IN THE SUPREME COURT OF THE UNITED STATES

MAYO COLLABORATIVE SERVICES, DBA MAYO MEDICAL LABORATORIES, ET AL., Petitioners v. PROMETHEUS LABORATORIES, INC. : No. 10-1150

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; for 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.; for Respondent.

C O N T E N T S

ORAL ARGUMENT OF PAGE

STEPHEN M. SHAPIRO, ESQ.

On behalf of the Petitioners 3

ORAL ARGUMENT OF

DONALD B. VERRILLI, JR., ESQ.

On behalf of the United States, 25

as amicus curiae

ORAL ARGUMENT OF

RICHARD P. BRESS, ESQ.

On behalf of the Respondent 35

REBUTTAL ARGUMENT OF

STEPHEN M. SHAPIRO, ESQ.

On behalf of the Petitioners 57

P R O C E E D I N G S

(10:05 a.m.)

CHIEF JUSTICE ROBERTS: We'll 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 pre-emption 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 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, it -- what it can't do is use any number from 400 up until infinity, and it believes that's the wrong number. And it can't have a -- a different standard for a legion of autoimmune diseases, and there are dozens and dozens of them. That's a broad field to pre-empt the natural phenomenon.

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

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

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

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

MR. SHAPIRO: Well, you know, actually it didn't, Your Honor. You'll see in that opinion, there

are two rulings. One is the 15 percent ruling, which lowers the number; but it said 400 and above all the way to infinity. There's no upper limit on this.

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

JUSTICE SOTOMAYOR: It can offer the test.

MR. SHAPIRO: -- you get one opinion.

Pardon me?

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

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

JUSTICE SOTOMAYOR: Tests do two things: They measure something --

MR. SHAPIRO: Yes.

JUSTICE SOTOMAYOR: -- and therapeutic range does something else. The tests can happen. The doctor gets a number. What the doctor does with that number is a different issue.

MR. SHAPIRO: And -- and what -- what Prometheus submitted and the court agreed is if you are

notified, if you are aware of their range when you're drawing blood, that's an infringement right then and there, if -- if you're aware or warned by their number.

So, any doctor in the United States that draws blood and is aware of this range of theirs is pre-empting. And the practical result is we haven't been able to offer this competing test now for 7 years.

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

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

JUSTICE KENNEDY: In thinking about what's pre-empted, I looked at the Diehr case involving the rubber molding --

MR. SHAPIRO: Yes.

JUSTICE KENNEDY: -- and the constant monitoring. And if you could take an analogy from that, let's -- let's suppose that there was a system of

measurements that you take every half-hour which constantly monitor how a drug is being retained in the tissues, and that there is a protocol for the admission of some two or three different drugs to get the balance right. In other words, it's much more complicated.

Is there some point at which that is patentable, even though this pre-empts a -- a whole range of different choices?

MR. SHAPIRO: Well, it may be patentable.

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

MR. SHAPIRO: The key is the specificity.

JUSTICE KENNEDY: -- see what the process is here.

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

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

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

MR. SHAPIRO: Yes. If you -- if you pre-empt all the numbers up to infinity and all autoimmune diseases, that's a vast field. It's much bigger than the field in Flook.

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

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

JUSTICE SCALIA: 550?

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

JUSTICE SCALIA: 830?

MR. SHAPIRO: No.

JUSTICE SCALIA: I mean, how are we supposed to apply that kind of a rule?

MR. SHAPIRO: Well, I think doctors have to have freedom to make their own judgments about these natural phenomena.

JUSTICE SCALIA: Above -- above 830 or below 830? Which?

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

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

MR. SHAPIRO: Well, it's the rule I believe

adopted in Bilski and in Flook, that you can't wipe out a whole field so no one else can have a competing test. The result for the public is that these numbers would be frozen for 20 years, and a very serious person couldn't get a second opinion from Mayo Clinic, which uses different numbers. That's why we think --

JUSTICE SCALIA: Doesn't -- doesn't any -- any medical patent rely on natural processes? I mean, even if you invent a new drug, what that new drug does is -- is natural. It affects the -- the human physiognomy --

MR. SHAPIRO: Oh, yes.

JUSTICE SCALIA: -- in a certain natural way.

MR. SHAPIRO: Oh, yes.

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

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

JUSTICE SCALIA: What's different here?

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

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

MR. SHAPIRO: Yes, it is a patent on a measurement --

JUSTICE KENNEDY: But you're giving a different answer.

MR. SHAPIRO: Well --

JUSTICE KENNEDY: I mean, that's how I would have answered the question. But that's obviously not --

MR. SHAPIRO: No, I --

JUSTICE KENNEDY: -- the right way to do it.

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

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

MR. SHAPIRO: You can't patent nature.

JUSTICE SCALIA: Right.

MR. SHAPIRO: That's correct.

JUSTICE SCALIA: And that relates to the question that I asked.

MR. SHAPIRO: But --

JUSTICE SCALIA: And tell me why you can't

patent nature, then?

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

JUSTICE BREYER: Yes. Yes, but your question --

JUSTICE KENNEDY: Nature always -- nature always has a reaction to the drug.

MR. SHAPIRO: Pardon me?

JUSTICE KENNEDY: Nature always has a reaction to the drug.

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

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

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

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

MR. SHAPIRO: Yes.

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

MR. SHAPIRO: Right.

JUSTICE BREYER: All right. So, in this case, what I think the claim is, is that we are applying a law of nature. Now, we read the words of applying it: Administer a drug, determine the level. And then it uses the word "wherein," which I'll ask them what that means. But -- but -- so, they say those two words, administer the drug, determine the level, are the application of the law of nature that they found.

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

MR. SHAPIRO: Yes.

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

MR. SHAPIRO: For us, the real oddity is that this numerical calibration that they've given

extends up to infinity, and it precludes every other blood test.

JUSTICE BREYER: All right. Suppose it didn't. Suppose I discover that if I take aspirin, someone takes aspirin, I discover they have to take aspirin for a headache, and, you know, I see an amazing thing: If you look at a person's little finger, and you notice the color, it shows the aspirin, you need a little more; unless it's a different color, you need a little less. Now, I've discovered a law of nature --

MR. SHAPIRO: Yes.

JUSTICE BREYER: -- and I may have spent millions on that. And I can't patent that law of nature, but I say I didn't; I said apply it. I said look at his little finger.

MR. SHAPIRO: Sure.

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

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

JUSTICE BREYER: Why not?

MR. SHAPIRO: It's not a good patent because --

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

MR. SHAPIRO: Well, because you've -- you've

added to a law of nature just -- just a simple observation of the man's little finger.

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

MR. SHAPIRO: Yes.

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

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

MR. SHAPIRO: There are several things that it can't be. After Bilski, which reaffirmed what was said in Flook, a conventional step isn't sufficient, because that's just adding a law of nature to prior art, and prior art plus prior art equals nothing that is patentable under the Flook decision.

And also, the step that you add has to narrow your pre-emption --

JUSTICE SCALIA: Excuse me. Does that render it nonpatentable because it's not novel? Is that the reason why it -- it renders it nonpatentable?

MR. SHAPIRO: Well --

JUSTICE SCALIA: That's not what we're

talking about here; we're not talking about novelty, are we?

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

JUSTICE GINSBURG: Mr. Shapiro, on that question and the question Justice Scalia just raised, the Government, you know, has taken the position that you're under the wrong section. It's not a question of patentability, but you've used the example of the finger; you said it's obvious. So, why didn't you raise the sections that the Government says would have been the appropriate ones on the novelty or anticipation of prior art and obviousness?

MR. SHAPIRO: That's a very important question for the medical community. They need a robust section 101 standard because under 102 and 103 you could patent E equals MC squared. That's new. It's nonobvious. But you can't patent it under 101 because it's a law of nature.

And it's important to keep this -- this

common domain, the storehouse of information that medical researchers need to have access to --

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

MR. SHAPIRO: Yes.

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

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

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

MR. SHAPIRO: Well --

JUSTICE SCALIA: Because it's novel.

MR. SHAPIRO: This -- this is the Court's 101 analysis in both Flook and in Bilski. So, we rely on the latest decision, Bilski, which took exactly that peek. But the other part of our answer is you don't even have to peek. If the step doesn't narrow the pre-emption of the natural phenomenon, if it's just an

incidental step that you need to use to observe the natural phenomenon, which this blood test is, you can't see the natural phenomenon.

JUSTICE BREYER: You are getting warmer, but --

(Laughter.)

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

MR. SHAPIRO: Oh, yes.

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

MR. SHAPIRO: Oh, sure.

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

MR. SHAPIRO: Yes.

JUSTICE BREYER: What?

MR. SHAPIRO: Our view --

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

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

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

JUSTICE BREYER: You're going on a limitation thing. So, you're going to say reject all the 15 fancy hypotheticals I'll also spare you.

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

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

MR. SHAPIRO: In the Diehr case --

JUSTICE BREYER: Which unfortunately we have to deal with.

MR. SHAPIRO: In the Diehr case, the natural phenomenon was limited with steps that confined the invention to a specific machine with doors opening and

closing, temperature being monitored so a product was cured. It was a very specific, concrete invention.

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

MR. SHAPIRO: Yes.

JUSTICE SOTOMAYOR: But you told me that there's a different range for the treatment of skin diseases.

MR. SHAPIRO: Yes.

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

MR. SHAPIRO: Absolutely.

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

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

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

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

MR. SHAPIRO: Here's what they say, joint appendix pages 13 through 14, the second volume. This is their patent. This is what it covers. It covers

hepatitis, lupus, Hashimoto's disease, Graves' disease, Addison's disease, diabetes, arthritis. And they say it even covers organ transplants. It covers heart, kidney, and liver transplants. So, it covers every autoimmune disease, and there are dozens and dozens of them --

JUSTICE KAGAN: Mr. Shapiro --

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

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

MR. SHAPIRO: Well, this --

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

MR. SHAPIRO: Well --

JUSTICE SOTOMAYOR: -- that involves some greater answer to the issue of limitation.

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

JUSTICE SCALIA: What if -- what if you -- what if they just split up the patent? They -- they got

one patent number for arthritis, another patent number for transplants, another patent number for each one of the autoimmune diseases you're talking about?

MR. SHAPIRO: Well --

JUSTICE SCALIA: Would each of them be okay, because it's --

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

JUSTICE BREYER: Yes, but what my opinion lacked, frankly, and that's sometimes the virtue of a dissent in such a case, it lacked -- and Novartis points this out very well in their brief -- it lacked an explanation as to why what I thought was a patent just said observe the correlation.

MR. SHAPIRO: Yes.

JUSTICE BREYER: Why isn't that an application of the law of nature? And if you look to LabCorp's dissent to find an answer to that question, you're better than I, because I couldn't find it.

MR. SHAPIRO: Well, if -- if observe the -- that's another area of the breadth of this patent,

because there's no specific action the doctor has to take. If the doctor has been informed of their range and draws blood and thinks about it, that's -- that is -- that is infringement. And a doctor here was accused of infringement, treble damages sought against this hospital in an injunction, because she thought about this correlation, and she had completely different numbers.

