21 And so what is your view about how much has
22 to be added to make it an application of a law of
23 nature? And how would you put that in words?

24 MR. SHAPIRO: There are several things that
25 it can't be. After Bilski, which reaffirmed what was

1 said in Flook, a conventional step isn't sufficient,
2 because that's just adding a law of nature to prior art,
3 and prior art plus prior art equals nothing that is
4 patentable under the Flook decision.

5 And also, the step that you add has to
6 narrow your preemption --

7 JUSTICE SCALIA: Well, excuse me. Does that
8 render it nonpatentable because it's not novel? Is that
9 the reason why it -- it renders it nonpatentable?

10 MR. SHAPIRO: Well --

11 JUSTICE SCALIA: That's not what we're
12 talking about here; we are not talking about novelty,
13 are we?

14 MR. SHAPIRO: No, we are really not. What
15 the Court -- what the Court said in Bilski is that a
16 conventional step plus a law of nature isn't sufficient,
17 and what the Court explained in Flook is that the law of
18 nature is part of the common domain, it's part of prior
19 art. So if you are adding prior art to prior art it's
20 nothing under section 101.

21 JUSTICE GINSBURG: Mr. Shapiro, on that
22 question and the question Justice Scalia just raised,
23 the government, you know, has taken the position that
24 you are under the wrong section. It's not a question of
25 patentability, but you used the -- the example of the

1 finger, you said it's obvious. So why didn't you raise
2 the sections that the government says would have been
3 the appropriate ones on the novelty or anticipation of
4 prior art and obviousness?

5 MR. SHAPIRO: That's a very important
6 question for the medical community. They need a robust
7 section 101 standard because under 102 and 103 you could
8 patent E equals mc -squared. That's new, it's
9 nonobvious; but you can't patent it under 101 because
10 it's a law of nature.

11 And it's important to keep this -- this
12 common domain, the storehouse of information that
13 medical researchers need to have access to --

14 JUSTICE KENNEDY: It's hard to resist the
15 temptation to peek into the obvious component or the
16 nonobvious component and then go back and apply it to
17 101.

18 MR. SHAPIRO: Yes.

19 JUSTICE KENNEDY: You want us to discipline
20 ourselves to talk just about 101 in this.

21 MR. SHAPIRO: Well, no, I think -- we have
22 two arguments on this point. The first is both *Flook*
23 and *Bilski* peeked and -- and they looked at the
24 conventional nature of the additional step, and
25 that's --

1 JUSTICE SCALIA: But once you say
2 conventional nature, you are saying it's not novel.
3 If -- if the step is not conventional, it's okay. Why?

4 MR. SHAPIRO: Well --

5 JUSTICE SCALIA: Because it's novel.

6 MR. SHAPIRO: -- this -- this is the Court's
7 101 analysis in both Flook and in Bilski. So we rely on
8 the latest decision, Bilski, which took exactly that
9 peek. But the other part of our answer is you don't
10 even have to peek. If the step doesn't narrow the
11 preemption of the natural phenomenon, if it's just an
12 incidental step that you need to use to observe the
13 natural phenomenon, which this blood test is, you can't
14 see the natural phenomenon.

15 JUSTICE BREYER: You are getting warmer,
16 but --

17 (Laughter.)

18 JUSTICE BREYER: But the -- the words, look,
19 "a simple conventional step." Hmmm. You see, whether
20 it's true in this case or not, discovering natural laws
21 is often a very expensive process.

22 MR. SHAPIRO: Oh, yes.

23 JUSTICE BREYER: And there's lots of
24 investment to be protected.

25 MR. SHAPIRO: Oh, sure.

1 JUSTICE BREYER: But they can't, okay? So
2 now you are going to say, well, what do they have to add
3 to that? And now we run into problems, because if you
4 have to just not look at the law of nature, don't look
5 at it when you decide whether it's novel, that not only
6 runs into conflict with prior cases, but it doesn't make
7 much sense because really the novel thing is often the
8 law of nature. But you say you have to add something.

9 MR. SHAPIRO: Yes.

10 JUSTICE BREYER: What?

11 MR. SHAPIRO: Our view --

12 JUSTICE BREYER: Now that -- what do you
13 have to add? And it can't be that you take the law of
14 nature out and look to whether the rest of it meets the
15 patent criteria. It's -- it's pretty clear in the law
16 and I can give you reasons why, but forget the reasons.

17 But look, what do you want to say the rest
18 of it has to add up to?

19 MR. SHAPIRO: In our view, the rest of it
20 has to add up to some step that limits the natural
21 phenomenon, so that you have a concrete, specific --

22 JUSTICE BREYER: You are going on a
23 limitation thing. You are going to say reject all the
24 15 fancy hypotheticals I will also spare you.

25 MR. SHAPIRO: Well, in the Diehr --

1 JUSTICE BREYER: But it's pretty easy to
2 think of the same problem you have, you know, which
3 doesn't have this infinity in it.

4 MR. SHAPIRO: In the Diehr case --

5 JUSTICE BREYER: Which unfortunately we have
6 to deal with.

7 MR. SHAPIRO: In the Diehr case the natural
8 phenomenon was limited with steps that confined the
9 invention to a specific machine with doors opening and
10 closing, temperature being monitored so a product was
11 cured. It was a very specific, concrete invention.

12 JUSTICE SOTOMAYOR: I -- I don't know
13 what -- you keep saying you have to limit the product.

14 MR. SHAPIRO: Yes.

15 JUSTICE SOTOMAYOR: But you told me that
16 there is a different range for the treatment of skin
17 diseases.

18 MR. SHAPIRO: Yes.

19 JUSTICE SOTOMAYOR: So presumably there are
20 different ranges for treatment of other diseases.

21 MR. SHAPIRO: Absolutely.

22 JUSTICE SOTOMAYOR: So this patent has not
23 limited exploration in there. You are claiming it has.
24 That's an issue that your adversary can speak to. I
25 think they say no in their briefs.

1 But the point is, there's still a limit to
2 their range. You are claiming at one point they said it
3 was limitless, but if we disagree with that --

4 MR. SHAPIRO: Well, here's what --

5 JUSTICE SOTOMAYOR: -- how do you answer
6 Justice Breyer's question?

7 MR. SHAPIRO: Here's what they say, joint
8 appendix pages 13 through 14, the second volume. This
9 is their patent. This is what it covers. It covers
10 hepatitis, lupus, Hashimoto's disease, Graves' disease,
11 Addison's disease, diabetes, arthritis; and they say it
12 even covers organ transplants. It covers heart, kidney
13 and liver transplants. So it covers every autoimmune
14 disease, and there are dozens and dozens of them --

15 JUSTICE SOTOMAYOR: Mr. Shapiro --

16 MR. SHAPIRO: -- and they do have different
17 numbers. That's the key point.

18 JUSTICE SOTOMAYOR: So we -- so do we add up
19 all of the diseases in the world, all the potential
20 diseases, and pick a percentage that this covers within
21 that range?

