SUPREME COURT
OF THE UNITED STATES

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AMGEN INC., ET AL.,)

Petitioners,)

v.) No. 21-757

SANOFI, ET AL.,)

Respondents.)

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Washington, D.C.

Monday, March 27, 2023

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

APPEARANCES:

JEFFREY A. LAMKEN, ESQUIRE, Washington, D.C.; on behalf of the Petitioners.

PAUL D. CLEMENT, ESQUIRE, Alexandria, Virginia; on behalf of the Respondents.

COLLEEN R. SINZDAK, Assistant to the Solicitor General, Department of Justice, Washington, D.C.; for the United States, as amicus curiae, supporting the Respondents.

C O N T E N T S

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 21-757, Amgen versus Sanofi.

Mr. Lamken.

ORAL ARGUMENT OF JEFFREY A. LAMKEN

ON BEHALF OF THE PETITIONERS

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

Amgen invented a new class of antibodies that lower cholesterol that bind to a small spot on PCSK9, the sweet spot, and thereby block that protein from binding to and destroying LDL receptors that remove cholesterol. Amgen had in hand 384 examples before the Texas article Sanofi cites as hypothesizing such antibodies, before Sanofi began researching PCSK9.

This case concerns the reasonable -- the requirement that patents enable skilled artisans to make and use the invention. The roadmap in Amgen's patents -- patents allows skilled artisans to easily make those antibodies every time using two new anchor antibodies that

cover the entire sweet spot so skilled artisans can be certain to make all the claims' antibodies, including defendants' examples.

The Federal Circuit here never identified a single actual antibody that's in the claims that can't be made or requires undue experimentation. Instead, it invoked something that no one will defend is even relevant here: The cumulative effort to make all or some large group of an invention's potentially myriad variations.

This Court's cases, however, reflect the Act's pragmatic boots-on-the-ground focus on enabling skilled artisans who want to practice the invention on a concrete action, making and using the invention. Patents thus satisfy the law when sufficiently definite to guide artisans' successful application of the invention wherein there's some practical way of putting them into operation, requiring reasonableness with due regard to the patent's subject matter.

In concrete terms, that means that those who are seeking to overto the P -- overturn the PTO's issuance of a patents and

verdicts upholding them, here two verdicts, have to do two things: One, at least have evidence of some variant of the invention, some category, that require what this Court has called painstaking experimentation, and, two, if they identify that, show why that matters to skilled artisans, because the statute is about skilled artisans seeking to make and use the invention and reasonableness, not theoretical far corners never shown to affect the ability to do so.

I, of course, welcome the Court's questions.

JUSTICE THOMAS: Mr. Lamken, would you take a minute and tell us exactly what the invention is?

MR. LAMKEN: Yes. It's the class of antibodies that bind to a particular spot --

JUSTICE THOMAS: Well, let's -- let's deal with that. The -- you only have 26 that you have invented, right?

MR. LAMKEN: No, that's not correct. The patent states that there -- that Amgen had 384. There are only 26 that are specified by amino acid structure where you put out in the patent, as an example, here's the structure of

the -- the antibody.

JUSTICE THOMAS: So does this process only produce 386?

MR. LAMKEN: No, Your Honor. It -- the -- the testimony was that it will produce every antibody within the claims. And there's a reason for that. Our expert explained that, first, you get a -- if you do the super-immunization protocol, you get a robust response across the spectrum. And, in addition, if the mouse -- this is a humanized transgenic mouse. If it has the DNA in it to produce that antibody, it will produce that antibody.

And then, there was no evidence that there was some particular antibody that was harder to make that, for some reason, you would expect it more difficult to come out of that.

JUSTICE THOMAS: So, in other words, you can't say how many?

MR. LAMKEN: No, Your Honor, I think we can say how many, and I think there's two things. First, the evidence shows in this art that about 400 you would get from -- coming out of the mouse. That's the number that we came up with, the -- the number that Sanofi came up

with, and anybody else came up with. And that's all that's known to date.

And you wouldn't expect there to be a large number because it's a very tight, small sweet spot. It's got unusual hills and valleys. It's 15 amino acids out of 700. So you wouldn't expect there to be a lot to do there.

To get to a larger number, you would have to engage in a process which is called conservative substitution, which means you take one of the ones you know already works, and you take one amino acid out or two amino acids out, and you swap in a very similar amino acid, one that behaves very similarly, and if you cut --

JUSTICE THOMAS: But I think you're making the point, though -- excuse me for interrupting you. I just want to end the -- my consumption of the time. But -- but, in saying that, you don't know how many there are because that -- if you're going to -- the others are going to add, if that's a part of your process, whether it's conservative or random.

MR. LAMKEN: No, Your Honor, I think that when you do the conservative substitution, antibody scientists aren't going to consider

those near-identical twins to be distinct antibodies. They're 99.99 percent similar, and nobody is going to consider them distinct.

But even if you were to say, well, gee, there's a large number out there, the difficulty of making any next antibody is straightforward. The -- the record is clear and the -- and the patents points out that this is sort of a routine process. It's very easy to go and say, I'm going to swap out this amino acid for another. According to the table, it tells you which ones to do. And it's routine to test it. And so it only gets in the way of making any antibody you want. If you're saying, gee --

JUSTICE SOTOMAYOR: I'm sorry --

MR. LAMKEN: -- what's the cumulative effort to make them all --

JUSTICE SOTOMAYOR: -- if -- if -- if it's so easy, why haven't you made all the 400?

MR. LAMKEN: Pardon?

JUSTICE SOTOMAYOR: Why haven't you made the 400 if it's that easy?

MR. LAMKEN: So it's -- it's easy --

JUSTICE SOTOMAYOR: And what happened and why did it take you so long to do the

post-filing discovery of more?

MR. LAMKEN: So the reason we have -- we only specified the 26 and you -- we came up with 384 is a skilled artisan in this area isn't looking for every possible antibody. They're just looking for ones that bind to the right place and, therefore, block.

And so, once you get those, your job is done. You've got exactly --

JUSTICE SOTOMAYOR: Could you tell me how your patent is different from finding antibodies, the process? What's unique about your process?

MR. LAMKEN: Well, the patent isn't for process. It's for the class of antibodies themselves, right?

JUSTICE SOTOMAYOR: Oh, I know what you're -- but -- but it sounds to me like it's all about just process.

MR. LAMKEN: Well, Justice --

JUSTICE SOTOMAYOR: You're -- you're telling researchers find all these antibodies. And you tell me that process is common. Everybody knows how to find those. And then what's your next step for the process?

MR. LAMKEN: Well, Your Honor, when you're talking about the --

JUSTICE SOTOMAYOR: Or the method?

MR. LAMKEN: -- the -- yeah, process or method, which is --

JUSTICE SOTOMAYOR: Right.

MR. LAMKEN: -- the -- the enablement, how you get those, and it starts with something that didn't exist before, and that's these two anchor antibodies that cover the two parts of the sweet spot, and that allows you to find anything that's going to bind the sweet spot because they'll compete with that, and that's the first step.

After that, it sets forth a super-immunization protocol --

JUSTICE SOTOMAYOR: Except that you found and all of your disclosures only have three or four, five sweet spots, but you're claiming up to 26, and I don't think you've disclosed any -- any binding that's up to 26.

MR. LAMKEN: Right. I think, if you're referring to the 16 amino acid residue --

JUSTICE SOTOMAYOR: I'm sorry, I misspoke.

MR. LAMKEN: Yeah.

JUSTICE SOTOMAYOR: Sixteen, yes.

MR. LAMKEN: And -- and so that chart that I think that you're referring to has two key characteristics about it. The first is the evidence was that everything on that chart is enabled. The fact that our -- the ones that we identified as the 26 examples in ours doesn't mean that -- that it doesn't produce it. The experts explain exactly why you would get all of those. And there is simply no evidence of anybody immunizing mice and saying there's something here missing, this doesn't work, I'm not getting everything I want.

And so, on this record and in this art, it's understood that -- that -- that all of those are enabled, all those can be made. And so the chart doesn't work against us in that way.