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

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

JUSTICE KAGAN: So, if they had added a treatment protocol, that would have been a completely different case?

MR. SHAPIRO: Yes, and --

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

MR. SHAPIRO: What makes it different is that leaves room for Mayo Clinic to come up with different numbers that it believes are more accurate and more helpful for patients that are suffering from these

life-threatening diseases. We shouldn't require Americans to get one opinion from Prometheus when they want an opinion from Mayo Clinic.

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

MR. SHAPIRO: Well, that could be specific enough, again, then others could have a rival test that -- that used a different treatment protocol. You'd have to look at that.

JUSTICE KAGAN: So, if the idea --

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

MR. SHAPIRO: Oh, I think --

JUSTICE KENNEDY: I think I'm having the same trouble as Justice Kagan.

MR. SHAPIRO: I think it would be patentable.

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

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

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

MR. SHAPIRO: I think you'd need both. You'd have to look at it in practical terms. Is there room for somebody else to make use of this natural correlation, so that they could come up with different numbers, different ranges, and different treatments? And if there's room left, then there is no pre-emption of the natural phenomenon. That's a vastly different case, and that's what is missing here. I -- I do see my time -- yes?

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

MR. SHAPIRO: My view is there are only a couple of them. LabCorp is like this. This one is like

this. The others that are referred to in this -- these amicus briefs are vastly different. They're specific patents with specific treatment protocols. And by the way, the Government admits this particular patent is invalid because it just attaches a mental step to prior art. And there are only a couple of them to our knowledge that would be affected by a decision in our favor.

But a decision in our favor would protect the storehouse of information that doctors really need. They have to be able to look at the body's reaction to injections, pills, chemotherapy, radiation; and different hospitals have to have different opinions to safeguard the health of our people.

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

CHIEF JUSTICE ROBERTS: Thank you, counsel.

General Verrilli.

ORAL ARGUMENT OF DONALD B. VERRILLI, JR.,

ON BEHALF OF THE UNITED STATES,

AS AMICUS CURIAE

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

Each party in this case has got a valid point. Mayo is correct that you can't get a patent by

tacking a mental step onto an utterly conventional process for administering drugs and testing their effects. But that is an issue under sections 102 and 103 of the Patent Act.

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

GENERAL VERRILLI: I think the answer, Justice Ginsburg, is that from the perspective of the United States and the PTO, it's exactly the opposite; that importing these -- taking -- as Justice Kennedy suggested, taking up the temptation to import a look into novelty and nonobviousness into the 101 inquiry is going to be very destabilizing; that 101, as Bilski said, is a threshold eligibility test, and the question is whether there is a process.

Here there is a process. It's the administration of a drug that changes the body chemistry, and there's then a test to determine the extent of the change, and then there's an inference at end of the test. That's a process.

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

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

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

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

CHIEF JUSTICE ROBERTS: That's patent -- that's patent- eligible.

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

JUSTICE BREYER: Why? Why is the question.

GENERAL VERRILLI: Because --

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

(Laughter.)

GENERAL VERRILLI: Most are pretty obvious.

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

GENERAL VERRILLI: Well, here's -- here's --

JUSTICE BREYER: -- cut them off at the pass, if you're prepared to say --

GENERAL VERRILLI: I'm sorry.

JUSTICE BREYER: Well, I'll add a little bit to this because I am questioning what you say here in the other direction. You say if you just look at everything minus the law of nature, hmm, and that is a process that's otherwise known or obvious in light of the prior art, you can't patent it. That seems to me maybe it goes too far the other direction, because we know that a lot of work goes into these laws of nature.

GENERAL VERRILLI: But our position is a little different.

JUSTICE BREYER: Yes, but I -- all right. So, there are both parts, but I'm more interested in --

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

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

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

CHIEF JUSTICE ROBERTS: I was just going to say, what is the great advantage you see of putting this critical question off until the 102, 103 analysis,

rather than cutting it off at the beginning, 101, which I understand your friend to say is very important because you don't want people to have to pause terribly long to see if this is something they can -- can do?

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

CHIEF JUSTICE ROBERTS: What about -- what about litigation? Is it -- it is easier to throw something out at the threshold level, isn't it, than to move further down the line?

GENERAL VERRILLI: Not -- not if one moves the novelty and the obviousness inquiries from 102 and 103 into 101. You've just taken --

JUSTICE KENNEDY: Well, I'm not so sure.

GENERAL VERRILLI: -- the complexity of 102 and 103 and moved it into 101.

JUSTICE KENNEDY: We're talking about summary judgment. It seems to me, rough rule, that summary judgment would be much more -- much easier under 101 than 102 and 103.

GENERAL VERRILLI: I think this case is a

pretty good illustration, Justice Kennedy, of why that's not true. Think of -- if I may pick up on the question Justice Scalia asked my friend, think of all the trouble we're having in this case figuring out what the standard is: How much pre-emption is too much? How do you even figure out the scope of pre-emption? What you're actually doing here is multiplying a whole new set of very difficult, complex questions that you don't have to answer if --

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

GENERAL VERRILLI: But there was no new process, Justice Kagan. There's exactly the same process that already exists, with a new inference drawn at the end, and that's why you can capture this under 102.

And I do think it's important to think about it in terms of the points Mr. Shapiro is making. If this patent had involved -- instead of standard old blood tests, had involved a breakthrough new test that allowed one to measure metabolite levels in a way that could never have been done before, of course the person who invented that could get this patent, even though it would have the excluding effect that Mr. Shapiro has identified.

Similarly, if the drug is a breakthrough drug and a patentable drug, any use of the drug during its patented period, including a use in a test like this, would be an infringement under 271.

JUSTICE SCALIA: What about the --

JUSTICE ALITO: Can I ask you about your --

CHIEF JUSTICE ROBERTS: Justice Scalia.

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

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

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

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

Suppose someone discovers the level at which a human pollutant that's present in the atmosphere, in the air or the water, has an adverse effect on human health. Is that not a natural phenomenon?

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

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

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

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

GENERAL VERRILLI: Yes, Justice Breyer, but those patents are not on the composition of matter.

JUSTICE BREYER: No, they don't have to be.

GENERAL VERRILLI: Those are process patents.

JUSTICE BREYER: You'd say -- you would say that where it's a new use there were some specifications, and the specifications limited the area to over here, I think -- and tell me if I'm wrong because I'm really asking just a question. They limit it over here, you see. And now we have a new use, and we're saying this composition of matter is being used over here. So, aren't you getting a -- simply a different area where you're using a composition of matter.

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

and --

JUSTICE BREYER: That isn't a process patent.

GENERAL VERRILLI: Yes, it's a process patent.

JUSTICE BREYER: Is a process --

GENERAL VERRILLI: It is a process patent, and the problem would be if one says --

JUSTICE BREYER: All right. I'll think about it.

CHIEF JUSTICE ROBERTS: Finish your sentence.

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

Thank you.

CHIEF JUSTICE ROBERTS: Thank you, General.

Mr. Bress.

ORAL ARGUMENT OF RICHARD P. BRESS

ON BEHALF OF THE RESPONDENT

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

I'd like to start out, I think, with a -- answering the question about what these patents cover

and what they don't. And I'm going to answer that really not because I think it has any relevance to the 101 issue. I actually don't think it has any relevance to 101. And I'll explain that it does perhaps have relevance under 102 or 103 and why the difference matters, if I may.

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

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

And then the court held that there was infringement, but it held it for two different reasons. It said that -- that the patent for Mayo -- or the --

sorry -- not the patent, the product Mayo had, which, by the way, was awfully close -- it was 235 to 450 -- fell within the 15 percent on the top side. It didn't look at the bottom side for purposes of this decision. But 450 was within 15 percent of 400. And it also said it violated it because 450 is greater than 400.

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

The court of appeals accepted that reading of it, and that reading wasn't disputed by Mayo and, on page 3a of the court of appeals' opinion, the court of appeals says has to be compared to a predetermined number.

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

Now for why it doesn't matter. If there's a

problem with the broad ranges here, in other words if there is a problem with the fact that we're saying over 400 indicates toxicity, let's think about what is that problem. Suppose we're right. I mean, at this stage, the Court certainly can't presume we're wrong in that. So, let's suppose that we're right. If we're right, then we're simply claiming the fact that we found, that after you administer the drugs and determine the metabolite level, if it's over 400, it indicates toxicity.

JUSTICE ALITO: And that's a natural phenomenon.

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

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

MR. BRESS: If it -- I think you could probably get a patent. I think you could get a patent, Your Honor, on the use of a lamp to induce photosynthesis, but you couldn't claim the underlying process, is all I'm saying, of photosynthesis. According to this Court's --

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

MR. BRESS: I'd love to, Your Honor.

JUSTICE BREYER: Well. A patent for -- we've discovered, at some expense, what counts as too little fertilizer and what counts as too much to make plants grow, a certain kind of fertilizer, very common. Less than an quarter of an inch, forget it; more than half an inch, you're going to burn the plant. Imagine that. Law of nature, absolutely, about the chemicals in the fertilizer. Patent: A method for determining when there's too little or too much fertilizer. Put some fertilizer in a field and measure how much there is, wherein less than a quarter of an inch is too little and wherein more than half an inch is too much.

Second example. Einstein never lived, but at a vast expense, you invented E equals MC squared, okay, a method for measuring energy which is very useful

that comes out of a cyclotron. Put some stuff in a cyclotron, measure the stuff in and measure how much it comes out, and keep -- wherein -- wherein the missing part is -- think about -- wherein -- no, it says wherein the missing part will be calculated as an amount of energy according to a formula E equals MC squared. Yes.

If your patent is valid, why aren't the two I just mentioned?

MR. BRESS: Okay.

JUSTICE BREYER: And if you -- if the two I just mentioned are valid, there is something wrong with this picture.

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

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

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

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

JUSTICE BREYER: I mean, my point --

MR. BRESS: -- it would fall under obviousness.

JUSTICE BREYER: Assume with me the eighth versus quarter of an inch, which is the law of nature part, is not obvious.

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

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

MR. BRESS: To make --

JUSTICE BREYER: And if you put too little in the answer to that question, I believe I can take things like E equals MC squared and make them patentable.

MR. BRESS: Okay. Well --

JUSTICE BREYER: And if you put too much in, you're going to wreck your own case. So, I'm very interested in hearing --

MR. BRESS: Your Honor, I will --

(Laughter.)

MR. BRESS: I will try very hard not to do either. Your Honor, this Court has looked at two different ways to try to limit what are laws of nature, abstract ideas, et cetera. One way it has looked at is to say we need something physical; it has to be in the world. In other words, you have to move things, you've got to transform them, you have to apply machinery to them, that sort of thing. So, we just know off the bat you're not literally claiming just a principle in the air.

So, in your example, if you used, you know, machines, implements, et cetera, to do it, at least we'd know that much. I think the problem that Your Honor is raising is more in the second stage, which is, okay, it isn't just a mere principle. I get that. But are we as

a practical matter pre-empting an abstract idea in such a way that we are going to too greatly suppress follow-on invention. And the classic example of that, Your Honor, is the Morse case, of course.