22 MR. SHAPIRO: Well, this --

23 JUSTICE SOTOMAYOR: I think Justice Breyer
24 is asking you for something that doesn't involve that.

25 MR. SHAPIRO: Well --

1 JUSTICE SOTOMAYOR: That involves some
2 greater answer to the issue of limitation.

3 MR. SHAPIRO: I -- I think what the Court
4 did in Flook and what it did in Bilski is ask if a broad
5 field is being preempted. This is broad numerically.
6 It goes up to infinity. It covers dozens and dozens of
7 autoimmune diseases.

8 JUSTICE SCALIA: What if -- what if they --
9 what if they just split up the patent? They -- they got
10 one patent number for arthritis, another patent number
11 for transplants, another patent number for each one of
12 the autoimmune diseases you are talking about?

13 MR. SHAPIRO: Well -- .

14 JUSTICE SCALIA: Would each of them be okay,
15 because --

16 MR. SHAPIRO: No, it wouldn't. That would
17 be LabCorp, where there was just one malady in the
18 patent; it was a vitamin deficiency with a natural
19 correlation. And Justice Breyer's opinion explained
20 that -- that is too preemptive of the natural
21 phenomenon.

22 JUSTICE BREYER: Yeah, but what my opinion
23 lacked, frankly, and sometimes that's the virtue of a
24 dissent in such a case, it lacked -- and Novartis points
25 this out very well in their brief -- it lacked an

1 explanation as to why what I thought was a patent just
2 said, observe the correlation --

3 MR. SHAPIRO: Yes.

4 JUSTICE BREYER: -- why isn't that an
5 application of the law of nature? And if you look to
6 LabCorp's dissent to find an answer to that question,
7 you are better than I, because I couldn't find it.

8 MR. SHAPIRO: Well, if -- if --
9 observe the -- that's another area of the breadth of
10 this patent, because there is no specific action the
11 doctor has to take. If a doctor has been informed of
12 their range and draws blood and thinks about it, that --
13 that is -- that is infringement, and the doctor here was
14 accused of infringement, treble damages sought against
15 this hospital in an injunction, because she thought
16 about this correlation, and she had completely different
17 numbers.

18 JUSTICE KAGAN: Is there -- Mr. Shapiro, is
19 there a patent that Prometheus could have written that
20 you think would have met the 101 test.

21 MR. SHAPIRO: Certainly. They could have
22 said: When you reach 400, a real number, a specific
23 number, you adjust the dosage by 20 percent. That's a
24 treatment patent.

25 JUSTICE KAGAN: So if they had added a

1 treatment protocol that would have been a completely
2 different case?

3 MR. SHAPIRO: Yes.

4 JUSTICE KAGAN: And what makes it a
5 completely different case?

6 MR. SHAPIRO: What makes it different is
7 that leaves room for Mayo Clinic to come up with
8 different numbers that it believes are more accurate and
9 more helpful for patients that are suffering from these
10 life-threatening diseases. We shouldn't require
11 Americans to get one opinion from Prometheus when they
12 want an opinion from Mayo Clinic.

13 JUSTICE KAGAN: Well, I think I'm not sure I
14 understand that. You said a specific number. But
15 suppose it uses ranges, but it also attaches treatment
16 decisions to those ranges?

17 MR. SHAPIRO: Well, that could be specific
18 enough again that others could have a rival test that --
19 that used a different treatment protocol. You would
20 have to look at that.

21 JUSTICE KAGAN: So if the idea --

22 JUSTICE KENNEDY: But then why didn't you
23 answer her first question that it was -- that it was not
24 patentable? I have the same --

25 MR. SHAPIRO: Well, I think --

1 JUSTICE KENNEDY: I think I am having the
2 same problem as Justice Kagan.

3 MR. SHAPIRO: I think it would be
4 patentable.

5 JUSTICE KENNEDY: Why can't you just go --
6 the hypothetical was -- was one range, one result --
7 pardon me, one measurement, one result. Suppose that
8 just continued over a range. And they said if it's 40
9 then you have this; if it's 50 you have this.

10 MR. SHAPIRO: Well, I don't think they
11 can -- they can wipe out the entire field so that others
12 can't have rival tests that use different numbers. They
13 tried to do that, by the way. They have a total of
14 eight patents here which use different numbers. But you
15 can't preempt the whole field so others can't make any
16 use of the natural phenomenon.

17 JUSTICE KAGAN: I guess the question -- the
18 question I'm asking is, in your response to me is the
19 difference the -- the extent of the ranges, or is the
20 difference that there would be clear treatment decisions
21 attached to those ranges?

22 MR. SHAPIRO: I think you would need both.
23 You would have to look at it in practical terms. Is
24 there room for somebody else to make use of this natural
25 correlation, so that they could come up with different

1 numbers, different ranges and different treatments? And
2 if there's room left then there is no preemption of the
3 natural phenomenon. That's a vastly different case and
4 that's what is missing here. I -- I do see my time --
5 yes?

6 JUSTICE SOTOMAYOR: How many patents of this
7 type are out there?

8 MR. SHAPIRO: My view is there are only a
9 couple of them. LabCorp is like this, this one is like
10 this. The others that are referred to in these amicus
11 briefs are vastly different. They are specific patents
12 with specific treatment protocols. And by the way, the
13 government admits this particular patent is invalid
14 because it just attaches a mental step to prior art.

15 There are only a couple of them to our
16 knowledge that would be affected by a decision in our
17 favor. But a decision in our favor would protect the
18 storehouse of information that doctors really need.
19 They have to be able to look at the body's reaction to
20 injections, pills, chemotherapy, radiation; and
21 different hospitals have to have different opinions to
22 safeguard the health of our people.

23 So we urge the Court to reverse, and I would
24 reserve the balance of our time.

25 CHIEF JUSTICE ROBERTS: Thank you, counsel.

1 General Verrilli.

2 ORAL ARGUMENT OF DONALD B. VERRILLI, JR.,

3 ON BEHALF OF THE UNITED STATES,

4 AS AMICUS CURIAE

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

7 Each party in this case has got a valid
8 point. Mayo is correct that you can't get a patent by
9 tacking a mental step onto an utterly conventional
10 process for administering drugs and testing their
11 effects. But that is an issue under sections 102 and
12 103 of the Patent Act.