And the nature of the chart itself actually explains why there's full enablement here. This is a chart of a bunch of -- a -- a -- a bunch of antibodies that work. They bind to the sweet spot and they block, and none of them is -- is identified to work better or

different than the other. So, to the skilled artisan, they're all the same, and --

JUSTICE GORSUCH: Mr. Lamken, just a -- a few questions I hope that are quick ones. Do -- do you agree that a -- a patent fails the enablement test if it would force a person skilled in the art to undertake undue experiment to produce the claimed invention?

MR. LAMKEN: I think that's a -- a -- a fair statement of the law --

JUSTICE GORSUCH: You -- you'd accept that?

MR. LAMKEN: -- undue experiment -- painstaking experimentation to produce the invention. And, by that, I would mean the various categories or classes within that invention that would be important to a skilled artisan, yes.

JUSTICE GORSUCH: I'll take that as a yes.

MR. LAMKEN: Fair.

JUSTICE GORSUCH: Okay. Do you accept the Wands factors? Do you think they're useful? Do you think this Court should endorse them?

MR. LAMKEN: So the Wands factors can

be useful, particular cases when properly applied. The problem with the Wands factors is they become something of a checklist that's abstracted and therefore replaces the ultimate statutory standard.

The statute's about looking at a skilled artisan, a person there, the guy in a lab coat in his lab or a mechanic in his office, and it's a -- about reasonably enabling them to make and use the invention. It's not about this checklist.

Now I'll give you one example why -- how it gets abstracted and doesn't work, and that's predictability. The Federal Circuit tends to say, gee, it's predictable or it's not predictable in the art just generally.

But that's not the question, we're talking about enablement. The question is, can the skilled artisan using the patent and the tools available reliably get to the invention?

JUSTICE GORSUCH: So sometimes is the answer for that one?

MR. LAMKEN: Yeah, I think the answer is they once probably were, but they kind of have outgrown their utility because they've

become abstracted and tend to replace what really should ask every time.

JUSTICE GORSUCH: That first test that we talked about a moment ago?

MR. LAMKEN: The Wands test.

JUSTICE GORSUCH: Okay.

MR. LAMKEN: Yeah, the Wands factors.

JUSTICE GORSUCH: Well, no, the Wands factors are useful to the extent they illuminate what we discussed is the standard but not when they don't.

MR. LAMKEN: I think that's right. And then you need to ask each one with respect to the standard itself, not in the abstract.

JUSTICE GORSUCH: Okay. And do you agree that the broader the patent, the more difficult it is to prove enablement?

MR. LAMKEN: Not necessarily, Your Honor. You could have a -- a relatively broad patent and you just need to have enablement commensurate with its scope. And if the -- if -- for example, if you have lots of categories within that patent, then you would have to enable what is important to the artisan within the category.

JUSTICE GORSUCH: But, as a general matter, would you agree that the broader the patent, the more you have to do to show what a skilled artisan would have to undertake to accomplish?

MR. LAMKEN: I -- I -- you know, it's -- it's hard for me to agree with that in the abstract because it always depends --

JUSTICE GORSUCH: Well, I understand --

MR. LAMKEN: -- on the nature of the --

JUSTICE GORSUCH: -- it would be hard for you to agree with it.

(Laughter.)

MR. LAMKEN: No, it's -- it's because it --

JUSTICE GORSUCH: But is it a fair statement of the law?

MR. LAMKEN: It -- it's -- it has to be commensurate at the start, but harder and broader aren't necessarily synonymous. You can have something that's harder because it's narrower because somebody leaves out a key thing to get that narrow part that's within the claim.

So I think, yes, as a general matter, it -- often, if you have a broader claim, it may be harder, but it's hard to say that in every art for every circumstance that makes it more difficult.

JUSTICE GORSUCH: Thank you.

MR. LAMKEN: It's always with reasonableness with due nature of the art.

CHIEF JUSTICE ROBERTS: What --

JUSTICE KAGAN: What --

CHIEF JUSTICE ROBERTS: -- you mentioned I think a couple of times there, and you do on your reply brief at page 7, you said the -- "where an invention has many embodiments, the patent enables the invention's full scope if skilled artisans can reasonably make and use variations."

Could you flesh out "reasonably" a little bit for me?

MR. LAMKEN: Yes. I think that it means that when you're looking at it, you're looking at what's important to the skilled artisan. If you can find just some oddity that can't be made, that doesn't invalidate the patent because we're looking at what's important

to skilled artisans.

So, for example, if a patent, for example, taught you to make metal airplanes, you wouldn't invalidate it because somebody said, gee, you know what, it would be really hard to make one out of lead. That's the type of thing you would automatically set aside.

So you always look at -- from the perspective of the skilled artisan, and you ask two questions: Is there something here that takes undue experimentation, what this call -- calls painstaking experimentation, to make? And if you can find something, that might be concrete enough.

CHIEF JUSTICE ROBERTS: Well, how long --

MR. LAMKEN: And then the next question is, does it matter? Does it somehow impede the skilled artisan from practice -- reasonably practicing that full scope of the invention?

CHIEF JUSTICE ROBERTS: Well, I don't -- how -- how long? And that may be the wrong measure, but, if you're judging reasonableness, how much experimentation do you have to put into

it? I mean, part of the allegation in -- in -- in your case is that this is simply trial and error. And so how long does it take?

MR. LAMKEN: Right. And I think the answer is it always depends. You're looking at the skilled artisan and you're saying what is a skilled artisan in this art willing to do. It might take a long time for a skilled mechanic, for example, to build an old Buick from the ground up, a year, but it's not unenabled because the instructions are there, he knows how to do it --

CHIEF JUSTICE ROBERTS: Well --

MR. LAMKEN: -- there's no wrong turn.

CHIEF JUSTICE ROBERTS: -- how long did it take Amgen to come up with one?

MR. LAMKEN: With the 384? It's -- from start to finish, injecting the mice and coming out, it's a matter of months to produce them. And it's -- I think it's important, and if the Court will indulge me to describe how you get from --

JUSTICE SOTOMAYOR: Producing them is one thing. Identifying them, do the whole process, don't take a piece.

MR. LAMKEN: I'm sorry?

JUSTICE SOTOMAYOR: Then continue with Justice --

MR. LAMKEN: Okay. Yes. I -- it's -- I think it's important to explain what's involved in getting from the 3,000 that Amgen, for example, got by immunizing two panels of 10 mice or the 1500 that Sanofi got from injecting a panel of mice down to the 384 that you're looking for, because that's in concrete terms what we're talking about.

And so what the -- what it is is not a trial and error like you're going through one after the other. You start with that 3,000 and you use our two anchor antibodies, and it simply costs $30 -- this is the record, according to Appeals Appendix 3909 -- to go through those 3,000 to knock it down to 384.

And why is that? It's because, in 2008, at the time, there's these high throughput machines with wells of 384, and the testimony is that the robotics do it very rapidly and very quickly, thousands of wells, hundreds of plates, in a very short period of time.

So, if someone's going to say it's

undue experimentation to take these 3,000 antibodies that the mice produce, these humanized mice produce, and put it in a machine and wait for it to -- at the cost of $30, that's undue experimentation, that is very odd. It's totally divorced from the nature of the art.

And, in fact, the Wands decision that we all have been citing back in 1988, back then, 35 years ago, described and said, look, the process of filtering -- the antibodies that you don't want, getting rid of that byproduct, is something that skilled artisans are prepared to do in the ordinary course. This is just what antibody scientists do. It's not due -- undue experimentation.

The patent examiner that looked at this understood that it was not undue experimentation, somebody who is himself skilled in the art. Two juries didn't think it was undue experimentation.

JUSTICE JACKSON: Can I ask you a clarifying question, though, because I guess I'm just trying to understand your argument relative to species versus genus.

So are you saying that if we find

undue experimentation with respect to a particular species, you know, that should not be enough to invalidate the patent?

In other words, doesn't that undue experimentation have to apply to every species?