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

And the second one that he tried to claim was the use of electricity to write at a distance. And the reason he didn't get that one is that it was expressed at such a level -- high level of abstraction, that it would pre-empt many, many things that he had never invented and never thought of. In fact, the Court's words were wonderful in that case: For aught we now know, the Court said, somebody may come up with wonderful inventions in the future. And, of course, now we have the fax machine, e-mail, et cetera.

That's the right way to think about it, which is, is the -- for the second step, which is, is what's being claimed at such a high level of generality that it's going to inhibit future innovation.

JUSTICE KENNEDY: Why couldn't someone come

up with the idea that at a level which is in the range that's within your patent, if at a certain level for a certain -- a person of a certain age, you administer a new drug, you have a new result? Why isn't that like the fax machine?

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

JUSTICE KENNEDY: But the --

MR. BRESS: They're building on it.

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

MR. BRESS: Well, there's a -- let me explain why I think there's not a problem with that, Your Honor. If you looked at the process for vulcanizing rubber, which Firestone patented many, many years ago, that involved you heat India rubber to a high temperature, you add sulfur and mineral salts, and that way you cure rubber into a usable way of using it.

Now, many years later in Diehr, this Court looked at a -- an improved process, if you will, for making rubber which -- which involved continuous measurement and the use of the Arrhenius equation to know when the rubber was cured. Now, there's no doubt

that if somebody came out with a second one 10 years after Firestone had gotten the patent on -- on vulcanization, they would have had to pay patent royalties for 10 years before their second one would have been free of patent royalties, right, because they would have had to respect the patent that Firestone got.

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

And if we take this case in the spectrum of what this Court has looked at, where you've got Morse on one side, on that same side you've got Benson, which was simply a formula for converting binary coded decimals to pure binary, which the Court said you could use for an infinite number of uses. It was way too broad.

If you look at Bilski, a general way of -- a general -- the concept of hedging. Now, Bilski was limited, admittedly, and this Court discussed it and said, well, they've tried to limit it with the conventional step of having the inputs determined by

random analysis techniques. I'd like to focus on that for a second, because the Court said that was not significant extra solution activity. It wasn't enough to either render the process a physical one in the world or to narrow its scope. Well, why is that? Because random analysis techniques are themselves just an abstract idea. So, you were adding one abstract idea to another one, and it's no wonder the Court found that it didn't narrow it to a patentable scope.

Now, on the other side of the line, we've cases Tilghman. Now, if you look at Tilghman, Tilghman was a patent on the fact that if you use water at a high heat and high pressure, you can separate out from fat bodies the fatty acids, on the one hand, and the glycerin, on the other. And this Court approved a -- a patent process on that. Now, that's of course a natural law, Justice Alito, no question about it, in terms of is it a law of nature that makes you do that? Yes.

But the Court was comforted in that case by the fact that the patent wasn't trying to generally patent -- monopolize the idea that water at high pressure and temperature is going to in general break bonds of chemicals. And it wasn't trying to either monopolize the whole idea of how you can separate fat acids and glycerin from fat bodies. There are other

ways, including the use of sulfuric acid.

Let's place this case in the continuum. Now, we're not trying to patent the general broad idea that you can use metabolite readings after you've administered a drug to determine what the likely -- what the best level of the next administration might be. That would be kind of like the Morse patent, and that's not what we're doing. What we're talking about here is (a) a very specific class of drugs, the thiopurines, used for --

JUSTICE KAGAN: But, Mr. Bress, here's what you have not done. What you haven't done is say at a certain number, you should use a certain treatment; at another number, you should use another treatment. So, I guess the first question is, why didn't you file a patent like that? Because that clearly would have been patentable. Everybody agrees with that.

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

JUSTICE KAGAN: And I think that the difference people are noting or some people are noting is that this is not a treatment protocol. It's not a treatment regimen. All you have done is pointed out a set of facts that exist in the world, that exist in the world, and are claiming protection for something that

anybody can try to make use of in any way. And you're saying you have to pay us.

MR. BRESS: Your Honor, I don't agree with that description, but let me explain why.

JUSTICE KAGAN: I thought you might not.

(Laughter.)

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

Now, why didn't we say, if it's over 400, you must decrease? Because that doesn't correspond with how doctors practice medicine, Your Honor. So, for example, you've got a patient for whom you've got a particularly sharp outbreak of Crohn's disease. You may well be willing to go above the normal 400 level if your other tests, your liver toxicities, your white blood cell counts, et cetera, tell you that for this patient at this time, given that condition, I'm willing to risk some additional toxicity.

On the lower end of the scale, you might have somebody under 230 who seems to be improving. They seem to be moving towards remission. Why push it? Why increase? And this is not unusual. And that's one of the things I think I've got to stress here, is the notion of a patent only in the end producing information is old in this country. And, by the way, to produce the information you're always going to have a step at the end that is some kind of an algorithm. Might be a very simple one but that takes the data, the raw data, and turns it into something useful.

So, for example, in the 19th century, there were patents on the use of electricity to locate veins of -- of ore and valuable minerals in the ground. Now, that patent didn't say after you found it, you've got to dig it out. And according to Mayo, that would have to be the next step. But, of course, you might have reasons for digging it out or not digging it out depending on your finances, depending how deep it is, depending on what kind of ore it is, et cetera.

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

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

MR. BRESS: Yes.

JUSTICE BREYER: All right? Fine. And the only new thing about it is the useful information. Anything like that in history, any patent case that you can -- that comes to mind that you say that was okay? Can you think of one?

MR. BRESS: Actually, Your Honor, yes.

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

MR. BRESS: Certainly. For example, there was a patent on the -- and I can talk about modern ones too, of course, but there was a patent on how to find the -- where there is a leak in a water main, and it was using vibration of the -- of the --

JUSTICE BREYER: No, no. That's not what I'm thinking of. I'm thinking of a patent to find useful information that chickens can only eat so much chicken food. That nobody has ever known before, you know. Okay. Now -- or something like that. But they tell you the useful information that's going to be found right in the patent. In other words, we have a patent to discover some useful information, and here is the

useful information, and now here's -- see, this is what their complaint is.

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

JUSTICE BREYER: But you don't know what you're going to find because you don't know how much ore you're going to find? Let's see. Okay. Let me think about it. Thank you.

MR. BRESS: Well -- and if we talk about modern days, because I think it's helpful now to move this forward, the Court has never suggested that there's an extra statutory limitation that prevents patents on developing useful information, even if they have a mental step at the end. And what would -- what do we have today? We've got inventions out there that, through identification of biomarkers or measuring the biomarkers, allow us to know which of 10 particular cancer drugs is going to work for a particular patient.

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

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

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

But under 101, these are precisely the sorts --

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

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

JUSTICE BREYER: You should not lose it.

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

So, in our case, what existed before in the prior art, so to speak, was people knew that you could administer thiopurines for these particular diseases. And, by the way, they're not all diseases; just -- we do specifically exclude in these patents, for example, host-versus-graft disease. We exclude leukemia, et

cetera. They're not in the asserted patents in this case.

But, in any event, administration of thiopurines to address certain diseases -- old in the art. Different methods for finding analytes in blood cells such as high-pressure liquid chromatography -- old in the art, no doubt.

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

And the idea that we are not novel because people took some of the same steps along the way to invention that we actually succeeded in is wrong. And, in fact, this Court said so in American Wood-Paper, where it said that incomplete and unsuccessful attempts to invent will not render not novel the successful inventor.

And, in Bell, the Court said the difference between those who -- those who did not get the patents and Bell was only the difference between failure and

success, and didn't say that because many of them had used similar methods but had not understood that continuous electrical lines as opposed to intermittent or pulsing electrical lines was going to be the difference for a working telephone.

Similar here. I don't think we ought to lose on novelty for that ground. But let's put that to the side, because that's for remand, and it's something that, you know, hopefully, I'll get a chance --

JUSTICE SCALIA: Suppose somebody thinks you're wrong, that the numbers you've come up with are wrong. And they want to develop better numbers that will -- will help the medical profession. Your patent excludes them from doing that, right?

MR. BRESS: No, Your Honor.

JUSTICE SCALIA: No?

MR. BRESS: And let's explain why not.

JUSTICE SCALIA: All right.

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

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

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

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

This -- these aren't 101 problems.

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

MR. BRESS: Thank you, Mr. Chief Justice; I

appreciate the question.

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

And, of course, if you're going to follow these rules, you might as well follow them under that section. Now, it doesn't completely leave 101 bereft. This Court has said 101's very broad, but it does have limitations. And if you look at a case like Morse --

CHIEF JUSTICE ROBERTS: Well, but just to --

MR. BRESS: -- I think it helps explain it.

CHIEF JUSTICE ROBERTS: Sorry to interrupt. Your friend's point is that if you don't do this -- if you don't give 101 some more content, then the doctor is going to have to start worrying right from the get-go and then see, well, is there an exception that I might be able to rely on, as opposed to being able to say right away this -- I don't have to worry about this patent; I can treat the patient in this way.

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

So, 101 -- I think the primary -- the two things it's for -- it has to be a process in the physical world, a hands-on process, and it can't be so broad that it pre-empts all follow-on innovation. Those are the two things -- you know, this Court speaks sums about the statutory language, and it has to do some work. That's the work that --

JUSTICE SOTOMAYOR: So, it's novel? What's your answer about why this is novel?

MR. BRESS: Right. Your Honor, before Prometheus -- actually, the inventors in this case in Montreal came up with this method, doctors had no way to tailor for each individual based on their metabolism the right dosage of these powerful but potentially toxic drugs.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Mr. Shapiro, you have 4 minutes remaining.

REBUTTAL ARGUMENT OF STEPHEN M. SHAPIRO

ON BEHALF OF THE PETITIONERS

MR. SHAPIRO: Justice Scalia asked the critical question here: What if you think these numbers are wrong? What happens with patients around the country? Well, that's just what we concluded: These numbers were wrong. They say you go up to 400, and above 400, it's bad, it's harmful. We found that the right range was 450 up to 700, and sometimes even above 700, to cure some of these very serious diseases. And that different opinion was blockaded by this treble damages lawsuit and request for an injunction.

So, the -- the wrong information is --

JUSTICE SCALIA: He says the solution to that is -- your saying their patent is not useful.

MR. SHAPIRO: That it's not useful --

JUSTICE SCALIA: That would be your defense.

MR. SHAPIRO: It's important that 101 be the robust test here. This is the only provision under which this Court has issued decision after decision for 150 years protecting the public domain. It's not some rough gauge; it is the critical test defining what's in the storehouse of information for medical researchers to use. And to reduce it to a dead letter here would be just contrary to this Court's precedents and very harmful to the medical community. This is very

important to -- to doctors around the country.

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

Now, this is a clean legal issue. Under section 101, it's always been a legal issue. They say section 102 and 103 are the most elusive questions in the field of patent law. This is a 7-year-old lawsuit against a hospital; it's cost millions of dollars to defend. Two trips to this Court, two trips to the Federal Circuit. We're still litigating this treble damages case. It should be terminated under this Court's precedents, as the district court did giving summary judgment.