13 JUSTICE GINSBURG: Mr. Shapiro just told us,
14 when I asked him that question based on your brief, that
15 people need to know up front that this is not a
16 patentable subject matter; very important that it be 101
17 and not 102 and 103. So how do you answer his rejection
18 of the adequacy of prior -- as it's relating to prior
19 art or obviousness?

20 GENERAL VERRILLI: I think the answer,
21 Justice Ginsburg, is that from the perspective of the
22 United States and the PTO, it's exactly the opposite;
23 that importing these -- taking, as Justice Kennedy
24 suggested, taking up the temptation to import a look
25 into novelty and nonobviousness into the 101 inquiry is

1 going to be very destabilizing; 101, as Bilski said, is
2 a threshold eligibility test and the question is whether
3 there is a process.

4 Here there is a process. It's the
5 administration of a drug that changes the body chemistry
6 and there is then a test to determine the extent of the
7 change and then there is an end of the test. That's a
8 process.

9 CHIEF JUSTICE ROBERTS: That -- in your test
10 for that -- I see on page 9 of your brief you say: "A
11 classic patent-eligible process recites a series of acts
12 performed in the physical world that transforms the
13 subject of the process to achieve a useful result." So
14 I have a great idea. You take wood, you put it on a
15 grate, you light it, and you get heat. That is --
16 recites a series of acts performed in the physical world
17 that transforms the subject of the process, the wood, to
18 achieve a useful result, which is heat. So I can get a
19 patent for that?

20 GENERAL VERRILLI: No. It's not novel, and
21 it's obvious.

22 CHIEF JUSTICE ROBERTS: No, no, no, no.
23 Well, let me put it --

24 GENERAL VERRILLI: You can't get a patent
25 for it.

1 CHIEF JUSTICE ROBERTS: That's patent-
2 eligible?

3 GENERAL VERRILLI: But that's our -- that's
4 our point, Mr. Chief Justice, that the right way to look
5 at this issue is under 102 and under 103, and I think --

6 JUSTICE BREYER: Why? Why is the question.

7 GENERAL VERRILLI: Because --

8 JUSTICE BREYER: Look: Anything can be
9 transformed into a process. Look at those real estate
10 ones, lawyers ones. I have a way of making a great
11 argument in the Supreme Court. You know, you could
12 patent some of your arguments.

13 (Laughter.)

14 GENERAL VERRILLI: Most are pretty obvious.

15 JUSTICE BREYER: Why not cut them off at the
16 pass? That is, if you're really prepared to say -- it
17 has to do with process, not machines. In the 19th
18 century not many patent processes were granted, so they
19 are rather special because of the special problem the
20 Chief just noticed. So why not cut them off at the
21 pass, if you are prepared to say --

22 GENERAL VERRILLI: I'm sorry.

23 JUSTICE BREYER: Well, I will add a little
24 bit to this because I am questioning what you say here
25 in the other direction. You say if you just look at

1 everything minus the law of nature, hmm, and that is a
2 process that's otherwise known or obvious in light of
3 the prior art, you can't patent it. That seems to me
4 maybe it goes too far in the other direction, because we
5 know that a lot of work goes into these laws of nature.

6 GENERAL VERRILLI: Our position is a little
7 different.

8 JUSTICE BREYER: All right. So there are
9 both parts, but I'm more interested in --

10 GENERAL VERRILLI: Your Honor, if I could,
11 if I could. I do think that one has to think about
12 what -- this seems like a straightforward case on these
13 facts, but if one thinks about the principles that Mayo
14 is advocating and applying them in a different set of
15 circumstances I think you will see the problems.

16 Take for example nuclear stress tests that
17 cardiologists use. That's a process. The patient gets
18 on a treadmill, the heart rate gets elevated,
19 radioactive dye gets put into the body, it allows an
20 image to be taken of the heart with an x-ray machine.
21 That improves treatment. Now, the transformation there
22 is, as in this case, incidental to the process, it's not
23 the point of the process. But I don't think anyone
24 would suggest that that's not a patentable process, but
25 under Mayo's process it's not a patentable process.

1 Similarly I think -- I'm sorry,
2 Mr. Chief Justice.

3 CHIEF JUSTICE ROBERTS: I was just going to
4 say, what is the great advantage you see of putting this
5 critical question off until the 102, 103 analysis,
6 rather than cutting it off at the beginning, 101, which
7 I understand your friend to say is very important
8 because you don't want people to have to pause terribly
9 long to see if this is something they can do?

10 GENERAL VERRILLI: As a practical matter, at
11 the PTO, Mr. Chief Justice, it doesn't make any
12 difference, because the PTO examiner gets a patent
13 application and answers every question, 101, 102, 103,
14 112, and makes a decision about all of them. So it's
15 not going to lead to any benefit at the PTO.

16 CHIEF JUSTICE ROBERTS: What about
17 litigation? It is easier to throw something out at the
18 threshold level, isn't it, than to move further down the
19 line?

20 GENERAL VERRILLI: Not if one moves the
21 novelty and obviousness inquiries from 102 and 103 into
22 101. You've just taken the complexity of 102 and 103
23 and moved it into 101.

24 JUSTICE KENNEDY: Well, I'm not so sure.
25 We're talking about summary judgment. It seems to me,

1 rough rule, that summary judgment would be much more
2 easy -- much easier under 101 than 102 and 103.

3 GENERAL VERRILLI: I think this case is a
4 pretty good illustration, Justice Kennedy, of why that's
5 not true. Think of, if I may pick up on the question
6 Justice Scalia asked my friend, think of all the trouble
7 we are having in this case figuring out what the
8 standard is: How much preemption is too much? How do
9 you even figure out the scope of preemption? What you
10 are actually doing here is multiplying a whole new set
11 of very difficult, complex questions that you don't have
12 to answer.

13 JUSTICE KAGAN: But, General, I read you in
14 part as saying: Don't work, because if something
15 strikes you as wrong with this patent, we are going to
16 catch it under 102. And I guess I'm not sure why that's
17 true. There was novelty here. There were some doctors
18 who figured out some new things, which was new ranges of
19 effective drug treatment. And so why do you think you
20 are going to catch this as a 102 matter? If there is a
21 problem here, it seems to me not the fact that there was
22 something new. There was something new. It's that --
23 it's something else.