MR. LAMKEN: No, I'm not -- we're not saying that it would have to apply to every species. If you find undue experimentation to make a particular species, the next question is, okay, does that matter to the skilled artisan, or is this just an outlier because the PTO, as they say, it has to be commensurate with the scope, it has to reasonably correlate. But, if you just have a one-off that doesn't mean anything to skilled artisans, you're not going to invalidate the patent.

JUSTICE JACKSON: How many of those one-offs can you have, though?

MR. LAMKEN: So, in -- in term -- in -- in sort of numerical terms, how -- how many one-offs can you have?

If you have so many that it means that you're searching for a needle in a haystack and you don't have instructions on how to do it so that it's -- it is that trial and error for

years on end, it's Edison and Consolidated Electric going through every type of, then you would not be enabled, and there's a case called Atlas Powder from the Federal Circuit that explains that.

JUSTICE JACKSON: But I thought -- I guess I thought you would have to have the undue experimentation standard apply to every species.

MR. LAMKEN: No, Your Honor, I think it would -- you -- you would do it for every category that matters. So, if there's meaningful categories -- and there's a case from the Federal Circuit called Auto Tech and -- that explains this. If there's meaningful categories, then you would have to enable across those categories, what FibroGen called across the scope of the claim. So --

JUSTICE JACKSON: So what are the categories here?

MR. LAMKEN: So, in -- in this case, there isn't evidence before the jury that it really matters whether you bind to two, three, or seven. In fact, Sanofi's own expert testified that it has no correlation, there's no correlation between the number of amino acids

that are bound and the blocking. And that's at Court of Appeals Appendix 3787.

So, in a case like this, where you don't have evidence that they are anything but fungible, then you may only have one category. But, an Auto Tech, for example, that was an -- it was an impact sensor patent, and there were two types. There was mechanical and there was electrical. And it only taught skilled artisans how to do the mechanical sensors, not -- not the electrical. And, for that reason, there was a -- a requisite part of the invention that wasn't taught, that skilled artisans couldn't do.

And so, when you have that, then you have an enablement problem. But the fact that somebody can go and pick out one tiny enablement -- one tiny embodiment and say, oh, gee, this one would be hard to do, that swaps in for the perspective of the skilled artisan, the person who matters here, someone who wants to practice the claim --

JUSTICE JACKSON: I guess I just -- I -- I --

MR. LAMKEN: -- the creativity of an art -- the creativity of --

JUSTICE JACKSON: Yes, I understand your point, I think, but, I mean, you -- you've -- you've claimed 26, you say there's 300 or something antibodies, and then there's evidence that, you know, millions more can be made.

So how is it that you've satisfied enablement by focusing in on a -- on the smaller group?

MR. LAMKEN: So, no, Your Honor, I think that when you're enabling, the question is, can the skilled artisan, using the instructions you have, make the various embodiments, make the various variants? And --

JUSTICE JACKSON: With -- without undue experimentation?

MR. LAMKEN: Without undue experimentation, and that's exactly right, for any one to -- who has to take undue experimentation. And if you find one that takes undue experimentation, the next question is, okay, does that matter? Does it really meaningfully impede somebody, the skilled artisan, the guy who cares, from doing it?

And it's just never been the law --

JUSTICE JACKSON: And that's in the

First -- the Federal Circuit's case law, or are you just saying that right now?

MR. LAMKEN: Well, actually, if you look at page 11a of the appendix, where the court quotes a decision called McRO, that's actually the standard the Federal Circuit ordinarily would use but departed from in this case because it was --

JUSTICE KAGAN: Mr. -- Mr. Lamken, putting aside what the Federal Circuit said in -- in -- in the opinion here and the different views of how that should be read, do you understand the parties now all to agree on the appropriate legal test, and are we simply arguing now about how that test applies in this case?

MR. LAMKEN: So I think the parties all agree that the cumulative effort, the idea of reach the full scope, that that cannot be sustained. Everybody agrees on that.

I think the next question --

JUSTICE KAGAN: And everybody agrees also, I take it from your answers to Justice Gorsuch's question, that there is a requirement that the full scope of the invention has to be

embodied?

MR. LAMKEN: Enabled.

JUSTICE KAGAN: Has to be enabled.

MR. LAMKEN: I think that's right. The content of that is a subject of some disagreement, and then the question, once this Court says --

JUSTICE KAGAN: Yeah, so I guess what I'm asking is, putting aside any application to this test, what do you think the parties don't agree on at this point with respect to principles of law?

MR. LAMKEN: Yeah. So I think the differences are as follows: The government would propose a requirement that you have a structure that unifies your genus, and I don't think that can be sustained under the law.

It makes sense that if you have an -- you enable people to make your invention by structure, they have to build it, that you would teach the skilled artisan the structure that he has to build. But, when you have an invention that's biological in nature, that's made by the mouse, the -- the super-immunized mouse they do here, you wouldn't describe it by structure; you

would describe the process --

JUSTICE GORSUCH: Put that aside --

MR. LAMKEN: -- of how to make that.

JUSTICE GORSUCH: -- put that aside. Any other disagreements on law? And, if not, why isn't this just a fact-bound dispute?

MR. LAMKEN: Yeah, so it's not a fact-bound dispute in the slightest because there is a disagreement also -- Sanofi's test is what they call the specific undisclosed embodiment test, where, if you hypothesize one, that you -- that's it. That destroys the patent. But that can't be right either. This Court's cases don't go through and hypothesize --

JUSTICE GORSUCH: Okay. So put that aside. Any -- any other disagreements on law?

MR. LAMKEN: Other than -- no, I don't think beyond that. But I think that the key question on which we all agree and what's actually critically important for this Court to do, there should be no mistake that the court of appeals' decision saying that you reach the full scope or, page 15a, where they do this evaluation and they say the evidence showed that

the scope of the claims encompasses millions of candidates, and it would be necessary to first generate and then screen each candidate antibody to determine whether it meets the double function limitations, that's a statement saying you got to be able to make them all. That can't be right.

And even having that -- even if there's uncertainty as to what the Federal Circuit meant by that, that uncertainty calls for the Court to bring clarity, because you should -- make no mistake: This is a very damaging decision. It -- the impact is tremendous.

You cannot -- the PTAB now has twice invoked the decision for the idea that you have to be able to make them all within a reasonable period of time. There has to be able to do a cumulative scope test.

And companies can't invest billions of dollars in new therapies when they confront the risk that their patents will be invalidated based on the cumulative effort that -- necessary to make them all. And it's just why you have, for example, 14 amicus briefs on our side and

14 amicus briefs on the other side.

JUSTICE GORSUCH: I've got a lot of amicus briefs.

MR. LAMKEN: Yes.

JUSTICE GORSUCH: I've got so many friends I can hardly stand it.

(Laughter.)

MR. LAMKEN: It's --it's -- with friends like that, you end up staying up late reading.

But the key is, on this, if there's uncertainty about what the Federal Circuit did or are doing, the answer is actually to bring clarity. The case is critically important to industry and at least that.

And, once you get there, the question is, well, what other guidance can the Court bring? What other guidance should the Court give? And, for us, the critical guidance the Court can give is that you're looking from this Court's cases the perspective of the skilled artisan who's seeking to make it. It's a reasonableness standard, which means that you're not looking -- you're not from the perspective of somebody trying to create, oh, here's my

hypothetical embodiment that won't work. It's from that perspective. And that means --

JUSTICE GORSUCH: Let's --

MR. LAMKEN: -- in concrete terms --

JUSTICE GORSUCH: -- let -- let's say -- let's say we think that the Federal Circuit's decision is properly read to embody the test we've -- we've discussed this morning and that the -- the fact -- dispute really is fact-bound. Do you want a remand for a redo under -- under the -- under -- if we were to clarify what we understand the Federal Circuit's test to be and that you agree on and that you -- Mr. Clement may -- may or may not agree on, we'll find out?

MR. LAMKEN: So --

JUSTICE GORSUCH: But -- but would you want a remand to try again?