JUSTICE SOTOMAYOR: I guess my problem is, if we call this just simply an application of natural phenomenon or of a natural process, why are treatment

patents at all --

MR. SHAPIRO: Well, because --

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

MR. SHAPIRO: Yes. Well, I think that's right. That's -- that is a second issue. But the first issue here is the breadth of the pre-emption, which precludes anyone else in the country from saying, as Justice Scalia did, those numbers are wrong. And patients can't use those numbers safely or they won't get cured of this disease. For 20 years, the public is stuck with the erroneous information.

Now, counsel suggests that it's narrow pre-emption because it doesn't cover host-versus-graft or leukemia. Those are not autoimmune diseases. Every autoimmune disease is swept in here. And there are dozens and dozens of them. They have different characteristics. You don't take a "one size fits all" approach to autoimmune disease. There are different numbers for different diseases.

That's what Mayo is trying to do, to have some personalized medicine for skin disorders. And they said that -- that is an infringement and we're entitled to treble damages and an injunction.

Now, is this like the Morse case? Yes, it is like the Morse case. Prometheus is trying to pre-empt diseases it never researched, and it's trying to pre-empt numbers that differ from its numbers fundamentally.

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

So, we urge the Court to protect the research process here that's so fundamental to American health and to economy and the health care industry.

We thank the Court.

CHIEF JUSTICE ROBERTS: Thank you, counsel, counsel.

The case is submitted.

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

A

able 6:7 11:24 25:11 55:9 56:23,23
above-entitled 1:12 61:20
absolutely 19:12 39:17
abstract 42:14 43:1 46:7,7
abstraction 43:14
accepted 6:18 37:14
access 16:2
accurate 3:17 22:24
accused 22:5
achieve 27:5,10 57:5
acid 47:1
acids 46:14,25
Act 3:14 26:4
action 22:1
activity 46:3
acts 27:4,8
actual 3:24 43:8
add 14:5,19 17:16,22 18:2 18:8,10 20:9 28:18 44:19
added 14:1,11 22:16 41:23
adding 14:16 15:8 46:7
Addison's 20:2
additional 16:13 48:25
address 52:16 53:4
addresses 6:9 55:7
adequacy 26:10
adjust 22:14
administer 12:14,17 34:3 38:8 44:3 52:22
administered 47:5
administering 26:2 48:9 53:11
administration 26:22 33:21 47:6 53:3
admission 7:3
admits 25:4
admittedly 45:23
adopted 9:1
advantage 29:24 40:22
adversary 19:15
adverse 33:14
advocating 29:9
age 44:3
ago 41:16 44:18
agree 38:14 47:18 48:3
agreed 5:25 36:16
agrees 47:17
Ah 14:3
air 33:14,17 42:20
AL 1:4
algorithm 49:9 52:4
Alito 32:15 33:6 38:11,23 46:17
allow 51:19,21 51:24
allowed 32:5
allows 29:14
amazing 13:6
American 53:19 61:13
Americans 23:2
amicus 1:20 2:8 25:2,21
amount 40:5 48:13
analogy 6:24
analysis 16:21 29:25 46:1,6
analytes 53:5
Andreas 51:23
answer 7:11 10:1,8 16:23 19:21 20:18 21:22 23:14 26:10,12 31:9 36:1 40:13 42:2 52:16 55:14,14,20 56:2 57:16
answered 10:11
answering 35:25
answers 30:8
anticipating 26:11
anticipation 15:17
anybody 5:5 48:1
anyway 39:9
appeals 37:7,14 37:16,17,23,24
APPEARAN... 1:15
appendix 19:24
application 12:9 12:18 14:11 21:21 30:8 35:15 59:24
applied 3:13
apply 8:16,24 13:14 16:5 42:17 44:8 56:5
applying 12:12 12:13 29:9
appreciate 56:1
approach 55:19 60:20
appropriate 15:17
approved 46:15
arbitrary 45:13
area 21:25 34:16 34:22
argued 6:14 36:10 37:7
argument 1:13 2:2,5,9,12 3:3 3:7 25:19 28:4 33:7 35:20 57:25
arguments 10:17,17 16:11 28:5
Arrhenius 44:24
art 14:16,17,17 15:8,8,8,18 25:6 26:11 28:23 41:8 52:21 53:5,7
arthritis 20:2 21:1
asked 10:23 26:6 31:3 58:2
asking 20:15 24:9 34:18
aspirin 13:4,5,6 13:8
asserted 53:1
associate 54:24 55:1
associated 36:12
associates 55:2
assume 41:12 55:5
atmosphere 33:13
attached 24:12
attaches 23:6 25:5
attempts 53:20
aught 43:17
autoimmune 4:4 4:16,19 8:6 20:4,23 21:3 60:16,17,20 61:11
aware 6:1,3,5
awfully 37:2
a.m 1:14 3:2 61:19

B

B 1:18 2:6 25:19
back 16:5 37:20 40:14 55:21
bad 58:7 60:4
balance 7:4 25:16
base 55:5
based 26:6 53:14 57:20
basis 55:15
bat 42:18
beginning 30:1
behalf 2:4,7,11 2:14 3:8 25:20 35:21 58:1
believe 4:15 8:25 42:2
believes 4:3 22:24 54:22
Bell 53:23,25
beneficial 55:22
benefit 30:10
benefits 48:10
Benson 45:17
bereft 56:13
best 40:18 41:16 47:6
better 3:17 21:23 54:12
bigger 8:7
Bilski 7:21 9:1 14:14 15:4 16:12,21,22 20:20 26:18 45:21,22
binary 45:18,19
biomarkers 51:18,19
bit 28:18 36:18
blockaded 58:10
blood 6:2,5 13:2 17:2 22:3 32:4 48:22 53:5
boat 49:22,24

bodies 46:14,25
body 26:22 29:14 32:18 33:19,20
body's 25:11
bonds 46:23
bothering 39:9
bottom 37:4
breadth 21:25 60:8
break 46:22
breakthrough 32:4,10
Bress 1:21 2:10 35:19,20,22 38:13 39:1,10 40:9,13 41:5 41:10,15,25 42:5,9,11 44:6 44:11,14 47:11 47:18 48:3,7 50:4,10,13 51:3,11 52:15 52:18 54:15,17 54:19 55:25 56:17 57:1,17
Breyer 11:7 12:1,8,11,22 13:3,12,17,20 13:23 14:3,7 17:4,7,12,15 17:24 18:1,12 18:17,21 20:14 21:13,20 27:24 28:1,8,15,18 29:3 34:5,9,11 34:14 35:2,6,9 39:7,11 40:10 41:1,9,12,22 42:1,6 50:1,5 50:11,18 51:7 52:13,17
Breyer's 19:22 21:10
brief 6:12 21:16 26:7 27:2
briefs 19:16 25:2
broad 3:15 4:6 4:13 7:23 8:2 20:20,21 38:1 45:20 47:3 56:14 57:11
brother's 54:20
building 38:24 44:11
burn 39:16

C

C 2:1 3:1
calculated 40:5
calibrate 11:16
calibrating 53:13
calibration 12:25
call 34:1 59:24
cancer 51:20
capture 31:24
Caraco 32:24
cardiologists 29:12
care 61:14
carries 48:10
case 3:4 6:20 12:12 17:9 18:20,23 21:15 22:18,21 24:20 25:24 29:7,17 30:25 31:4 32:24 42:7 43:4,17 44:6 45:15 46:19 47:2 50:7 52:19,20 53:2 56:15 57:18 59:20 61:1,2 61:18,19
cases 14:8 17:20 46:11
catch 31:12,17 55:23
caused 32:18
ceiling 54:22
cell 48:23
cells 53:6
century 28:11 49:12
certain 9:13 39:14 44:2,3,3 47:13,13 53:4
certainly 22:12 38:5 48:11 50:13 55:9
cetera 42:14,22 43:20 48:23 49:20 53:1
Chakrabarty 38:16
chance 54:9
change 26:24 32:18
changed 4:9
changes 26:22
characteristics 60:19
chemical 9:23
chemicals 39:17 46:23
chemistry 26:23 33:19
chemotherapy 25:12
Chicago 1:16
chicken 50:21
chickens 50:20
Chief 3:3,9 25:17,22 27:1 27:14,18,21 28:13 29:22,23 30:6,11 32:16 35:11,18,22 55:18,25 56:16 56:18 57:23 61:16
choices 7:8
cholesterol 59:6 59:8,10
chromatograp... 53:6
chronic 3:22
Circuit 59:19
circumstances 29:10 33:4
claim 12:12 36:14 39:4 43:11
claimed 43:23
claiming 10:3 19:14,18 36:11 36:13,15 38:7 42:19 47:25 55:13
claims 43:5,7,7 48:8
class 47:9
classic 27:3 43:3
clean 59:13
clear 18:4 24:11 56:5 57:2
clearly 40:19 47:16 48:9
Clinic 3:16 9:5 22:23 23:3
close 37:2
closing 19:1
coded 45:18
Collaborative 1:3 3:4
color 13:8,9
combination 34:7
come 22:23 24:16 43:18,25 53:10 54:11 55:9 59:4,4,5
comes 40:1,3 50:8
comfortable 8:1
comforted 46:19
coming 13:24
common 15:7 16:1 39:14
community 15:20 58:25
compare 37:12
compared 37:17
comparison 37:9
competing 6:7 9:2,24
complaint 51:2
completely 22:7 22:17,21 55:11 56:13
complex 31:8
complexity 30:19
complicated 7:5
component 16:4 16:5
composition 34:8,10,20,22
composition-o... 34:25
concept 45:22
conceptualizing 45:10
concluded 58:5
concrete 18:11 19:2 61:9
condition 48:24
conditions 11:24
confined 18:24
conflict 17:20
confused 36:17
Congress 11:4
constant 6:23
constantly 7:2
content 56:20
continued 23:24
continuous 44:23 54:3
continuum 47:2
contrary 58:24
conventional 14:15 15:5 16:13,16,17 17:8 26:1 45:25
conversion 33:19
converting 45:18
core 51:25

correct 4:15 10:2,21 11:21 25:25 36:7,20 57:3
correlated 36:11 36:14
correlation 21:10,18 22:7 24:16
correlations 33:7
correspond 48:17
cost 59:17
counsel 25:17 57:23 60:14 61:16,17
country 7:19 49:7 58:5 59:1 60:9
counts 39:12,13 48:23
couple 24:25 25:6 48:12
course 7:22 32:6 43:4,19 46:16 49:17 50:15 56:11 59:3
court 1:1,13 3:10,11 4:22 5:25 6:14,17 7:21 11:4 15:4 15:4,6 20:19 25:15,23 28:4 32:23 35:23 36:8,9,16,19 36:23 37:7,14 37:16,16,20,21 37:22,23 38:5 38:15 42:12 43:18 44:21 45:9,16,19,23 46:2,8,15,19 51:13 53:19,23 55:10 56:7,14 57:12 58:19 59:18,21 61:12 61:15
court's 3:12,13 4:11 14:7 16:20 37:8 39:6 43:17 58:24 59:21
cover 35:25 60:15
covered 3:24 7:25
covers 19:25,25 20:3,3,4,11,22
crack 51:24,25
create 38:22
criteria 18:4
critical 29:25 58:3,21
Crohn's 48:20
cross-breeding 38:21
crystal-clear 6:12
cure 4:16 44:20 58:9
cured 19:2 44:25 60:12
curiae 1:20 2:8 25:21
cut 28:8,15 56:6
cutting 30:1
cyclotron 40:1,2