24 GENERAL VERRILLI: But there was no new
25 process, Justice Kagan. There is exactly the same

1 process that already exists, with a new inference drawn
2 at the end, and that's why you can capture this under
3 102. And I do think it's important to think about in
4 terms of the points Mr. Shapiro is making, if this
5 patent had involved, instead of standard old blood
6 tests, had involved a breakthrough new test that allowed
7 one to measure metabolite levels in a way that could
8 never have been done before, of course the person who
9 invented that could get this patent, even though it
10 would have the excluding effect that Mr. Shapiro has
11 identified. Similarly, if the drug is a breakthrough
12 drug and a patentable drug, any use of the drug during
13 its patented period, including a use in a test like
14 this, would be an infringement under 271.

15 JUSTICE SCALIA: What about --

16 CHIEF JUSTICE ROBERTS: Justice Scalia?

17 JUSTICE SCALIA: What about the discovery of
18 a new physical change in the body caused by an old drug?
19 You -- you find that it affects another part of the
20 human system. Is it -- is that discovery patentable?

21 GENERAL VERRILLI: Well, I think that's a
22 harder question, but there are, for example -- and I
23 think the Court was looking at some of this in the
24 Caraco case on Monday, follow-on patents with respect to
25 pharmaceutical products, where you patent it originally

1 for one use and then you can later patent it when you
2 discover a different use. And in fact there is an
3 entire regulatory system set up to deal with that. So I
4 do think there are circumstances in which that can be
5 patentable, yes.

6 JUSTICE ALITO: Could I ask you about your
7 argument that the correlations that were discovered and
8 that are involved here are not natural phenomenon
9 because the thiopurine are synthetic products of human
10 ingenuity? I found that a little difficult to
11 understand.

12 Suppose someone discovers the level at which
13 a human pollutant that is present in the atmosphere or
14 in the air or the water has an adverse effect on human
15 health. Is that not a natural phenomenon?

16 GENERAL VERRILLI: The existence of a
17 pollutant in the air and its effect probably is a
18 natural phenomenon, but the difference here is that
19 there is a conversion of the natural body chemistry.
20 The metabolites wouldn't be in the body but for the
21 administration of these drugs.

22 And I do think if one were to say that
23 that's an unpatentable natural phenomenon -- and this is
24 what I mean about the destabilizing risk of thinking
25 about this as a 101 issue rather than 102 or 103 --

1 you're going to call into question lots and lots,
2 thousands in fact, of medical use patents where the
3 patent is: Administer a therapeutically effective
4 dosage of this drug in order to treat this disease.

5 JUSTICE BREYER: Yes, but this drug is
6 patentable because it's a -- what is the third word.
7 You know, it's combination of nature. What's the --
8 it's a composition of matter.

9 GENERAL VERRILLI: Yes, Justice Breyer. But
10 those patents are not on the composition of matter.
11 Those are process patents.

12 JUSTICE BREYER: They don't have to be.
13 You'd say that where it's a new use there were some
14 specifications and the specifications limited the area
15 to over here, I think -- and tell me if I'm wrong
16 because I'm really asking just a question -- they limit
17 it over here, you see. And now we have a new use and we
18 are saying this composition of matter is being used over
19 here. So aren't you getting a -- simply a different
20 area where you are using a composition of matter?

21 GENERAL VERRILLI: Well, but that's a use
22 patent. That's not a composition-of-matter patent
23 and --

24 JUSTICE BREYER: That isn't a process
25 patent.

1 GENERAL VERRILLI: Yes, it's a process
2 patent. It is a process patent, and the problem would
3 be if one says --

4 JUSTICE BREYER: All right.

5 CHIEF JUSTICE ROBERTS: Finish your
6 sentence.

7 GENERAL VERRILLI: If one says that it's
8 nonpatentable because all you are doing is patenting the
9 application of a law of nature, you're invalidating all
10 those process patents.

11 Thank you.

12 CHIEF JUSTICE ROBERTS: Thank you, General.
13 Mr. Bress.

14 ORAL ARGUMENT OF RICHARD P. BRESS

15 ON BEHALF OF THE RESPONDENT

16 MR. BRESS: Mr. Chief Justice, and may it
17 please the Court:

18 I would like to start out, I think, with
19 answering the question about what these patents cover
20 and what they don't. And I'm going to answer that
21 really not because I think it has any relevance to the
22 101 issue. I actually don't think it has any relevance
23 to 101. And I will explain that it does perhaps have
24 relevance under 102 and 103 and why the difference
25 matters, if I may.

1 So the district -- my friend is correct that
2 in the district court at the initial infringement stage,
3 before the Court decided the validity of the patent, we
4 argued that the right way to look at our numbers was
5 that we were claiming that if a doctor correlated or
6 associated a number greater than 400 with toxicity,
7 that's what we were claiming, that would be within our
8 claim. And if the doctor correlated under 230 with not
9 enough drug, well, we were claiming that as well.

10 Now, the district court agreed with that and
11 said that those were the ranges. But then it confused
12 things a bit, and that's where we get to the 15 percent
13 plus or minus point. The court also said -- and by the
14 way, I think this is a correct reading -- that when we
15 said about 400, that means plus or minus 15 percent of
16 400, and about 230 plus or minus 230.

17 And then the court held that there was
18 infringement, but it held it for two different reasons.
19 It said that -- that the patent for Mayo -- or the --I'm
20 sorry, not patent, the product Mayo had, which by the
21 way was awfully close -- it was 235 to 450 -- fell
22 within the 15 percent on the top side. It didn't look
23 at the bottom side for purposes of this decision. But
24 450 was within 15 percent of 400. And it also said it
25 violated it because 450 is greater than 400.

1 At the court of appeals we argued that the
2 right way to read the district court's opinion was that
3 you had to actually do that comparison, that the ranges,
4 the 15 percents, mattered and that the doctor, in order
5 to infringe, would have to look at the result and say:
6 Is this or isn't this greater than 400 and compare it to
7 400, or 230.

8 The court of appeals accepted that reading
9 of it, and that reading wasn't disputed by Mayo, and on
10 page 38 of the court of appeals opinion, the court of
11 appeals says it has to be compared to a predetermined
12 number.

13 I think you could go either way on this. I
14 think, frankly, the Court could go back to the district
15 court and look at that, perhaps. But the problem with
16 that is that there was no objection at the court of
17 appeals. And I think any objection to how the court of
18 appeals understood it is probably waived at this point.