MR. LAMKEN: -- so, at the very least, we should have a remand so that we try again under the proper standard without the -- reach the full scope standard or try to hypothesize how long it takes to make millions of antibodies and then test each of them.

JUSTICE BARRETT: But -- but why? If

-- if -- I mean, maybe I misunderstood Justice Gorsuch's question.

JUSTICE GORSUCH: I don't think you did.

JUSTICE BARRETT: But, if the Federal Circuit got it right, I don't understand why you're saying a remand is in order.

MR. LAMKEN: Well, I don't think -- I mean, the key is the Federal Circuit could not possibly have gotten it right because of what I just read to you from page 15, where it looks at the effort to make each and every antibody of the potential millions. And so, at that -- very least, it has taken to account a feature that everybody now before this Court says isn't even relevant. And we should go back for that.

But I think, if you look at from what we're asking and what we think the Court's further guidance should be, that at the very least, somebody who's trying to overturn a PTO-issued patent and two jury verdicts should at least say here's an actual antibody, an actual embodiment, that is difficult to make. It requires undue experimentation to get there.

And then, if they have that, they

should also say why it matters, why this is something that genuinely impedes skilled artisans from making and using the invention --

JUSTICE SOTOMAYOR: Can I quote --

MR. LAMKEN: -- because --

JUSTICE SOTOMAYOR: -- two sections from the Federal Circuit -- two statements it made, and you tell me whether they're right or wrong.

The Federal said -- Circuit said: It was "appropriate" to look at the amount of effort needed to obtain embodiments outside the scope of the disclosed examples.

Is that a correct statement of law by this -- Federal Circuit?

MR. LAMKEN: So in part.

JUSTICE SOTOMAYOR: It said -- no, that's what it said, to look at the amount, appropriate to look at the amount.

MR. LAMKEN: And, if you're talking about the amount to make all or some number, the answer is no, it's not.

If you're talking about making another embod -- another embodiment that's not specifically characterized --

JUSTICE SOTOMAYOR: It said --
MR. LAMKEN: -- by amino acids --
JUSTICE SOTOMAYOR: -- to look at the amount of effort needed to obtain embodiments outside the scope of the disclosed example.
MR. LAMKEN: So I think, if it said an embodiment, that would be correct. Embodiments means that you're looking at the -- the full scope or the -- the -- the -- what it called reaching the full scope, and I think that is incorrect. When you get --
JUSTICE SOTOMAYOR: All it said, it was appropriate to look at.
MR. LAMKEN: Right. I don't think anybody but this Court thinks that the effort to make them all is --
JUSTICE SOTOMAYOR: Why is it approp -- inappropriate to at least look at it --
MR. LAMKEN: To look at --
JUSTICE SOTOMAYOR: -- as one of the Wands factors?
MR. LAMKEN: Yeah. So the effort to make every single embodiment within the invention simply means that if you have an invention of any scope, it's not going to be

enabled. There may be millions of ways to make the James Watt steam engine, but you're not invalidated simply because it would take a long time to make all of those different variants of the steam engine.

This Court can do the best service for the Federal Circuit if it does one thing beyond simply saying this cumulative effort standard has no place in the law, and that would be to say, look --

JUSTICE SOTOMAYOR: That's fine, counsel.

MR. LAMKEN: I'm sorry?

JUSTICE SOTOMAYOR: That's fine. You answered my question.

MR. LAMKEN: Okay. Thank you.

JUSTICE SOTOMAYOR: There's nothing wrong with it. You just don't want them to do a fairly simple one.

MR. LAMKEN: No, I think it's -- it's not correct if you're looking at embodiments in the plural. If you're looking at an embodiment in the singular, that would be correct. And what they did wrong was they looked at how long it takes to make the supposed millions. If each

of those is in -- individually enabled, you can make each one individually and reliably, test it individually and reliably, that's an enabled invention.

How long it takes to make -- to make all of them cumulatively simply has no bearing, and this Court can do a service and bring back to -- the -- the incentives to create these life-saving -- these life-saving inventions by making it clear that that just doesn't have a place, and --

JUSTICE JACKSON: And you said we can do one thing beyond that, and what is that?

MR. LAMKEN: I think that by bringing it back to the focus of this Court's cases, which is we're looking at skilled artisans, someone concrete trying to make the invention, and we're looking at reasonableness and not the hypothetical efforts to try and figure out ways to break the invention.

And so, if you're going to look at that, you're going to have to show two things if you're going to invalidate a PTO patent. One is you're going to have to show some embodiment, there's got to be something out there, some

variant, something, some category that requires undue experimentation to make.

And if you have that, you also have to say why it matters to the skilled artisan, how does this really genuinely impede the guy in the lab coat from making and using your invention across its scope.

JUSTICE ALITO: Is there something unique about the Federal Circuit's decision in this case, or has it been applying essentially the same approach to the enablement of antibody genus claims since around nine -- 2004?

MR. LAMKEN: So, as the Lemley article points out, there's been sort of a trajectory as it's been getting clearer and clearer what their -- what the Federal Circuit's doing in its basic hostility to the breadth of claims, and I think it -- this is basically the apogee. We've reached an endpoint where, frankly, the industry can't take it any longer because you can't invest $2.6 billion if the breadth of your claims is such that it means you can't get adequate protection because, if you cover everything you invented, then it's invalid because it's too hard to make them all.

So, yes, I think it's been a -- a -- a trajectory as opposed to a point, but this is actually the ultimate point.

JUSTICE ALITO: Well, if it isn't -- if what they did here isn't fundamentally different from what they've been doing for quite a period of time, would you stand by the suggestion that the Federal Circuit has inhibited research for antibody-based pharmaceuticals?

MR. LAMKEN: I think the Federal Circuit has been doing that for some time, but it hasn't been quite so stark or quite so apparent until now. And I think that's why the Lemley article really was catching onto it.

But this brings in very stark contrast, stark relief, exactly what the Federal Circuit is doing and why it has gone so far that you just can't invest in antibody research if you can't adequately protect the scope of the antibodies you invented.

Amgen had the first antibodies here. Amgen -- before Amgen and before our patent, these were not known antibodies. And we're -- our patent teaches everybody how to make each

and every antibody they might ever want to make, including the defendants' -- the competitor -- the supposed competitor antibodies.

And if that's true, there's simply no good reason why you would take away the patent. You don't -- the -- the patent depends on what the skilled artisan can do, not to create a hypothetical of the infringer who says, gee, you know, I can imagine an -- a hypothetical antibody that can't be made.

In this Court's cases, like Minerals Separation, they don't hypothesize limits. Like Minerals Separation, the Court didn't hypothesize, you know what, there might be an ore out there for which this is going to be too hard, even though there are infinite varieties of compositions of ores and each presented its own particular difficulties.

The Court -- Justice Story in Carver didn't say, gee, you know what, I can imagine a type of cotton for this -- which this might not work. The Court in Mowry didn't say, you know what, there might be some train wheels for which this cooling process won't work.

That isn't what the Court does. You

look at concrete evidence, what are the skilled artisans doing, is there something here that can't be done, and if there is, you ask if it matters.

JUSTICE ALITO: Can you explain how your roadmap differs from the basic research plan that you and your competitors have been using since the mid-2000s when you were all attempting to discover or identify antibodies that bind to PCSK9 and block LDL receptors?

MR. LAMKEN: Yes. And I think the first and most critical thing about the roadmap is these two new antibodies that didn't exist before our invention, one that sits a little bit on the left of that -- of the PCSK9, one on the -- little bit on -- on the right of PCSK9.

And what those do is they allow you to find everything that will bind to the sweet spot in PCSK9 because they cover it completely. Because the way this is done is you do a competition assay. If one antibody is covering it and it blocks the other antibody from doing it, you know that they're binding to the same spot.

By providing these two, that is a

shortcut to finding these because you run your competition assays against these two. And that's why in the roadmap the very first step are these two antibodies that didn't previously exist but will lead you, they're your divining rod, your magnetometer or whatever you want to call it to all the antibodies within the claims.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Justice Thomas, anything further?