D

D 3:1
damages 22:5 58:11 59:20 60:25
dangerous 61:8
dangerously 11:20
data 49:10,10
days 51:12
DBA 1:3
dead 58:23
deal 18:22 33:3
December 1:10
decide 17:19 48:15
decided 36:9
decimals 45:18
decision 3:12 14:18 16:22 25:7,9 30:9 37:4 58:19,19
decisions 23:7 24:11
decrease 48:17
deep 49:19
defend 59:18
defense 58:16
deficiency 21:9
defining 58:21
Department 1:19
depending 49:19,19,20 52:8
depends 8:2
describe 6:10
described 43:9
description 48:4
destabilizing 26:18 33:24
determine 12:14 12:17 26:23 38:8 47:5 48:13 51:24
determined 45:25
determining 39:18 48:13 53:12
develop 3:25 54:12
developing 51:15
diabetes 20:2
Diehr 6:20 14:8 18:15,16,20,23 44:21
differ 61:4
difference 9:21 10:3 24:10,11 30:7 33:18 36:5 38:17 47:21 53:23,25 54:5
different 4:4 5:15,23 7:4,8 7:17,18 9:6,20 10:8 11:17,19 13:9 19:7,11 20:7 22:7,18 22:21,22,24 23:10 24:3,5 24:16,17,17,19 25:2,13,13 29:2,9 33:2 34:22 36:24 42:13 43:5,6 53:5 58:10 60:18,20,21
difficult 31:8 33:10
dig 49:16
digging 49:18,18
direction 28:20 28:24
disagree 19:19
disagreed 11:4
discipline 16:8
discover 13:4,5 33:2 50:25
discovered 13:10 33:7 39:12
discovering 17:9
discovers 33:12
discovery 32:17 32:20
discussed 40:17 43:6,7 45:23
disease 3:22 20:1,1,2,5 34:4 48:20 52:25 60:12,17,20 61:11
diseases 4:5,16 4:19 5:8 7:24 8:6 19:8,11 20:10,11,23 21:3 23:1 52:22,23 53:4 58:9 60:16,21 61:3
disorders 11:20 60:23
disputed 37:15
dissent 21:15,22
distance 43:12
district 3:12 4:10,22 6:14 6:17 36:7,8,16 37:8,20 59:21
doctor 5:13,21 5:22 6:4 22:1,2 22:4 36:11,14 37:10 48:14 56:20
doctors 8:17 11:14,16 25:10 31:14 48:18 57:19 59:1,9 60:5
doctrine 11:3 12:3
doing 31:7 35:14 47:8 53:11 54:14
dollars 59:17
domain 15:7 16:1 58:20
DONALD 1:18 2:6 25:19
doors 18:25
dosage 5:13 22:14 34:3 57:21
dose 53:14
doubt 44:25 53:7
dozens 4:5,5,19 4:20 20:5,5,22 20:22 60:18,18
Dr 54:22
draw 41:19 45:10
drawing 6:2

drawn 31:23 45:9
draws 6:5 22:3
drug 7:2 9:9,9 9:19,22 11:10 11:13 12:14,17 26:22 31:16 32:10,11,11,11 32:18 34:4,5 36:15 44:4 47:5 61:8
drugs 3:20 7:4 9:24,24,25 26:2 33:9,21 38:8 47:9 51:20 57:22
dye 29:14
D.C 1:9,19,21

E

E 2:1 3:1,1 15:22 39:24 40:6 42:3
earthquake 51:23
easier 30:12,23
easy 18:17
eat 50:20 59:6,8
economy 61:14
edges 45:11 55:13
effect 32:8 33:14 33:17
effective 31:16 34:3
effects 26:3
eight 24:5 43:6
eighth 41:3,12
Einstein 39:23
either 37:19 42:12 46:4,23 59:9
electrical 54:3,4
electricity 43:12 49:13
elevated 29:13
eligibility 26:19
eligible 27:19
eliminate 55:23
elusive 45:12 59:15
el-Azhary 54:22
embedded 41:21
energy 39:25 40:6
entire 24:2 33:3
Entirely 59:12
entitled 60:24
equals 14:17 15:22 39:24 40:6 42:3
equation 44:24
erroneous 60:13
ESQ 1:16,18,21 2:3,6,10,13
essentially 40:18 55:22 56:7
estate 28:2
et 1:4 42:14,22 43:20 48:23 49:20 52:25
event 53:3
Everybody 47:17
exactly 16:22 26:14 31:22
examiner 30:7
example 15:14 29:11 32:22 38:19 39:23 42:21 43:3 48:19 49:12 50:13 52:19,24 54:20 57:2
examples 39:7
exception 56:22
exclude 52:24 52:25
excludes 54:14
excluding 32:8
Excuse 14:21
exist 38:17,18 47:24,24
existed 11:3 52:20
existence 33:16
exists 12:3 31:23
expense 39:12 39:24
expensive 17:10
explain 36:4 40:15 44:15 48:4 54:17 56:17
explained 15:6 21:10
explanation 21:17 54:20
exploration 19:14
expressed 43:14
extends 13:1
extent 24:10 26:24
extra 46:3 51:14
e-mail 43:20

F

facially 57:3
fact 9:18 31:18 33:2 34:2 38:2 38:7 41:21 43:16 45:7 46:12,20 52:7 53:19 55:11
facts 29:8 47:24
failure 53:25
faithfully 3:13
fall 41:10 55:21
fancy 18:14
far 28:24
fast 40:21
fat 46:13,24,25
fatal 3:21
fatty 46:14
fault 51:23
favor 25:8,9
fax 43:20 44:5
Federal 59:19
fell 37:2
fertilizer 39:13 39:14,18,19,20 40:18 41:17
field 4:6 7:22,23 8:6,7 9:2 20:21 24:2,6 39:20 59:16
figure 31:6
figured 31:15
figuring 31:4
file 47:15
finances 49:19
find 21:22,23 32:19 50:15,19 51:5,6,8,9 53:12
finding 4:11 53:5
finds 60:4
Fine 50:5
finger 13:7,15 14:2 15:15
Finish 35:11
Firestone 44:17 45:2,6
first 3:4 16:11 23:14 40:17 41:15 44:7 47:15 48:7 60:7
fit 11:17
fits 60:19
Flook 8:7 9:1 14:8,15,18 15:6 16:11,21 20:20
focus 46:1
fog 49:22
follow 56:11,12
following 56:9
follow-on 32:24 43:3 57:11
food 50:21
forget 18:5 39:15
formula 9:23 40:6 45:18
formulas 11:6
forward 51:13
found 6:17 11:19 12:18 33:10 38:7 46:8 49:15 50:23 58:7
frankly 21:14 37:20
free 3:25 45:5
freedom 8:18
French 59:6
friend 30:2 31:3 36:7
friend's 56:19
front 26:7
frozen 9:4
fun 53:11
fundamental 61:13
fundamentally 61:5
further 30:14 45:8
future 43:19,24

G

G 3:1
gauge 58:21
general 1:18 25:18,22 26:12 27:12,16,20,25 28:7,14,17 29:1,5 30:5,15 30:19,25 31:10 31:21 32:21 33:16 34:9,12 34:24 35:4,7 35:13,18 45:21 45:22 46:22 47:3
generality 43:23
generally 46:20
generate 50:2
getting 17:4 34:21 55:4
get-go 56:21
Ginsburg 15:10

26:5,13
give 18:5 56:20
given 12:25 48:24
gives 48:14 59:7
giving 10:7 59:21
glycerin 46:15 46:25
go 16:5 23:21 37:19,20 48:21 49:24,25 56:4 58:6
goal 57:5
goes 20:22 28:24 28:25
going 17:16 18:12,13 26:18 29:23 30:10 31:12,17 34:1 36:1 39:16 40:23,24 42:7 43:2,24 45:12 46:22 49:8 50:23 51:6,8,9 51:20 54:4,24 56:11,21 57:5
good 13:17,21 31:1 50:11 52:3
gotten 45:2
Government 15:12,16 25:4 57:3
granted 28:11
grate 27:7
Graves 20:1
great 27:6 28:4 29:24
greater 20:18 36:12 37:6,12
greatly 43:2
ground 49:14 54:7 55:12
grow 39:14
guess 23:4 24:8 31:13 47:15
59:23

H

half 39:16,22
half-hour 7:1
hand 38:21 46:14
hands-on 57:10
happen 5:21
happens 58:4
happy 52:15
hard 7:10 16:3 42:11
harder 32:22 57:4
harmful 58:7,25
Hashimoto's 20:1
headache 13:6
health 25:14 33:15 61:14,14
hear 3:3
hearing 42:8
heart 20:3 29:13 29:15
heat 27:7,11 44:18 46:13
hedging 45:22
held 36:23,24
help 53:15 54:13
helpful 22:25 51:12
helps 56:17
hepatitis 20:1
high 11:21 43:14 43:23 44:18 46:12,13,21 59:7
high-pressure 53:6
history 50:7
hmm 28:21
Hmmm 17:8
Honor 4:15,25 29:5 38:14 39:3,10 40:13 41:5,15 42:9 42:12,23 43:4 44:6,16 47:18 48:3,7,18 50:10 51:4 52:15 54:15 57:1,17
hopefully 40:14 54:9
hornbook 12:5,8
hospital 22:6 59:17
hospitals 25:13
host-versus-gr... 52:25 60:15
huge 3:19 41:4 61:10
human 9:10 32:20 33:9,13 33:14 59:7,9
hypothesize 59:10
hypothetical 23:22
hypotheticals 7:11 18:14