19 Now for why it doesn't matter. If there is
20 a problem with the broad ranges here, in other words if
21 there is a problem with the fact that we're saying over
22 400 indicates toxicity, let's think about what is that
23 problem. Suppose we are right. I mean, at this stage
24 the Court certainly can't presume we are wrong in that.
25 So let's suppose that we are right. If we are right,

1 then we are simply claiming the fact that we found, that
2 after you administer the drug and determine the
3 metabolite level, if it's over 400, it indicates
4 toxicity.

5 JUSTICE ALITO: And that's a natural
6 phenomenon.

7 MR. BRESS: It is a -- It's according to a
8 law of nature, and I will agree with that, Your Honor.
9 The term "natural phenomenon" as this Court has used it,
10 for instance, in Chakrabarty or in J.E.M. has referred
11 to the difference between things that exist in nature
12 with the intervention of man and things that exist
13 without the intervention of man. So, for example,
14 photosynthesis would be a process that is a natural
15 phenomenon. On the other hand, cross-breeding plants to
16 create a new variety, that wasn't the natural
17 phenomenon.

18 JUSTICE ALITO: Yes, but if photosynthesis
19 is induced by a lamp inside a building, then it's not a
20 natural phenomenon?

21 MR. BRESS: I think you could probably get a
22 patent. I think you could get a patent, Your Honor, on
23 the use of a lamp to induce photosynthesis, but you
24 couldn't claim the underlying process, is all I'm
25 saying, of photosynthesis.

1 JUSTICE BREYER: I thought of two examples
2 that will try to get you to talk about the problem
3 that's really bothering me here, anyway.

4 MR. BRESS: I would love to, Your Honor.

5 JUSTICE BREYER: Well. A patent for --
6 we've discovered, at some extent, what counts as too
7 little fertilizer and what counts as too much to make
8 plants grow, a certain kind of fertilizer, very common.
9 Less than an quarter of an inch, forget it; more than
10 half an inch, you are going to burn the plant.

11 Imagine that. Law of nature, absolutely,
12 about the chemicals in the fertilizer. Patent: A
13 method for determining when there is too little or too
14 much fertilizer. Put some fertilizer in a field and
15 measure how much there is, wherein less than a quarter
16 of an inch is too little and wherein more than half an
17 inch is too much.

18 Second example. Einstein never lived, but
19 at vast expense you invented E equals mc -squared, a
20 method for measuring energy which is very useful that
21 comes out of a cyclotron. Put some stuff in a
22 cyclotron, measure the stuff in and measure how much
23 comes out, and keep -- wherein, wherein, the missing
24 part is -- think about -- wherein -- - it says: Wherein
25 the missing part will be calculated as an amount of

1 energy according to a formula E equals mc -squared.

2 If your patent is valid, why aren't the two
3 I just mentioned? And if you -- if the two I just
4 mentioned are valid, there is something wrong with this
5 picture.

6 MR. BRESS: Okay, You Honor. I will answer
7 them in turn and then hopefully I'll get back to my
8 range and explain what the 102 and 103 problems are with
9 that for you all as well.

10 The first patent you've discussed, which is
11 how best to use fertilizer essentially for plants.
12 Patent-eligible subject matter, but clearly novel and
13 novel in a way that you could get rid of on summary
14 judgment just as fast as you could get rid of it on 101.
15 There is no advantage, in other words, to saying: I am
16 going to label my summary judgment motion 101 and import
17 lack of novelty into that versus saying I'm going to
18 label --

19 JUSTICE BREYER: Where is lack of novelty?
20 Nobody has these numbers before. They always thought it
21 was a quarter, an eighth of an inch. It's huge novelty.

22 MR. BRESS: Your Honor, the law, as you well
23 know, recognizes that under section 103, if something
24 would have been obvious to someone with ordinary skill
25 in the art --

1 JUSTICE BREYER: I mean, my point -- assume
2 with me the eighth versus quarter of an inch which is
3 the law of nature part is not obvious.

4 MR. BRESS: Your Honor, the first person who
5 came up 10,000 years ago with the best way to do -- to
6 use fertilizer in a way that nobody had ever done before
7 would presumably get it. If your question is at what
8 level of sort of microns you can draw a line between
9 obviousness and novelty, there are questions of fact
10 embedded in that.

11 JUSTICE BREYER: No, no. My question is,
12 what has to be added to a law of nature to make it a
13 patentable process?

14 MR. BRESS: To make --

15 JUSTICE BREYER: And if you put too little
16 in the answer to that question, I believe I can take
17 things that like E equals mc -squared and make them
18 patentable. And if you put too much in, you are going
19 to wreck your own case.

20 MR. BRESS: Your Honor, I will try very hard
21 not to do either.

22 Your Honor, this Court has looked at two
23 different ways to try to limit what are laws of nature,
24 abstract ideas, etcetera. One way it has looked at is
25 to say we need something physical; it has to be in the

1 world. In other words, you have to move things, you've
2 got to transform them, you have to apply machinery to
3 them, that sort of thing. So we just know off the bat
4 you are not literally claiming just a principle in the
5 air.

6 So in your example, if you used, you know,
7 machines, implements, et cetera, to do it, at least we
8 would know that much. I think the problem that Your
9 Honor's raising is more in the second stage, which is,
10 okay, it isn't just a mere principle. I get that. But
11 are we as a practical matter preempting an abstract idea
12 in such a way that we are going to too greatly suppress
13 follow-on invention. And the classic example of that,
14 Your Honor, is the Morse case, of course.

15 In Morse there were two different claims
16 that were being discussed, actually eight different
17 claims being discussed. But one of the claims had to do
18 with the actual invention of how you can make a
19 telegraph work. And Morse described a working telegraph
20 system and he got a patent for that.

21 And the second one that he tried to claim
22 was the use of electricity to write at a distance. And
23 the reason he didn't get that one is that it was
24 expressed at such a level -- high level of abstraction,
25 that it would preempt many, many things that he had

1 never invented and never thought of. In fact, the
2 Court's words were wonderful in that case:

3 "For aught we now know," the Court said, somebody may
4 come up with wonderful inventions in the future. And of
5 course now we have the fax machine, e-mail, et cetera.
6 That's the right way to think about it, which is, is
7 the -- for the second step, which is, is what's being
8 claimed at such a high level of generality that it's
9 going to inhibit future innovation.

10 JUSTICE KENNEDY: Why couldn't someone come
11 up with the idea that at a level which is in the range
12 that is within your patent, that if at a certain level
13 for a certain -- a person of a certain age, you
14 administer a new drug, you have a new result? Why isn't
15 that like the fax machine?