JUSTICE THOMAS: Mr. Lamken, several times you referred to invention of the antibodies, and I think I'm somewhat confused as to exactly what your invention is. You said it's not just the 26, but it -- it definitely is not millions. So what is it exactly? Because I do -- we talk about enablement and we talk about someone being able to replicate it, but we're not talking about what has been invented with any particular precision.

MR. LAMKEN: Right. And I think the claims are that -- which define the invention, the class of antibodies that bind to a particular spot, that, what's called the sweet spot, and therefore have what is a desired

effect, which is blocking this PCSK9 from interacting with the --

JUSTICE THOMAS: Yeah, I understand all that, but --

MR. LAMKEN: And I think I could clarify a little.

JUSTICE THOMAS: -- which ones? I mean --

MR. LAMKEN: Yeah, I should clarify.

JUSTICE THOMAS: Yeah.

MR. LAMKEN: When you say an invention, like the James Watt steam engine, you don't say which variant, which embodiment of the steam engine have you claimed. It's the steam engine, that principle, the invention which cover -- encompasses myriad types of inventions.

There might be -- and this Court's cases describe it -- there can be lots and lots of different variations on an invention, but what -- to determine what the invention is, you look at the claim, and the claim tells you what the scope of that invention is here.

And the fact that it's described in terms of the way -- binds to a particular location which has been decried as functional,

but that actually is an important way of doing things, the antibody science, because it leads to a shape -- a shape that fits into that unusual sweet spot.

It's also -- it -- also clear that you can do that because -- because 112(b) -- we're talking about 112(a) right now as that's enablement. But, when you talk about how the patents are claimed, that's a different section of the Patent Act. It's Section 112(b). And it says that the claims have to be -- particularly point out and distinctly claim the subject matter which the invention regards as the invention. That's just not at issue here.

The PTO regularly issues patents which have that sort of functional piece that says things that fit in this location or have this characteristic. And the very first --

JUSTICE THOMAS: I know you refer to the steam engine, but that's not -- it just seems as though -- I -- I grant you that, it -- but it seems as though you're actually trying to patent the use of steam pressure and -- which you could use for almost anything, and -- and that's -- and that makes it very difficult

because then you're looking at what can it be used for.

So, here, I'm -- I'm still not getting -- if you said we're just patenting the 26 that we have found or the 300 that we have found, I don't think we would be having this discussion, and what I'm trying to understand is what it is that you're patenting beyond the antibodies that are there, those 300 or those 26.

MR. LAMKEN: Right. And I think, if you're asking what is the category or the group of meaningfully distinct antibodies that fit in that claim, that are -- fit that claim, we're talking something in the range of 400.

But, if the question is different, if it's asking what -- what do you mean when you say the antibodies that bind to a particular sweet spot and therefore block, that category is what we invented. That didn't exist before. We teach the world how to --

JUSTICE THOMAS: So you invented the category, so you're not claiming just the antibodies but the whole category of those antibodies?

MR. LAMKEN: That -- that is the

nature of a -- a genus claim or any claim that has considerable scope. We don't claim just the variants of the steam engine. You categorize the steam engine, and that's entirely legitimate.

JUSTICE THOMAS: So let me ask you this question. How do you respond to the example in one of the amicus briefs about the -- the -- the complicated lock and that you simply figure out the combinations by trial and error?

MR. LAMKEN: Yeah. And I think the answer is, for -- for enablement here, which is the question, the roadmap gives you all of the antibodies that are going to fit to that spot. All the ones that are going to fit into those hills and valleys, the evidence is the roadmap gives them all because, if the mouse has the DNA to produce them and the robust immunization protocol is going to give you something across the full spectrum of the claims, that is within the claims.

And I should close -- I should point out that this enhances innovation. Look, the patent means that others aren't going to go in separately -- they're going to look for things

that are separately patentable. It pushes them away from sort of copycat antibodies that operate on identical principles and identical ways with identical results.

If you truly want different therapies, you protect this sort of patent, and it tells people, well, if you're going to do this sort of -- sort of thing, it has to be better and separately patentable as a result, or it pushes them to completely different nonantibody proced -- treatments.

Novartis, for example, has an siRNA solution that they -- they're working on. Novo Nordisk is looking at a small molecule, which means you might be able to take it as a pill. Or you have antibodies that work by a different principle. So Novartis has an H1 fab that binds outside the sweet spot but blocks anyway, or Merck has something called 1G089 which binds on another location still, but it mitigates the impact of PCSK9 not by blocking but by affecting how it affects when it's absorbed into the matter.

CHIEF JUSTICE ROBERTS: Thank you.

Justice Alito?

Justice Sotomayor?

Justice Gorsuch?

Justice Kavanaugh?

JUSTICE KAVANAUGH: Just a couple things to make sure I'm clear. You said to Justice Gorsuch, I think, that you accept the Federal Circuit precedent in Wands. Are our precedents also precedents that you accept, or are there any that you would say have steered us in the wrong direction as we approach this?

MR. LAMKEN: Your Honor, I -- I accept all this Court's precedents, and I think I should be clear about Wands. We think those factors can in individual cases be helpful on the facts, but it's been abstracted to replace what is actually the statutory text. And this Court's approach was just to concretely look at actual examples, the concrete -- look at the skilled artisan, concrete -- look at reasonable -- reasonable enablement, not to look at the abstract hypotheticals of, gee, is there some outer limit that I could find that doesn't -- just no impact on what the skilled artisans really need to do, which is make and use to practice the invention.

JUSTICE KAVANAUGH: In the interest of providing clarity, the Solicitor General's brief at pages 14 and 15 had three hypotheticals about cake, stew, and bread. I don't know if you're remembering all three of those hypotheticals, but do you agree with how they presented those, if you remember them?

MR. LAMKEN: So I -- I'm having a hard time remembering what they were exactly, but, certainly, if the skilled artisan knows what the ingredients -- what the ratios for the ingredients are for cake, you wouldn't invalidate the patent simply because it doesn't give the ratios. That's something the skilled artisan can provide.

And when you're using something -- and sometimes things like that, which are chemical interactions, aren't particularly good analogies when you're dealing with a biological invention, which is the way you make and use this, the way you generate these antibodies isn't by following a -- a cake and bread formula. It's by super-immunizing the mice, taking the results and filtering them down using this high through speed -- this high-throughput process that takes

those very quickly down to the ones you desire.

And if that gets you every embodiment within the claim or every embodiment that anybody cares about, it's enabled. And someone who has the clear and convincing burden before the jury, it's a critical point, and then, when the jury rules against them, they have the burden of proving that no reasonable juror could think they failed to meet their clear and convincing burden, that's a very high burden, and it means you're going to have to come with something concrete that can't be made or requires undue experimentation and explain why it matters.

JUSTICE KAVANAUGH: Thank you.

CHIEF JUSTICE ROBERTS: Justice Barrett?

JUSTICE BARRETT: Just one question. What if before the jury you have an expert who shows why? I mean, proving the negative would be pretty hard for Sanofi to do, right? So what if you have an expert who can tell the jury this is why the -- the function described would not be capable of producing them all?

MR. LAMKEN: Yes. So I think that is

one way to do it, and they could even also say it would take undue effort. But, in this case, it's interesting because you have no testimony saying why it would be in principle, on some reasoned basis, harder to make Praluent or the competitor antibodies than what Amgen produced. And, in fact, our expert, Dr. Rees, explained that he thought that even Praluent was among our original 384 because the mouse's DNA can make it and you have a super-immunization protocol, which means you get a robust result across the claims.

And so, against that evidence, when they have the burden of proof, they're going to have to explain pretty convincingly to the jury, clear and convincing evidence, why there's something out there that isn't easy enough to make that it doesn't constitute undue experimentation.

JUSTICE BARRETT: Thank you.

CHIEF JUSTICE ROBERTS: Justice Jackson?