I

idea 23:12 27:6 43:1 44:1 46:7 46:7,21,24 47:3 53:16
ideas 42:14
identification 51:18
identified 32:9
identify 51:22
ill 53:15
Illinois 1:16
illustration 31:1
image 29:15
Imagine 39:16
imbue 56:7
implements 42:22
import 26:16 40:23
important 11:18 11:23 15:19,25 26:8 30:2 32:1 58:17 59:1
importing 26:15
improved 44:22
improvement 44:7,9
improvements 45:8
improves 29:16
improving 49:2
inch 39:15,16,21 39:22 41:3,13
incidental 17:1 29:17
including 32:12 47:1
incomplete 53:20
increase 49:4
indeterminate 45:11
India 44:18
indicates 38:3,9
individual 53:14 57:20
induce 39:3
induced 38:24
industry 61:14
inference 26:24 31:23
infinite 45:20
infinity 4:2,19 5:3 8:5 13:1 18:19 20:22
information 11:15,25 16:1 25:10 48:14 49:6,8 50:3,6 50:20,23,25 51:1,15 52:3 58:12,22 60:13
informed 22:2
infringe 37:11
infringement 6:2 22:4,5 32:13 36:8,24 44:13 60:24
infringing 4:12
ingenuity 33:10
inhibit 43:24
initial 36:8
injections 25:12
injunction 22:6 58:11 60:25
innovation 43:24 57:11
inputs 45:25
inquiries 30:16
inquiry 26:17
inside 38:24
instance 38:16 56:7
interested 29:4 42:8
intermittent 54:3
interrupt 56:18
intervention 38:18,19 59:7 59:9
invalid 25:5
invalidate 55:12 55:15
invalidating 35:15
invent 9:9,22,23 53:21
invented 32:7 39:24 43:16
invention 18:25 19:2 43:3,8 52:8 53:18
inventions 43:19 51:17
inventor 53:22
inventors 57:18
investment 17:13
involve 20:15
involved 32:3,4 33:8 44:18,23
involves 20:17
involving 6:20

issue 5:23 6:9 19:15 20:18 26:3 27:22 33:25 36:3 59:13,14 60:7 60:8
issued 58:19

J

joint 19:23
JR 1:18 2:6 25:19
judge-made 45:13
judgment 30:22 30:23 40:21,23 59:22
judgments 8:18
Justice 1:19 3:3 3:9,23 4:7,21 5:9,12,17,20 6:8,14,19,23 7:10,14 8:1,8 8:11,13,15,20 8:23 9:7,13,16 9:20 10:1,2,7 10:10,13,16,20 10:22,25 11:7 11:9,12 12:1,8 12:11,22 13:3 13:12,17,20,23 14:3,7,21,25 15:10,11 16:3 16:8,15,19 17:4,7,12,15 17:24 18:1,12 18:17,21 19:3 19:6,10,13,21 19:22 20:6,9 20:14,14,17,24 21:5,10,13,20 22:9,16,20 23:4,12,13,17 23:18,21 24:8 24:22 25:17,22 26:5,13,15 27:1,14,18,21 27:24 28:1,8 28:15,18 29:3 29:22,23 30:6 30:11,18,21 31:1,3,10,22 32:14,15,16,16 32:17 33:6 34:5,9,11,14 35:2,6,9,11,18 35:22 38:11,23 39:7,11 40:10 41:1,9,12,22 42:1,6 43:25 44:10,12 46:17 47:11,20 48:5 50:1,5,11,18 51:7 52:13,17 54:10,16,18 55:18,25 56:16 56:18 57:15,23 58:2,13,16 59:23 60:3,10 61:16
J.E.M 38:16

K

Kagan 20:6 22:9 22:16,20 23:4 23:12,18 24:8 31:10,22 47:11 47:20 48:5
keep 15:25 19:4 40:3
Kennedy 6:8,14 6:19,23 7:10 7:14 10:1,7,10 10:13 11:9,12 16:3,8 23:13 23:17,21 26:15 30:18,21 31:1 43:25 44:10,12
key 7:13,20 20:8
kidney 20:3
killing 55:11
kind 8:16 39:14 47:7 49:9,20
knew 52:21
know 4:24 7:11 12:23 13:6 15:12 18:18 19:3 26:7 28:3 28:5,25 34:7 41:6 42:18,21 42:23 43:18 44:25 50:12,22 51:7,8,19 54:9 54:24 57:12
knowledge 25:7
known 28:22 50:21

L

LabCorp 21:8 24:25
LabCorp's 21:22
label 40:23,25
Laboratories 1:4,7 3:5
lack 40:24 41:1 52:5,9,10 56:3 57:4
lacked 21:14,15 21:16
lamp 38:24 39:3
language 57:13
latest 16:22
Laughter 17:6 28:6 42:10 48:6
law 11:2 12:3,5 12:6,8,9,13,18 13:10,13 14:1 14:11,16 15:5 15:6,24 17:18 17:22 18:2,5 21:21 28:21 35:15 38:14 39:17 41:5,13 41:23 45:13 46:17,18 59:16
laws 17:9 28:25 42:13
lawsuit 58:11 59:16
lawyers 28:3
lead 30:10
leak 50:16
leave 3:21 56:13
leaves 7:16 22:23
left 24:18
legal 59:13,14
legion 4:4
letter 58:23
let's 6:25,25 38:3,6 47:2 51:9 54:7,17 55:5
leukemia 52:25 60:16
level 12:14,17 30:13 33:12 38:9 41:19 43:14,14,23 44:1,2 47:6 48:21 54:23 60:4
levels 32:5
life-threatening 5:7 11:24 23:1
light 27:7 28:22
limit 5:3 6:16 19:4,17 34:18 42:13 45:24
limitation 18:13 20:18 51:14
limitations 56:15
limited 18:24 19:14 34:16 45:23
limitless 19:19
limits 18:10
line 30:14 41:19 45:9 46:10
lines 45:11 54:3 54:4
lingering 3:22
liquid 53:6
literally 42:19
litigating 59:19
litigation 30:12
little 3:21 13:7,9 13:10,15 14:2 28:18 29:2 33:10 39:13,19 39:21 42:1
lived 39:23
liver 20:4 48:22 59:4
locate 49:13
location 51:22
long 30:4
look 7:24 11:16 13:7,15 14:7 17:7,18,18 18:3,7 21:21 23:11 24:14 25:11 26:16 27:22 28:1,2 28:20 36:10 37:3,11,21 45:14,21 46:11 52:3 56:15 59:10
looked 6:20 16:12 42:12,14 44:16,22 45:16
looking 32:23
lose 52:9,10,17 52:18 54:7
lot 28:25
lots 17:12 34:1,1
love 39:10
lower 4:11 49:1
lowers 5:2
lupus 20:1

M

M 1:16 2:3,13 3:7 57:25
machine 3:24,25 18:25 29:15 43:20 44:5
machinery 42:17
machines 28:10

42:22
main 50:16
making 28:4 32:2 44:23
malady 21:8
man 38:18,19
man's 14:2
matter 1:12 5:4 26:8 30:5 31:17 34:8,10 34:20,23 37:25 40:19 43:1 61:20
mattered 37:10
matters 36:6 54:21
Mayo 1:3,4 3:4 3:16,24 9:5 22:23 23:3 25:25 29:8 36:25 37:1,15 49:16 52:1 55:9 60:22
Mayo's 29:20
MC 15:22 39:24 40:6 42:3
mean 8:2,15 9:8 10:10 28:3 33:24 38:4 41:9
meaning 60:3
means 5:6 12:16 36:21
measure 5:18 32:5 39:20 40:2,2
measurement 10:4,6 23:23 44:24
measurements 7:1
measuring 39:25 51:18
medical 1:4 9:8 9:24 15:20 16:2 34:2 54:13 58:22,25
medicine 3:20 48:18 60:23
meets 18:3
mental 25:5 26:1 51:16 52:2
mentioned 40:8 40:11
mere 42:25
met 22:11
metabolism 53:15 57:20
metabolite 3:17 5:5 32:5 38:9 47:4
metabolites 33:20 48:13 59:4
method 39:18 39:25 49:22 53:13 57:19
methods 51:21 53:5 54:2
microns 41:19
million 7:11
millions 13:13 59:17 61:10,11
mind 50:8
mineral 44:19
minerals 49:14
minus 28:21 36:19,21,22
minutes 57:24
missing 24:20 40:3,5
modern 50:14 51:12
molding 6:21
Monday 32:24
monitor 7:2
monitored 19:1
monitoring 6:24
monopolize 46:21,24
monopolized 11:5
Montreal 57:19
morning 3:4
Morse 43:4,5,9 45:16 47:7 56:15 61:1,2
motion 40:23
move 30:14 42:16 51:12
moved 30:20
moves 30:15
moving 49:3
multiplying 31:7

N

N 2:1,1 3:1
narrow 14:20 16:24 46:5,9 60:14
narrowed 4:22
narrower 4:8
natural 4:6 8:19 9:8,10,13 16:25 17:2,3,9 18:10,23 21:9 21:11 24:7,15 24:19 33:8,15 33:18,19,23 38:11,15,20,22 38:25 46:16 59:2,3,12,24 59:25 60:5
nature 10:18,19 11:1,3,5,9,9,12 12:3,6,9,13,18 13:10,14 14:1 14:12,16 15:5 15:7,24 16:13 16:16 17:18,22 18:3 21:21 28:21,25 34:7 35:15 38:14,17 39:17 41:13,23 42:13 46:18
navigate 49:21
necessary 4:16
need 13:8,9 15:20 16:2 17:1 24:13 25:10 26:7 42:15
Neither 11:5
never 11:4 32:6 39:23 43:16,16 51:13 61:3
new 3:25 9:9,9 15:22 31:7,15 31:15,19,19,21 31:23 32:4,18 34:15,19 38:22 44:4,4 50:6 53:12,13
nonobvious 15:23 16:5
nonobviousness 26:17
nonpatentable 14:22,23 35:14
normal 48:21
notice 13:8
noticed 28:13
notified 6:1
noting 47:21,21
notion 49:6
notions 56:8,8
Novartis 21:15
novel 14:22 16:16,19 17:19 17:21 27:12 40:19,20 48:11 53:16,21 55:14 57:2,15,16
novelty 15:1,17 26:17 30:16 31:14 40:24 41:2,4,20 52:6 52:9 54:7 56:3 57:4
nuclear 29:11 51:25
number 4:2,3,11 4:15 5:2,22,22 6:3,15 11:21 11:21 21:1,1,2 22:13,14 23:5 36:12 37:18 45:20 47:13,14 61:6,7,7,9
numbers 3:18 7:17 8:5 9:3,6 11:19 20:8 22:8,24 24:3,5 24:17 36:10 41:2 54:11,12 58:3,6 60:10 60:11,21 61:4 61:4
numerical 12:25
numerically 20:21

O

O 2:1 3:1
objection 37:22 37:23
observation 14:2
observe 17:1 21:18,24
obvious 15:15 16:4 27:13 28:7,22 41:7 41:14 55:14
obviously 10:11
obviousness 15:18 26:11 30:16 41:11,20 52:10 56:4
odd 12:19
oddity 12:24
offer 5:5,9,12 6:7
offering 3:17
oh 9:12,15 17:11 17:14 23:16 55:23
okay 8:9 13:17 16:17 17:15 21:5 39:25 40:9,13 42:5 42:24 50:8,22 51:9 52:15

54:23
old 32:3,18 49:7 52:5 53:4,6
once 16:15
ones 15:17 28:3 28:3 50:14
opening 18:25
opinion 4:25 5:6 5:10 9:5 21:10 21:13 23:2,3 37:8,16 58:10
opinions 11:17 11:19 25:13
opposed 54:3 56:9,23
opposite 26:14
oral 1:12 2:2,5,9 3:7 25:19 35:20
order 34:4 37:10 48:15 53:12
ordinary 41:7
ore 49:14,20 51:5,8
organ 20:3
originally 33:1
ought 54:6
outbreak 48:20