16 MR. BRESS: Your Honor, in that case they
17 could get an improvement patent on it, first of all, no
18 question about it, that they could apply for an
19 improvement patent.

20 JUSTICE KENNEDY: But the --

21 MR. BRESS: They're building on it.

22 JUSTICE KENNEDY: -- Petitioner is saying
23 that if you think about that, it's an infringement.

24 MR. BRESS: Well, there's a -- let me
25 explain why I think there is not a problem with that,

1 Your Honor. If you looked at the process for
2 vulcanizing rubber, which Firestone patented many, many
3 years ago, that involved you heat India rubber to a high
4 temperature, you add sulfur and mineral salts, and that
5 way you cure rubber into a usable way of using it.

6 Now, many years later in Diehr this Court
7 looked at an improved process, if you will, for making
8 rubber which involved continuous measurement and the use
9 of the Arrhenius equation to know when the rubber was
10 cured. Now, there is no doubt that if somebody came out
11 with a second one 10 years after Firestone had gotten
12 the patent on vulcanization, they would have had to pay
13 patent royalties for 10 years before their second one
14 would have been free of patent royalties, right, because
15 they would have had to respect the patent that Firestone
16 got.

17 So the simple fact, in other words, that
18 there may be further improvements to what you've done
19 isn't where the court has ever drawn the line. And I do
20 think that in conceptualizing where to draw these lines,
21 because at the edges they're indeterminate, they're
22 elusive and they're going to be somewhat arbitrary.
23 This is judge-made law. I think that what you've got to
24 look to is what you've done before.

25 And if we take this case in the spectrum of

1 what this Court has looked at, where you've got Morse on
2 one side, on that same side you've got Benson, which was
3 simply a formula for converting binary coded decimals to
4 pure binary, which the court said you could use for an
5 infinite number of uses. It was way too broad.

6 If you look at Bilski, a general way of -- a
7 general -- the concept of hedging. Now Bilski was
8 limited, admittedly and this Court discussed it and
9 said, well, they tried to limit it with the conventional
10 step of having the inputs determined by random analysis
11 techniques. I would like to focus on that for a second,
12 because the Court said that was not significant extra
13 solution activity. It wasn't enough to either render
14 the process a physical one in the world or to narrow its
15 scope. Well, why is that?

16 Because random analysis techniques are
17 themselves just an abstract idea. So you were adding
18 one abstract idea to another one and it's no wonder that
19 the Court found that it didn't narrow it to a patentable
20 scope.

21 Now on the other side of the line we have
22 cases Tilghman. Now if you look at Tilghman, Tilghman
23 was a patent on the fact that if you use water at a high
24 heat and high pressure, you can separate out from fat
25 bodies, the fatty acids on the one hand and the glycerin

1 on the other. And this Court approved a process -- a
2 patent process on that. Now that's of course a natural
3 law, Justice Alito, no question about it, in terms of is
4 it a law of nature that makes you do that, yes.

5 But the Court was comforted in that case by
6 the fact that the patent wasn't trying to generally
7 patent monopolize the idea that water at high pressure
8 and temperature is going to in general break bonds of
9 chemicals. And it wasn't trying to either monopolize
10 the whole idea of how you can separate fat acids and
11 glycerin from fat bodies. There are other ways,
12 including the use of sulfuric acid.

13 Let's place this case in the continuum.
14 Now, we are not trying to pass the general broad idea
15 that you can use metabolite readings after you
16 administer the drug to determine what the likely, what
17 the best level of the next administration might be.
18 That would be kind of like the Morse patent, and that's
19 not what we are doing. What we are talking about here
20 is A, a very specific class of drugs, the thiopurines
21 used for --

22 JUSTICE KAGAN: But, Mr. Bress, here's what
23 you have not done. What you haven't done is say at a
24 certain number you should use a certain treatment, at
25 another number you should use another treatment. I

1 guess the first question is why didn't you file a patent
2 like that? Because that clearly would have been
3 patentable. Everybody agrees with that.

4 MR. BRESS: I agree it would, Your Honor.
5 Two responses if I may.

6 JUSTICE KAGAN: And I think that the
7 difference that people are noting or some people are
8 noting is that this is not a treatment protocol, it's
9 not a treatment regimen, all you have done is pointed
10 out a set of facts that exist in the world, that exist
11 in the world, and are claiming protection for something
12 that anybody can try to make use of in any way and you
13 are saying you have to pay us.

14 MR. BRESS: Right. Your Honor, I don't
15 agree with that description, but let me explain --

16 JUSTICE KAGAN: I thought you might not.

17 MR. BRESS: -- why. All right, Your Honor,
18 first of all most of the claims here have three steps.
19 So you have an administering step which clearly carries
20 its own benefits with it. It's not novel, but it's
21 certainly a process step that in and of itself could be
22 a process. We couple that with determining -- you
23 determine the amount of metabolites and the next step
24 gives the doctor valuable information in order to decide
25 what to do next.

1 Now why didn't we say, if it's over 400 you
2 must decrease because that doesn't correspond with how
3 doctors practice medicine, Your Honor. So for example,
4 you've got a patient for whom you've got a particularly
5 sharp outbreak of Crohn's disease. You may well be
6 willing to go above the normal 400 level if your other
7 tests, your liver toxicities and your white blood cell
8 counts etc., tell you that for this patient at this time
9 given that condition I am willing to risk some
10 additional toxicity.

11 On the lower end of the scale you may have
12 somebody under 230 who seems to be improving, they seem
13 to be moving towards remission, why push it, why
14 increase. And this is not unusual. And that's one of
15 the things I think I've got to stress here is the notion
16 of a patent only in the end producing information is old
17 in this country. And by the way to produce the
18 information you are always going to have a step at the
19 end that is some kind of an algorithm. Like a very
20 simple one. But it takes the data, the raw data and
21 turns it into something useful.

22 So for example, in the 19th century there
23 were patents on the use of electricity to locate veins
24 of ore and valuable minerals in the ground. Now that
25 patent didn't say after you found it, you have got to

1 dig it out. And according to Mayo, that would have to
2 be the next step. But of course you might have reasons
3 for digging it out or not digging it out depending on
4 your finances, depending on how deep it is and depending
5 on what kind of ore it is, etc.

6 There were patents on how to navigate your
7 boat in the fog, it was a primitive sonar based method.
8 And it didn't tell you in the end you had must steer
9 your boat to X and go there. It just told you a likely
10 way to go. There was not --

11 JUSTICE BREYER: What about a process that
12 all the steps are -- it's a process to -- to generate
13 some useful information.