JUSTICE JACKSON: So I understand your burden points, but is there evidence in this record that the experimentation required to

produce undisclosed species using your roadmap is routine as it --

MR. LAMKEN: Yes, Your Honor. It is -- the -- the -- the methods disclosed in the thing -- in the -- in the roadmap are routine as routine can be. This is what skilled artisans have been doing since 1988, and the Wands factors, we said this is routine. Filtering out what they call the hybridomas or what the antibodies that aren't wanted to get the antibodies you want is routine.

And I give you one example. So our expert explained that the -- that all these machines that are used for would be in any properly organized lab and would do it rapidly and very quickly, thousands of wells, hundreds of plates, in a very short period of time. That's as routine as routine can be. This is what antibody scientists do.

JUSTICE JACKSON: And can I just go back to Justice Thomas's point? So, given the routine nature of this, can you just help me to understand the numbers? So you did this and got 26, but you say there are 300.

MR. LAMKEN: So the patent itself

explains -- and this is on page 236 of the court of appeals appendix -- that when we did around two panels of 10 mice, we got 3,000, which were filtered down to 384. The 26 are something different. The 26 are the ones where we went through and figured out the exact amino acid sequence and then listed them in the patent.

And there's a reason why you don't go and do 384 amino acid sequences for every one of them in the patent. First is that patent laws never required you to list all of your embodiments in there. That's just never been a rule. And it's not a rule for good reason. The Patent Act requires you to make -- have your patent be concise. Our patent is already 380 pages long with just those 26 amino acids sequences.

JUSTICE JACKSON: All right. But isn't the -- is the question whether, starting with the 26, someone without undue experimentation could get to the 384 and then possibly to the 3,000? Is that the way to look at this?

MR. LAMKEN: No, Your Honor. I think the -- the 3,000 amount it initially produces,

only 384 are going to bind to the sweet spot, and so you don't want to go the reverse direction to the ones that don't bind to the sweet spot, so --

JUSTICE JACKSON: All right. But at least to the 384?

MR. LAMKEN: Right. So you would go from your 3,000 to your 384, and that's where you stop.

Now, if you want to make variants of those that may not be meaningfully distinct, you can do something called conservative substitution, and the patent explains that that is also a routine and well-known way of doing it. You take one of the amino acids --

JUSTICE JACKSON: Can I just ask you as a very simple --

MR. LAMKEN: Yeah.

JUSTICE JACKSON: So you say that you are claiming the class of antibodies that bind to a particular spot and therefore block. That's my sort of --

MR. LAMKEN: Mm-hmm.

JUSTICE JACKSON: -- shorthand for what you've said. So is that class comprised of

384 species or more?

MR. LAMKEN: I -- you know, it's somewhere in the 400 range. I couldn't tell you if there's -- that it -- that's exactly 384. I would say that that 384 probably covers the full range of meaningfully distinct antibodies. It was probably --

JUSTICE JACKSON: So, when we see millions, someone said millions, you -- you say that's not even a -- a reasonable estimation?

MR. LAMKEN: So it's important to -- for me that the millions comes from a different way of making additional antibodies. You start with one that works, one of those 26, for example, and you swap out an amino acid or two for one that's very similar according to a table that's in our patent.

JUSTICE JACKSON: So would you be claiming those or not?

MR. LAMKEN: Yes. So those -- those are fully enabled because it's very routine. The patent describes that it's routine to swap out one amino acid for another that's very similar. And the -- the evidence shows that those routinely work.

But, even if it were, you know, you could make millions that way and you could count hypothetically by swapping out every single one of these amino acids along this chain, you can count --

JUSTICE JACKSON: So just to be clear, you're -- beyond the 400, you claim all of the swaps?

MR. LAMKEN: Yeah. So those swaps are all enabled. They're all within the claims. There's two pieces to it, though. First, an antibody scientist isn't going to look at that near-identical twin and say that's a different antibody. That's -- they're 99.9 percent similar. That's going to be basically the same antibody.

But, even if you want to consider that a different antibody, it's enabled because everybody is able to do that routine process, a swapping out the amino acid, everybody. If you want to test it to confirm that it works, you -- probably not necessary because the evidence showed that they all reliably work, Sanofi didn't identify a single one that doesn't work, that somehow breaks its ability to bind. If you

want to do testing, that's routine.

So any one you want to make from those 26 by doing an amino acid swap, you can make it. And that is the -- that is clearly enablement. That's what you're looking for, the ability to make the next one and always succeed in making it and it's routine across the board.

JUSTICE JACKSON: And you think that gives -- gives others enough notice as to what you've claimed? I mean, to the extent that you could swap out any of the antibodies and suddenly we're in the millions, I guess I had understood the patent also was -- to some extent, your specifications were about notice to other people and other inventors.

MR. LAMKEN: So, the -- the -- certainly, it's very easy to determine whether or not you're inside or outside the claims, and there's two different techniques you could use. One was I talk about was the competition assays. If you compete with something that binds to the sweet spot, and if you can't bind when that's already present on the sweet spot, then you're within the claims because you also bind to the sweet spots.

There's also something called alanine scanning, and alanine scanning in 2008 was very common, and it not only tells you if you bind to the sweet spot; it actually tells you the specific residues that you bind to in the sweet spot. So, yes, we --

JUSTICE JACKSON: But I've got to do the experiment in order to know this, right?

MR. LAMKEN: Well, yeah. You -- you would have to do that, but it is routine to do that and was routine in 2008. And it's not at all -- when you're dealing with some very -- something very small, you can't always just sort of hold it up and look at it to see if it matches. You're going to have to do a little bit of work to make sure that it's --

JUSTICE JACKSON: All right.

MR. LAMKEN: But that's routine.

JUSTICE JACKSON: Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

MR. LAMKEN: Thank you.

CHIEF JUSTICE ROBERTS: Mr. Clement.

ORAL ARGUMENT OF PAUL D. CLEMENT

ON BEHALF OF THE RESPONDENTS

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

Section 112 sets forth the heart of the patent bargain: The more you claim, the more you need to enable. If you claim a lot and enable a little, the public is short-changed and the patent is invalid. The Federal Circuit has long enforced that basic principle by requiring the patentee to enable the full scope of the patent without undue experimentation.

Amgen does not take issue with that test, with the Wands factors, I think, or the vast bulk of the Federal Circuit's enablement precedent. But the full scope test, which they don't take issue with at least as I understand it, dooms their claims here, as well illustrated by the chart on page 15 of the red brief.

Amgen claims antibodies that -- that bind on 16 residues in the epitope, but their -- their specification does not enable skilled artisans to reliably produce them when they bind at 10 or more. And those aren't hypothetical

examples. Those are the competitive antibodies that independently develop by their competitors in the four right-hand columns. They're disclosed embodiments, that 26 do not bind at more than nine residues. They've overclaimed, they've underenabled, their patent is invalid.

This Court has long applied the same principle in Morse, in Lamp, and in Holland Furniture. Samuel Morse invented the telegraph. He did not invent the fax machine. That is why this Court correctly rejected the final broad functional claim in his patent.

Thomas Edison discovered the key to incandescent light, but we'd all be fumbling around in the dark if this Court had not invalidated the broad unenabled claims in Sawyer and Man's patent in the Lamp case.

The stakes here are comparable. Pfizer independently developed its own antibody and patented it by amino acid sequence. It seemed like a promising candidate, but it failed in clinical testing.

If Pfizer had followed Amgen's lead and claimed the whole genus for its own, we would have no large molecule therapy for

cholesterol. We're better off with two competing independently developed therapies.

I welcome the Court's questions.

JUSTICE THOMAS: Mr. -- Mr. Clement, could you just reiterate or at least expand on what you said about what is being claimed here?

You -- you made the point that the more you claim, the more you have to enable. And I think it's important to -- since starting point is what you claim, I'd like to have a good sense of exactly what we are talking about.

MR. CLEMENT: So the numbers don't lie, Justice Thomas. I mean, my friend likes to come up with that 384 number. That is not the scope of what they have claimed as their invention.

The numbers don't lie. They have claimed millions and millions of antibodies. And their reassurance that, don't worry, all of those millions that you get with conservative substitution, they're all going to work the same, that's inconsistent with their own expert's testimony in the court below.