P

P 1:21 2:10 3:1 35:20
page 2:2 27:2 37:16
pages 19:24
Pardon 5:11 11:11 23:23
part 10:15 11:15 15:7,7 16:23 31:11 32:19 40:4,5 41:14 55:7,21
particular 9:23 25:4 51:19,20 52:8,22
particularly 48:20
parts 29:4
party 25:24
pass 28:9,16
patent 3:14,15 3:24 4:17 7:23 8:24 9:8 10:4,5 10:18,19 11:1 13:13,18,21 15:22,23 18:4 19:13,25 20:25 21:1,1,2,9,17 21:25 22:10,15 25:4,25 26:4 27:11,16,18,19 28:5,11,23 30:7 31:12 32:3,7,25 33:1 34:3,25,25 35:3,5,7 36:9 36:25 37:1 39:2,2,11,18 40:7,17 43:10 44:2,7,9 45:2,3 45:5,6 46:12 46:16,20,21 47:3,7,16 49:6 49:15 50:7,14 50:15,19,24,24 51:4 52:5 54:13,25 55:1 55:10 56:25 58:14 59:16
patentability 9:17 15:14
patentable 7:7,9 14:18 23:15,20 26:8 29:19,20 32:11,20 33:5 34:6 41:24 42:4 46:9 47:17 56:9
patented 9:19 9:25 12:6,9 32:12 44:17 61:6
patenting 35:14
patents 24:5,22 25:3 32:24 34:2,10,13 35:16,25 49:13 49:21 51:14,21 51:23 52:2,24 53:1,24 55:15 60:1
patent-eligible 27:3 40:19
patient 3:22 29:12 48:19,23 51:20 53:14 54:23 56:25
patients 3:20 5:6 11:23 22:25 53:15 55:11 58:4 60:11 61:10,11
pause 30:3
pay 45:3 48:2
peek 16:4,23,24
peeked 16:12
people 25:14 26:7 30:3 47:21,21 52:21 53:9,17
percent 4:23 5:1 22:14 36:18,21 37:3,5
percentage 20:11
percents 37:10
performed 27:4 27:8
period 32:12
permissible 60:3
person 9:4 32:6 41:15 44:3
personalized 60:23
person's 13:7
perspective 26:13
Petitioner 44:12
Petitioners 1:5 1:17 2:4,14 3:8 58:1
pharmaceutical 32:25
phenomena 8:19 33:8
phenomenon 3:16 4:6 16:25 17:2,3 18:11 18:24 21:12 24:7,19 33:15 33:18,23 38:12 38:15,21,22,25 59:11,25
photosynthesis 38:20,23 39:4 39:5
physical 3:15 27:4,9 32:18 42:15 46:4 57:10
physiognomy 9:11
pick 20:11 31:2
picture 40:12
Pieces 11:5
pills 25:12
place 47:2 56:4
plant 39:16
plants 38:21 39:14 40:18
please 3:10 10:2 25:23 35:23
plus 14:17 15:5 36:19,21,22
point 7:6 16:11 19:17,18 20:8 25:25 27:21 29:18 36:19 37:24 41:9 55:4 56:19
pointed 47:23
points 21:15 32:2
pollutant 33:13 33:17
position 4:17,22 5:16 6:18 15:12 29:1
possibly 8:24
potential 20:10
potentially 57:21
pour 56:9
powerful 57:21
practical 3:19 5:4 6:6 24:14 30:5 43:1
practice 48:18
precedents 3:13 58:24 59:21
precisely 52:11
precluded 9:17
precludes 13:1 60:9
preconceived 56:8
predetermined 37:17
prepared 28:9 28:16
present 33:13
pressed 55:20
pressure 46:13 46:22
presumably 19:10 41:18
presume 38:5
pretty 18:4,17 28:7 31:1
prevents 3:16 51:14
pre-empt 4:6 7:22 8:5 24:6 43:15 61:3,4
pre-empted 6:10,20 20:21
pre-empting 6:6 43:1
pre-emption 3:15 5:16 14:20 16:25 24:18 31:5,6 60:8,15
pre-emptive 21:11

pre-empts 4:18 7:7 57:11
primary 57:8
primitive 49:22
principle 42:19 42:25
principles 29:8 57:6
prior 14:16,17 14:17 15:7,8,8 15:18 17:20 25:5 26:10,11 28:23 52:21
probably 33:17 37:24 39:2
problem 3:14,19 14:4,4 18:18 28:12 31:18 35:8 37:21 38:1,2,4 39:8 42:23 44:15 55:19 56:3,3,6 59:23 61:10
problems 17:17 29:10 40:15 55:17
procedures 7:18
proceed 57:4,6
process 7:14 17:10 26:2,20 26:21,25 27:3 27:5,10 28:2 28:10,22 29:12 29:17,18,19,20 31:22,23 34:12 35:2,4,6,7,16 38:20 39:5 41:24 44:16,22 46:4,16 48:11 48:12 50:1,2 57:9,10 59:2,3 59:25 61:13
processes 9:8 28:11
produce 49:7
produces 52:2
producing 49:6
product 19:1,4 37:1
products 32:25 33:9
profession 54:13
Prometheus 1:7 3:5,14 4:17 5:25 22:10 23:2 57:18 61:2
proposing 4:11
protect 25:9 61:12
protected 17:13
protecting 58:20
protection 47:25
protocol 7:3 22:17 23:10 47:22
protocols 25:3
provision 58:18
PTO 26:14 30:6 30:7,10
public 9:3 58:20 60:12
pulsing 54:4
pure 45:19
purposes 37:4 54:19
push 49:3
put 14:12 27:7 27:15 29:14 39:19 40:1 42:1,6 54:7
putting 29:24

Q

quarter 39:15 39:21 41:3,13
question 10:11 10:23 11:8 12:4,5 15:11 15:11,13,20 19:22 21:22 23:14 24:8,9 26:6,19 27:24 29:25 30:8 31:2 32:22 34:1,18 35:25 41:18,22 42:2 44:8 46:17 47:15 56:1 58:3 59:3
questioning 28:19
questions 31:8 41:21 59:15

R

R 3:1
radiation 25:12
Radioactive 29:14
raise 15:15
raised 15:11 59:3
raising 42:24
random 46:1,6
range 4:8,10 5:15,20 6:1,5 7:8 19:7,18 20:12 22:2 23:22,24 40:15 44:1 55:2 58:8
ranges 4:9 19:11 23:6,7 24:10 24:12,17 31:15 36:17 37:9 38:1 59:10
rate 29:13
raw 49:10
reach 22:13
reaction 11:10 11:13,16 25:11
reactor 51:25
read 6:11,11 12:13 31:10 37:8
reading 36:20 37:14,15
readings 47:4
reaffirmed 14:14
real 12:24 22:13 28:2
really 15:3 17:21 25:10 28:9 34:18 36:2 39:9
reason 14:23 43:13
reasons 12:3 18:5,6 36:24 49:18
REBUTTAL 2:12 57:25
recites 27:3,8
recognizes 41:6
recommend 5:13
reduce 58:23
referred 25:1 38:16
regimen 47:23
regulatory 33:3
reinstate 3:12
reject 18:13
rejection 26:10
relates 10:22
relevance 36:2,3 36:5
relevant 12:4
rely 9:8 16:21 56:23
remaining 57:24
remand 54:8
remission 49:3
render 14:22 46:4 53:21
renders 14:23
request 58:11
require 23:1
research 61:13
researched 61:3
researchers 16:2 58:22
reserve 25:16
resist 16:3
respect 32:25 45:6
Respondent 1:22 2:11 6:9 10:3 35:21
response 24:9
responses 47:19
rest 18:3,7,9
restaurant 59:6
result 6:6 9:3 10:4 23:22,23 27:6,10 37:11 44:4
retained 7:2
reverse 25:15
RICHARD 1:21 2:10 35:20
rid 40:20,21
right 6:2 7:5 10:13,20 12:1 12:10,11 13:3 27:21 29:3 35:9 36:10 37:8 38:4,6,6 43:21 45:5 48:7 50:5,24 53:13 54:14,18 54:22 56:4,21 56:24 57:17,21 58:8 60:7
risk 33:24 48:24
rival 23:9 24:3
ROBERTS 3:3 25:17 27:1,14 27:18 29:23 30:11 32:16 35:11,18 55:18 56:16,18 57:23 61:16
robust 15:20 58:18
room 5:4 7:16 9:24 22:23 24:15,18
rough 30:22 58:21
royalties 45:4,5
rubber 6:21 44:17,18,20,23 44:25

rule 8:16,24,25 30:22
rules 56:5,10,12
ruling 5:1
rulings 5:1
run 17:17
runs 17:20

S

S 2:1 3:1
safeguard 25:14
safely 60:11
salts 44:19
San 51:23
saying 16:16 19:4 31:11 34:20 38:2 39:5 40:22,24 44:12 48:2 58:14 60:9
says 6:16 10:17 15:16 35:8,13 37:17 40:4 54:24 55:1 58:13
scale 49:1
Scalia 8:1,8,11 8:13,15,20,23 9:7,13,16,20 10:2,16,20,22 10:25 14:21,25 15:11 16:15,19 20:24 21:5 31:3 32:14,16 32:17 54:10,16 54:18 58:2,13 58:16 60:10
scope 31:6 46:5 46:9
second 9:5 19:24 39:23 42:24 43:11,22 45:1 45:4 46:2 60:7
section 3:13 15:9,13,21 41:6 55:7 56:13 59:14,15
sections 15:16 26:3 56:4
see 4:14,25 6:13 7:14 11:17 12:2 13:6 17:3 17:8 24:20 27:2 29:10,24 30:4 34:19 51:1,9 56:22
seek 55:15
sees 54:23
sense 17:21
sensible 59:11
sentence 35:12
separate 46:13 46:24
series 27:3,8
serious 9:4 58:9
seriously 53:15
Services 1:3 3:5
set 29:9 31:7 33:3 47:24 61:9
Shapiro 1:16 2:3 2:13 3:6,7,9 4:1,14,24 5:10 5:14,19,24 6:13,22 7:9,13 7:16 8:4,10,12 8:14,17,22,25 9:12,15,18,21 10:5,9,12,14 10:19,21,24 11:2,11,14 12:7,10,21,24 13:11,16,19,21 13:25 14:6,13 14:24 15:3,10 15:19 16:7,10 16:18,20 17:11 17:14,23,25 18:9,15,20,23 19:5,9,12,20 19:23 20:6,7 20:13,16,19 21:4,7,19,24 22:9,12,19,22 23:8,16,19 24:1,13,24 26:5 32:2,8 57:24,25 58:2 58:15,17 60:2 60:6
sharp 48:20
short 56:6
shows 13:8
side 37:3,4 45:17,17 46:10 54:8
significant 46:3
similar 54:2,6
Similarly 29:21 32:10 55:12
simple 14:1 17:8 45:7 49:10
simply 34:21 38:7 45:18 59:24
size 51:22 60:19
skill 41:7
skin 11:20 19:7 60:23
Solicitor 1:18
solution 46:3 58:13
somebody 24:15 43:18 45:1 49:2 54:10
somewhat 45:12
sonar-based 49:22
sorry 3:23 28:17 29:21 37:1 56:18
sort 41:19 42:18
sorts 52:12
SOTOMAYOR 3:23 4:7,21 5:9 5:12,17,20 19:3,6,10,13 19:21 20:9,14 20:17 24:22 57:15 59:23 60:3
sought 22:5
spare 12:2 18:14
speak 19:15 52:21
speaks 57:12
special 28:12,12
specific 7:19 18:11,25 19:2 22:1,13 23:5,8 25:2,3 47:9
specifically 52:24
specifications 34:16,16
specificity 7:13 7:20 9:22
spectrum 45:15
spectrums 55:13
spent 13:12
split 20:25
squared 15:22 39:24 40:6 42:3
stage 36:9 38:4 42:24
standard 4:4 15:21 31:4 32:3
start 35:24 56:21
States 1:1,13,20 2:7 5:7 6:4 25:20 26:14
stating 4:13
statutory 51:14 57:13
steer 49:23
step 14:15,19 15:5 16:13,17 16:24 17:1,8 18:10 25:5 26:1 43:22 45:25 48:9,11 48:14 49:8,17 51:16 52:2
STEPHEN 1:16 2:3,13 3:7 57:25
steps 18:24 48:8 50:2 53:17
stop 60:5
storehouse 11:15 16:1 25:10 58:22
straightforward 29:7
strawberries 59:8
stress 29:11 49:5
strikes 31:11
strong 3:20
stuck 60:13
stuff 40:1,2
subject 4:10 26:8 27:5,9 40:19
submitted 5:25 61:18,20
succeeded 53:18
success 54:1
successful 53:21
suffering 22:25 61:11
sufficient 14:15 15:5
suggest 29:19
suggested 26:16 51:13
suggests 60:14
sulfur 44:19
sulfuric 47:1
summary 30:22 30:23 40:20,23 59:22
sums 57:12
suppose 6:25 13:3,4 23:6,23 33:12 38:4,6 54:10 55:12
supposed 8:15
suppress 43:2
Supreme 1:1,13 28:4
sure 13:16 17:14