14 MR. BRESS: Yes.

15 JUSTICE BREYER: Fine. And the only new
16 thing about it is the useful information.

17 MR. BRESS: Yes.

18 JUSTICE BREYER: Anything like that in
19 history, any patent case that comes to mind that you say
20 that was okay? Can you think of one?

21 MR. BRESS: Actually, Your Honor, yes.

22 JUSTICE BREYER: What? Good. That's what I
23 would like to know.

24 MR. BRESS: Certainly. For example, there
25 was a patent on the -- and I can talk about modern ones

1 too, of course, but a patent on how to find the -- where
2 there is a leak in a water main and it was using
3 vibration of --

4 JUSTICE BREYER: No, no. That's not what
5 I'm thinking of. I'm thinking of a patent to find
6 useful information that chickens can only eat so much
7 chicken food. That nobody has ever known before, you
8 know. Okay. Now there's something like that. But they
9 tell you the useful information that's going to be found
10 right in the patent. In other words, we have a patent
11 to discover some useful information and here is the
12 useful information. And now here's -- see, that's what
13 they're complaint --

14 MR. BRESS: I'm not sure that I am
15 understanding, Your Honor, because the patent that tells
16 you where to find the ore is telling you what you're
17 going to --

18 JUSTICE BREYER: But you don't know what you
19 are going to find because you don't know how much ore
20 you are going to find? Let's see, okay. Let me think
21 about it.

22 MR. BRESS: Well, and if we talk about
23 modern days because I think it's helpful now to move
24 this forward, the court has never suggested that there
25 is an extra statutory limitation that prevents patents

1 on developing useful information, even if they have a
2 mental step at the end. And what do we have today?
3 We've got inventions out there that through
4 identification of biomarkers or measuring the biomarkers
5 allow us to know which of 10 particular cancer drugs is
6 going to work for a particular patient.

7 We have got patents on methods that allow us
8 to identify the likely location and size of the next
9 earthquake in the San Andreas fault. We have got
10 patents that allow us to determine where there is a
11 crack and what type of crack in a nuclear reactor core.

12 Now, according to Mayo, because all of these
13 patents end with a mental step that produces
14 information, they're no good. Or perhaps if you look at
15 them and say everything up to that algorithm at the end
16 is old, you can't get a patent because you lack novelty.

17 Now, it may be to -- it may be in fact,
18 depending on the particular invention, that you should
19 lose for lack of novelty on one or other of those, or
20 that you should lose for lack -- for obviousness.

21 But under 101, these are precisely --

22 JUSTICE BREYER: What's your view? What's
23 your view?

24 MR. BRESS: Okay, Your Honor, I'm happy to
25 address that, too. The answer is no, and here's why.

1 JUSTICE BREYER: You should not lose it.

2 MR. BRESS: You should not lose. And this
3 is why -- and I'll use my case as a wonderful example.

4 So in our case, what existed before in the
5 prior art, so to speak, was people knew that you could
6 administer thiopurines for these particular diseases,
7 and by the way, they're not all diseases, just -- we do
8 specifically exclude in these patents, for example,
9 Host-versus-graft disease. We exclude leukemia, et
10 cetera. They're not in the asserted patents in this
11 case.

12 But in any event, administration of
13 thiopurines to address certain diseases: old in the
14 art. Different methods for finding analytes in blood
15 cells such as high pressure liquid chromatography? Old
16 in the art, no doubt.

17 They were used together before we did them,
18 but why were they used? They were used by people who
19 were trying to come up with what we came up with. They
20 weren't doing it for fun. They were administering.
21 They were determining in order to try to find a new
22 treatment method, a new way of calibrating the right
23 dose for each individual patient based on their
24 metabolism, and help seriously ill patients.

25 And the idea that we are not novel because

1 people took some of the same steps along the way to
2 invention that we actually succeeded in is wrong. And
3 in fact, this Court said so in *American Wood-Paper*,
4 where it said that "incomplete and unsuccessful attempts
5 to invent will not render not novel the successful
6 inventor."

7 And in *Bell*, the Court said the difference
8 between those who -- those who did not get the patents
9 in *Bell* was only the difference between failure and
10 success, and didn't say that because many of them had
11 used similar methods but had not understood that
12 continuous electrical lines as opposed to intermittent
13 or pulsing electrical lines was going to be the
14 difference for a working telephone.

15 Similar here. I don't think we ought to
16 lose on novelty to that ground. But let's put that to
17 the side, because that's for remand, and it's something
18 that hopefully --

19 JUSTICE SCALIA: Suppose somebody thinks
20 you're wrong, that the numbers you've come up with are
21 wrong. And they want to develop better numbers that
22 will -- will help the medical profession. Your -- your
23 patent occludes them from doing that. Am I right?

24 MR. BRESS: No, Your Honor.

25 JUSTICE SCALIA: No?

1 MR. BRESS: And let's explain why not. And
2 I will even take for purposes of this explanation my
3 brother's example of over 400 and under 230, because I
4 don't think it matters. So you've got Dr. el-Azhary,
5 who believes that the right ceiling level is 300. Okay?
6 So if she sees a patient and says, "I'm going to -- you
7 know, I associate 290 with toxicity," that won't violate
8 our patent in the least.

9 Our patent says if you associate over 400
10 with toxicity, that's within our range. If she
11 associates 290 with toxicity, no violation.

12 Now, getting more to the point, though, if
13 we're totally wrong -- let's assume we're off base
14 and -- and this doesn't work at all. There's another
15 participant of section 101 that addresses that, and
16 that's utility.

17 And certainly Mayo would be able to come
18 into court and say that patent has no utility, it's
19 completely wrong. In fact it's killing patients. And
20 try to invalidate us on that ground. Similarly, suppose
21 at the very edges of the spectrums that we're claiming,
22 the answer is obvious, the answer is not novel. They
23 can seek to try to invalidate our patents on that basis
24 as well.

25 This -- these aren't 101 problems.

1 CHIEF JUSTICE ROBERTS: Well, it seems to me
2 that's your -- the problem with your whole approach is
3 that every time you're pressed on 101, your answer is to
4 fall back to 102 or 103 or the utility part of 101. And
5 I'm just wondering why it's beneficial to essentially
6 eliminate 101 and say oh, we'll catch everything later
7 on.