Dr. Rees and Dr. Petsko testified to this. Dr. Petsko, their expert, Court of Appeal

-- Appeals Appendix page 3891, says, if you change one thing in the antibody sequence, you have to retest it. You have to go through that whole experimental process again to confirm that it binds in the right place.

And, I mean, look, it -- I -- I can imagine this is frustrating because Mr. Lamken and I are going to tell you different things about the way the science works here. Please don't take my word for it. Please don't take Mr. Lamken's word for it.

I urge you to read Sir -- Sir Gregory Winter's amicus brief. He has gotten a Nobel Prize for his contributions to this field, and he will tell you that you can't look at function -- and part of the problem here is these are purely functional claims. You can't look at function and say, oh, that tells me about the structure of the antibodies that are going to bind and block in the right way, and you also can't look at the structure of one antibody and say, oh, well, if I just tweak it a little bit, it's going to do exactly the same thing.

Sir Gregory Winter doesn't think that. Their own expert doesn't think that.

And if I could try to address one thing that's come up. I do not agree with Mr. Lamken that everybody here says that the cumulative effort is irrelevant.

It is not a -- an appropriate test standing alone, which is why the Federal Circuit didn't apply it as the test. It never even used the word "cumulative." But, as Justice Sotomayor in her question said, is it an appropriate consideration? Yes, it's an appropriate consideration.

And if I could illustrate that with a hypothetical. Here's a situation where the cumulative effort to exhaust the species would not be particularly relevant.

If I came up with a brand-spanking-new process for making paint and I claimed that process in all the paints that were produced as a result of that as new compositions of matter and one step in my process patent was add pigment for the desired color, well, then a skilled artisan would be able to use that, an actual roadmap, and they would say, all right, I want robin egg blue, and they could produce it every time. And if they wanted chartreuse

instead, they could produce it anytime.

Now, obviously, there's a lot of colors in the rainbow, so to actually produce every one of them would take a lot of time and it wouldn't invalidate the patent because it enables the skilled artisan to produce what they want every single time. But this patent does not work this way. What they give you is their roadmap is trial and error.

JUSTICE GORSUCH: I -- I -- Mr. Clement, I appreciate that clarification, but, as I understand it, there is a point of agreement with respect to cumulative effort, that that should not be dispositive.

MR. CLEMENT: Absolutely --

JUSTICE GORSUCH: Is that right?

MR. CLEMENT: -- Justice Gorsuch.

JUSTICE GORSUCH: Okay. Okay.

MR. CLEMENT: And that's not just to --

JUSTICE GORSUCH: No, I -- no, I -- that's that's great.

MR. CLEMENT: Yeah.

JUSTICE GORSUCH: That's enough.

The other -- the other point Mr.

Lamken suggested that we -- we should clarify is that -- that there has to be a reasonable embodiment, not an embodiment -- enablement, sorry -- in every instance, that it just needs to be reasonable.

Do you agree with that as well? I don't know much turns on it in your case because millions are millions and -- and reasonableness is going to be somewhere -- you -- you could still prevail under that standard, but do -- do you -- do you agree with him that it's reasonable enable -- enablement, not -- not down to every jot and tittle in every --

MR. CLEMENT: Yes. I think reasonable is just maybe the flip side of undue experimentation.

JUSTICE GORSUCH: Yeah. Exactly.

MR. CLEMENT: Right, so --

JUSTICE GORSUCH: Okay. So, if we agree on the law, what's left --

MR. CLEMENT: Well --

JUSTICE GORSUCH: -- for -- for this Court?

MR. CLEMENT: -- nothing, except maybe a DIG.

(Laughter.)

MR. CLEMENT: I mean, that -- that seems -- and -- and, honestly --

JUSTICE KAGAN: And, Mr. Clement, is there any other point of law that you feel as though you and Mr. Lamken are in disagreement on?

MR. CLEMENT: Well, I -- I think there is a disagreement as follows.

Mr. Lamken thinks it's very helpful to his case that somebody who runs the -- the experiments necessary in the roadmap is going to produce an antibody within the range every time.

And I think that can't be right, it can't be particularly interesting, because that rewards breadth. And what -- what skilled artisans want is not to randomly generate something within the broad range that's claimed, but they want to be able to pick a specific embodiment, not a hypothetical one but a specific one.

So just to give you a concrete example, I mean, if -- if they claimed a 15 binder, there are 15 binders in the real world. If you want to use their roadmap to produce a 15

binder, you are consigned to trial and error.

JUSTICE KAGAN: So I understand that as a view of the inadequacy of their roadmap, but are you trying to suggest that it's reflective of a disagreement about what the legal principles or legal standards are?

MR. CLEMENT: I -- I think it must be, because Mr. Lamken is a very smart man, and he makes a big deal out of the fact that, don't worry, this produces something in the range every time, and skilled artisans can produce something in the range every time, and if you give them an infinite amount of time, they will produce everything in the range.

And he seems to think that that's good enough as a matter of law to enable his patent. And I think, wow, that is not close to good enough. That consigns people skilled in the art to Sisyphean tasks forever, and it's not what they do.

And one of the things I find particularly persuasive about Sir Gregory Winter's brief is he explains this roadmap is not a shortcut at all. It just describes the routine processes that people use to make

independent inventions, the same process that Pfizer used, that Merck used, that we use to get our own independent antibodies, and then it adds additional steps that somebody skilled in the art wouldn't want to do and are just basically an additional step, additional test they have to run to see whether they infringe, because the people skilled in the art don't really care where it binds. They -- they care that it blocks.

But figuring out where it binds, whether it binds to the 15 that they've claimed as part of their roadmap, is actually a useless process that slows down the artisan in the field.

And -- and I do think there's an important point that shouldn't get lost in all of this. Part of the reason, I agree, this isn't a close case is because what they are trying to do, there's no meaningful structure in these genus claims, and the structure they've given is an elaborate description of the epitope, the 15 or 16 residues on the PCSK9 where you want the antibodies to -- to -- to bind.

The problem is and the reason they can't claim that as an invention is because of this Court's Myriad case, because that exist in nature. These antibodies are independently generated by scientists, but the antigen and the epitope, all of that exists, in -- you know, in -- in nature.

And so what you have before you is a particularly pernicious kind of claim because not only is it a full -- a -- a genus claim that's purely functional or double functional, as the Federal Circuit described it, but it's really a workaround of Myriad because, basically, they're pointing to something that exists in nature and they're saying, we claim everything that works to bind there and block.

JUSTICE JACKSON: Mr. -- Mr. Clement --

JUSTICE ALITO: Mr. Clement, could I -- I just take you back to what you said about cumulative time and effort? Is time and effort relevant at all, or is it the nature of the effort that's required?

MR. CLEMENT: So --

JUSTICE ALITO: You say cumulative

time and effort is -- is not the test, but at the other extreme is the relevant factor, the effort necessary to make and use any individual embodiment. So just -- would you just clarify what -- what is the relevance of time and effort?

MR. CLEMENT: So I -- I think they are both relevant. I actually agree with Mr. Lamken that they're both sort of relevant evidence that gets to the ultimate inquiry, which is, is there undue experimentation?

And in some respects, the more important word isn't "undue;" it's "experimentation." And let me just contrast the particular claims that go by antibody sequence, our claim to Praluent, their claim to Repatha, the Pfizer claims. They give you the amino acid sequence. And so somebody -- a skilled artisan every time doesn't have to really engage in any independent experimentation. They can look at it. They can reproduce the amino acid sequence. Regardless of how time much it takes, there's no experimentation in there at all.

But, under their broad genus claims, you can't do that. You can do it as to the 26,

and we'll -- we'll give them the 26, but, as the chart on page 15 shows, we're not even close to infringing the 26. We are structurally fundamentally different.