23:4 30:18 31:13 51:3
swept 60:17
synthetic 33:9
syringe 59:5
system 6:25 32:20 33:3 43:10

T

T 2:1,1
tacking 26:1
tailor 57:20
take 5:16 6:9,24 7:1 13:4,5 18:2 22:2 27:6 29:11 42:2 45:15 54:19 60:19
taken 15:12 29:15 30:17
takes 13:5 49:10
talk 16:9 39:8 50:14 51:11 57:6
talking 15:1,1 21:3 30:21 47:8
techniques 46:1 46:6
telegraph 43:9,9
telephone 54:5
tell 10:25 13:23 34:17 48:23 49:23 50:23
telling 51:5
tells 51:4 60:5
temperature 19:1 44:19 46:22
temptation 16:4 26:16
term 38:15
terminated 59:20
terms 24:14 32:2 46:17
terribly 30:3
test 3:17 5:5,9 5:12,14 6:7 7:18 9:2 13:2 17:2 22:11 23:9 26:19,23 26:25 27:1 29:20 32:4,12 58:18,21 59:5
testing 26:2
tests 5:17,21 7:17 24:3 29:11 32:4 48:22
thank 3:9 25:17 35:17,18 51:10 55:25 57:23 61:15,16
theirs 6:5
therapeutic 5:15 5:20
therapeutically 34:3
thing 13:7 14:8 14:9 17:21 18:13 42:18 50:6
things 5:17 14:13 31:15 36:18 38:17,18 42:3,16 43:15 49:5 57:9,12
think 3:24 8:10 8:12,17,22 9:6 10:14 12:3,5 12:12 16:10 18:18 19:16 20:14,19 22:11 23:16,17,19 24:1,13 26:12 27:23 29:6,6 29:10,18,21 30:25 31:2,3 31:16 32:1,1 32:21,23 33:4 33:22 34:17 35:9,24 36:2,3 36:20 37:19,20 37:23 38:3 39:1,2 40:4 42:23 43:21 44:13,15 45:10 45:13 47:20 49:5 50:9 51:9 51:12 54:6,21 56:2,17 57:8 58:3 59:11 60:6
thinking 6:19 33:24 50:19,19
thinks 22:3 29:8 54:10
thiopurine 3:20 33:9
thiopurines 47:9 52:22 53:4
third 34:6
thought 10:1 21:17 22:6 39:7 41:3 43:16 48:5 61:7
thousands 34:2
three 7:4 48:8
threshold 26:19 30:13
throw 30:12
Tilghman 46:11 46:11,11
time 24:21 25:16 48:24 55:20
tissues 7:3
today 3:11 51:17
told 19:6 26:5 49:24
top 37:3
total 24:4
totally 55:5
toxic 57:21 61:8
toxicities 48:22
toxicity 36:12 38:3,10 48:25 54:25 55:1,3
transform 42:17
transformation 29:16
transformed 28:2
transforms 27:4 27:9
transplants 20:3 20:4 21:2
treadmill 29:13
treat 34:4 56:25
treatment 19:7 19:11 22:15,17 23:6,10 24:11 25:3 29:16 31:16 47:13,14 47:22,23 53:13 59:25
treatments 24:17
treble 22:5 58:10 59:19 60:25
tried 24:4 43:11 45:24
trips 59:18,18
trouble 23:18 31:3
true 17:9 31:2 31:13
try 39:8 42:11 42:13 48:1 53:12 55:12,15
trying 7:12 46:20,23 47:3 53:10 60:22 61:2,3
tube 59:5
turn 40:14
turns 49:11
two 4:8 5:1,17 7:4 12:16 16:11 36:24 39:7 40:7,10 42:12 43:5 47:19 57:8,12 59:18,18
type 24:23 51:25

U

underlying 39:4
understand 23:5 30:2 33:11
understanding 13:24 51:4
understood 37:24 54:2
unfortunately 18:21
United 1:1,13,20 2:7 5:6 6:4 25:20 26:14
unpatentable 33:23
unsuccessful 53:20
unusual 49:4
upper 5:3 6:16
urge 3:11 25:15 61:12
usable 44:20
use 4:2 17:1 24:3,5,7,15 29:12 32:11,12 33:1,2 34:2,15 34:19,24 39:3 40:18 41:17 43:12 44:24 45:19 46:12 47:1,4,13,14 48:1 49:13 52:19 58:23 60:11
useful 27:5,10 39:25 49:11 50:3,6,20,23 50:25 51:1,15 58:14,15
uses 9:5 12:15 23:6 45:20
utility 55:8,10 55:21
utterly 26:1

V

v 1:6 3:5

valid 25:24 40:7 40:11
validity 36:9
valuable 48:14 49:14
variety 38:22
various 4:16
vast 8:6 39:24
vastly 24:19 25:2
veins 49:13
Verrilli 1:18 2:6 25:18,19,22 26:12 27:12,16 27:20,25 28:7 28:14,17 29:1 29:5 30:5,15 30:19,25 31:21 32:21 33:16 34:9,12,24 35:4,7,13
versus 40:24 41:13
vibration 50:17
view 12:20 14:10 17:25 18:9 24:24 52:13,14
violate 54:25
violated 37:6
violation 55:3
virtue 21:14
vitamin 21:9
volume 19:24
vulcanization 45:3
vulcanizing 44:17

W

waived 37:24
want 12:22 16:8 18:7 23:3 30:3 54:12
warmer 17:4
warned 6:3
Washington 1:9 1:19,21
wasn't 37:15 38:22 46:3,20 46:23
water 33:14 46:12,21 50:16
way 4:18 5:2 6:10 9:14 10:13 11:17,20 24:4 25:4 27:22 28:4 32:5 36:10,20 37:2,8,19 40:20 41:16,17 42:14 43:2,21 44:20,20 45:20 45:21 48:1 49:7,24 52:23 53:13,17 56:25 57:19 59:9
ways 42:13 47:1
Wednesday 1:10
weren't 53:11
we'll 3:3 6:11 55:23 57:6
we're 3:11 14:3 14:25 15:1,3 30:21 31:4,12 34:20 38:2,4,5 38:6,6,7 47:3,8 47:8 55:5,5,13 57:2 59:19 60:24
we've 39:12 46:10 51:17,21 51:23
white 48:22
wild 59:8
willing 48:21,24
wipe 9:1 24:2
wonder 46:8
wonderful 43:17 43:19 52:19
wondering 55:22
wood 27:6,10
Wood-Paper 53:19
word 12:15 34:7
words 7:5 12:13 12:16 14:12 17:7 38:1 40:22 42:16 43:17 45:7 50:24
work 28:25 43:9 51:20 55:6 57:14,14
working 43:9 54:5
world 9:25 20:10 27:4,9 42:16 46:4 47:24,25 57:10
worry 31:11 56:24
worrying 56:21
wouldn't 21:7 33:20
wreck 42:7
write 43:12
written 22:10
wrong 4:3 11:21 15:13 31:12 34:17 38:5 40:11 53:18 54:11,12 55:5 55:11 58:4,6 58:12 60:10 61:9

X

x 1:2,8 49:24
X-ray 29:15

Y

years 6:7 9:4 11:3 41:16 44:18,21 45:1 45:4 58:20 60:12 61:9

1

10 45:1,4 51:19
10,000 41:16
10-1150 1:6 3:4
10:05 1:14 3:2
101 3:14 15:9,21 15:23 16:6,9 16:21 22:11 26:9,17,18 30:1,8,17,20 30:24 33:25 36:3,4 40:21 40:23 52:11 55:7,17,20,21 55:23 56:13,20 57:5,6,7,8 58:17 59:14
101's 56:14
102 15:21 26:3,9 27:22 29:25 30:8,16,19,24 31:13,17,25 33:25 36:5 40:15 55:21 57:4 59:15
103 15:21 26:4,9 27:22 29:25 30:8,17,20,24 33:25 36:5 40:15 41:6 55:21 59:15
11:06 61:19
112 30:9
13 19:24
14 19:24
15 4:22,23 5:1 18:14 36:18,21 37:3,5,10
150 11:3,22 58:20
19th 28:10 49:12

2

20 9:4 22:14 60:12 61:9
2011 1:10
230 36:14,22,22 37:13 49:2 54:21
235 37:2
25 2:7
271 32:13
290 54:24 55:2

3

3 2:4
3a 37:16
300 11:22 54:23 60:4
35 2:11

4

4 57:24
40 23:24
400 4:2,18 5:2 6:15,15 11:21 22:13 36:12,21 36:22 37:5,6 37:12,13 38:3 38:9 48:16,21 54:20 55:1 58:6,7
450 4:15 37:2,5 37:6 58:8

5

50 23:25
550 8:11
57 2:14
5700 61:7

7

7 1:10 6:7
7-year-old 59:16
700 4:15 8:8 58:8,9
7000 61:6

8

830 8:13,20,21

9

9 27:2