8 MR. BRESS: Thank you, Mr. Chief Justice; I
9 appreciate the question.

10 I -- I think that the answer is that when
11 the problem is lack of novelty, when the problem is
12 obviousness, the right place to go are the sections that
13 actually have very clear rules on how to apply those,
14 and that the problem with taking a short cut in that
15 instance is, essentially, the Court would just imbue its
16 own notions or pre-conceived notions of what should be
17 patentable and pour it into it as opposed to following
18 those rules.

19 And of course, if you're going to follow
20 these rules, you might as well follow them under that
21 section. Now, it doesn't completely leave 101 bereft.
22 This Court has said 101's very broad, but it does have
23 limitations.

24 And if you look at a case like Morse --

25 CHIEF JUSTICE ROBERTS: Well, just as -- I'm

1 sorry to interrupt. Your friend's point is that if you
2 don't do this -- if you don't give 101 some more
3 content, then the doctor is going to have to start
4 worrying right from the get-go, and they say well, is
5 there an exception that I might be able to rely on, as
6 opposed to being able to say right away this -- I don't
7 have to worry about this patient; I can treat the
8 patient in this way.

9 MR. BRESS: Well, Your Honor, again, if --
10 if it's very clear that we're not novel. For example,
11 if -- if the government is correct here that facially,
12 we lack novelty, it's no harder to proceed under 102 to
13 achieve that goal than it is under 101. If you're going
14 to proceed under 101, then we'll talk about principles
15 that 101 speaks to.

16 So 101 -- I think the primary -- the two
17 things explored: it has to be a process in the physical
18 world, a hands-on process. And it can't be so broad
19 that it preempts all follow-on innovation. Those are
20 the two things -- you know, this Court speaks about
21 statutory language, and it has to do some work.

22 That's the work that --

23 JUSTICE SOTOMAYOR: So that's novel. What's
24 your answer about why this is novel?

25 MR. BRESS: Right. Your Honor, before

1 Prometheus -- actually, the inventors in this case in
2 Montreal came up with this method -- doctors had no way
3 to tailor for each individual based on their metabolism
4 the right dosage of these powerful but potentially toxic
5 drugs.

6 CHIEF JUSTICE ROBERTS: Thank you, counsel.

7 Mr. Shapiro, you have 4 minutes remaining.

8 REBUTTAL ARGUMENT OF STEPHEN M. SHAPIRO

9 ON BEHALF OF THE PETITIONERS

10 MR. SHAPIRO: Justice Scalia asked the
11 critical question here: what if you think these numbers
12 are wrong? What happens with patients around the
13 country? Well, that's just what we concluded: these
14 numbers were wrong. They say you go up to 400, and
15 above 400, it's bad, it's harmful. We found that the
16 right range was 450 up to 700 -- and sometimes above
17 700 -- to cure some of these very serious diseases.

18 And that different opinion was blockaded by
19 this treble damages lawsuit, and request for an
20 injunction.

21 So the -- the wrong information is --

22 JUSTICE SCALIA: He says the solution to
23 that is that -- you're saying their patent is not
24 useful. That would be your defense.

25 MR. SHAPIRO: It's important that 101 be the

1 robust test here. This is the only provision under
2 which this Court has issued decision after decision for
3 150 years protecting the public domain. It's not some
4 rough gauge; it's the critical test defining what's in
5 the storehouse of information for medical researchers to
6 use. And reduce it to a dead letter here would be just
7 contrary to this Court's precedence, and very harmful to
8 the medical community. This is very important to -- to
9 doctors around the country.

10 Now, is this a natural process? The
11 question was raised. Of course it's a natural process.
12 These metabolites come from the liver. They don't come
13 from a test tube. They don't come from a syringe. It's
14 just like cholesterol. If I eat in a French restaurant,
15 there's some human intervention there that gives me high
16 cholesterol. And if I eat wild strawberries, there's no
17 human intervention. But either way, the doctors get to
18 look at my cholesterol and hypothesize ranges that they
19 think are essential. It's the very same phenomenon.
20 Entirely natural.

21 Now, this is a clean legal issue. Under
22 section 101, it's always been a legal issue. They say
23 section 102 and 103 are the most elusive questions in
24 the field of patent law. This is a Federal lawsuit
25 against a hospital; it's cost millions of dollars to

1 defend.

2 Two trips to this Court, two trips to the
3 Federal circuit. We're still litigating this treble
4 damages case. It should be terminated under this
5 Court's precedence, as the district court did giving
6 summary judgment.

7 JUSTICE SOTOMAYOR: I guess my problem is,
8 if we call this just simply a application of natural
9 phenomenon or of a natural process, why are treatment
10 patents at all --

11 MR. SHAPIRO: Well, because --

12 JUSTICE SOTOMAYOR: -- permissible, meaning
13 if someone finds out that at level 300, it's bad, and
14 tells doctors to stop, that's natural, too.

15 MR. SHAPIRO: Yes. Well, I think that's
16 right. That's -- that is a second issue. But the first
17 issue is the breadth of the preemption, which precludes
18 anyone else in the country, from similarly as
19 Justice Scalia did -- those numbers are wrong. And
20 patients can't use those numbers safely or they won't
21 get cured of this disease.

22 For 20 years, the public is stuck with the
23 erroneous information. Now, counsel suggests that it's
24 narrow preemption because it doesn't cover
25 Host-versus-Graft or leukemia. Those are not autoimmune

1 diseases. Every autoimmune disease is swept in here.
2 And there are dozens and dozens of them. They have
3 different characteristics. You don't take a "one size
4 fits all" approach to autoimmune disease. There are
5 different numbers for different diseases.

6 That's what Mayo is trying to do, to have
7 some personalized medicine for skin disorders. And they
8 said that -- that is an infringement and we're entitled
9 to treble damages and an injunction. Now, is this like
10 the Morse case? Yes, it is like the Morse case.
11 Prometheus is trying to preempt diseases it never
12 researched, and it's trying to preempt numbers that
13 differ from its numbers fundamentally.

14 They have the number 7000 in their patented
15 number. We thought the number should be 5700. This is
16 a very dangerous toxic drug. If you get the wrong
17 number set in concrete for 20 years, that is a huge
18 problem for patients. And there are millions and
19 millions of patients suffering from autoimmune disease.

20 So we urge the Court to protect the research
21 process here that's so fundamental to American health
22 and to the economy and the healthcare industry.

23 We thank the Court.

24 CHIEF JUSTICE ROBERTS: Thank you, counsel.

25 Counsel.

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The case is submitted.

(Whereupon, at 11:06 a.m., the case in the
above-entitled matter was submitted.)

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