So, to get to the genus, what you do is you go in a lab and you start injecting mice and you inject them with the anti -- the -- the antigen, PCSK9, and then you get a bunch of antibodies that are produced. Then you pour them over and see which ones bind on PCSK9. And you might be able to test them for blocking. And then --

JUSTICE JACKSON: But, Mr. -- Mr. Clement, isn't the -- isn't the issue whether or not that is not routine or that's undue? I mean, you sort of took undue out of it, but, as I read the test or understood the test, some experimentation by the skilled artist is allowed. So how do we know whether the steps that you're talking about are undue for the purpose of this -- of this standard?

MR. CLEMENT: Well, here's -- here's the thing, Just -- Justice Jackson: I think the problem is certain -- in -- in certain scientific areas, a -- a form of experimentation

is routine, but it's still experimentation, and it's still not what you're supposed to get in a -- when a patent, you're not supposed to just say, all right, do what we did, start from scratch, start with mice --

JUSTICE JACKSON: Yeah, but it sounds like you're -- you're -- it sounds like you are going beyond the undue experimentation test. You're saying that unless the claims in this patent are such that a skilled artisan could pick it up and go right from one to the other without any experimentation, the patent is invalid. And I didn't understand that to be the case.

MR. CLEMENT: And -- and -- and -- and then I must have misspoke, because that is not my position at all. And just in --

JUSTICE JACKSON: Isn't that what predictability is about? And isn't the work of predictability in your argument that you say, unless you can predictably, by doing what the roadmap says, reach this particular result, the patent is invalid?

MR. CLEMENT: No. Predictability goes to experimentation and undue. If you have

something that enables the skilled artisan to pick essentially any point in the genus, as in my paint example. I want a particular shade of paint. I can produce that one very readily. I mean, maybe I have to do a little bit of mixing with the pigment, but that doesn't -- that's not the kind of thing -- that's the reasonableness. That's not a problem.

But, if you tell me that the way I have to produce robin blue -- robin-egg blue paint is to just throw in a pigment and wait until, like -- I'll get a random color and wait until robin-egg blue comes up, that is both undue and it's experimentation and it's not covered by the patent. I was just trying to explain to Justice Alito that I think both words are important because, you know, there are some things that are -- involve time and effort, but they're really just sort of tweaks at the margins.

And I don't think it's an accident -- just to go to this Court's cases and the cases my friend relies on, I don't think it's an accident that all his best cases are process patents because, if you think about a process

patent, it's often going to be the case that if it's -- you know, if you have a process patent for making bricks or for cooling railroad tires, well, if it's a humid day, it might react a little bit differently. You might have to tweak it a little bit to get the mix right on a humid day that's different from a day when it's zero humidity. And, in the same way, if it's 90 degrees out, maybe your cooling process for the -- the wheels differs if it's 30 degrees out.

And those are the kind of tweaks that you expect a mechanic to be able to do. And you'd say that's without undue experimentation.

But it seems quite strange to me that when you're claiming compositions of matter and millions and millions of them, that the only way that you can get there is to essentially replicate the experimental process that the four innovative companies went through to come up with these in the first place, plus, as Sir Gregory Winter says, an additional step that doesn't help anybody but just ends up taking more time because you're basically testing as to whether or not you infringe their patent.

JUSTICE SOTOMAYOR: Mr. Clement, could

you put things in simpler form for me? It -- it sounded to me that your adversary was saying that most of this work is done by computers, that you inject the mice, the -- the antigens appear, and the computer then sorts them out to see which have the sweet spot or not. That's what I understood him to say, and if that's true, I don't know why that's undue experimentation or why it's costly or why it's time-consuming.

You're saying there's more to this process than that. So break it down to me into steps so that I can understand why you're saying that this is undue. I -- I understand it with the paint.

MR. CLEMENT: Right.

JUSTICE SOTOMAYOR: But I'm not understanding it with this process, so --

MR. CLEMENT: So, in -- in this process, let me just hypothetically say what would happen if I wanted to say -- if I were a scientist and I wanted to say I want to use their roadmap to produce a 15 binder because I want to test whether the 15 binder is any better than the 7 binder, which is their Repatha, and I

want to be able to test that. I'm a scientist. So here's what I would have to do.

JUSTICE SOTOMAYOR: All right.

MR. CLEMENT: I would have to --

JUSTICE SOTOMAYOR: So the difference is, in his way of doing this, he's not telling me how to find his -- he's not going to give me a way to get to his drug without undue experimentation? Is that your point?

MR. CLEMENT: That is my point. It's not my only point --

JUSTICE SOTOMAYOR: Okay.

MR. CLEMENT: -- because, you know, I'm -- I'm -- I -- I think this most dramatically illustrates it because I -- I assume that's what somebody in the field would want. They wouldn't want a randomly generated one somewhere in the genus. They'd want to say, well, Mr. Lamken tells you --

JUSTICE SOTOMAYOR: Well, I don't think we care about what people want. We care about what's being claimed and --

MR. CLEMENT: Okay.

JUSTICE SOTOMAYOR: Okay. So --

MR. CLEMENT: But -- but he's the one

actually who cares what a skilled artisan wants.

JUSTICE SOTOMAYOR: Okay.

MR. CLEMENT: And what's being claimed is this entire genus. And if I want to pick a spot --

JUSTICE SOTOMAYOR: So go back and tell me what --

MR. CLEMENT: Yep.

JUSTICE SOTOMAYOR: -- steps you have to do to get to him.

MR. CLEMENT: Okay. So I have to start by injecting mice --

JUSTICE SOTOMAYOR: To his --

MR. CLEMENT: -- which is not just done with, like, you know, computers. It's done by scientists in the lab. They inject the mice with the antigen. Then they get --

JUSTICE SOTOMAYOR: I did that and I wasn't skilled, but go ahead.

(Laughter.)

MR. CLEMENT: Okay. Well -- probably more skilled than I am. But -- so -- so -- so you get the results of that. You get a whole bunch of antibodies. And then you have to figure out which ones are essentially candidates

to bind on PCSK9.

JUSTICE SOTOMAYOR: So does a computer do that? And why is it undue?

MR. CLEMENT: I -- I don't --

JUSTICE SOTOMAYOR: Do they have to look under a microscope? What do they have to do?

MR. CLEMENT: I -- I -- I think it's a process they do in the lab. I don't think they actually do that with the computers. Then they get to the next step, which is they have what you might think of as like their candidate antibodies, and then they have to test them to figure out whether they bind on the -- the -- the 16 residues that are claimed.

And that is a time-consuming process. It is not just a simple matter of, like, running a computer. Again, people do that in the labs. I don't understand all the details, to be -- to be candid.

But -- but -- but here's what I do understand, is, at that process, let's say they get, you know, 26 or 384. Then they -- then -- then, if what they wanted was a 15 binder to start with, they've got to figure out whether

they got one, and there's an excellent chance that they didn't get one of those at all.

JUSTICE GORSUCH: Can I ask this question?

MR. CLEMENT: Sure.

JUSTICE GORSUCH: So the 26, you agree, fair enough, Mr. Lamken's got that in the bag. What about the 384?

MR. CLEMENT: He doesn't get the 384.

JUSTICE GORSUCH: No? Why?

MR. CLEMENT: He didn't disclose them by -- I mean, he could have got them if he gave me the anti- -- the -- the -- the amino acid sequence for all of them. But the reason that he doesn't get the 384 is because he doesn't tell us anything about the 384. I mean --

JUSTICE GORSUCH: Well, let me -- let me just pause there for a second. I understand completely your argument -- well, I think I understand completely, let me put it that way, your argument about conservative substitution and the potential millions of variants and -- and the trial and error that's required there.

I'm not sure I understand how that applies to the 384.

MR. CLEMENT: So, like, honestly, the 384, I just have to take Mr. Lamken's word for it. I mean, he says that, oh, Praluent might have been in there. I mean, please. If Praluent were in there, their scientists would have produced that evidence.

And if you look at the chart at page 15, it is not a surprise. I assume that the 26 --

JUSTICE GORSUCH: That's a -- that's a nice demonstrative.

MR. CLEMENT: Yeah.

JUSTICE GORSUCH: I've got it.

MR. CLEMENT: Yeah.

JUSTICE GORSUCH: Yeah.

MR. CLEMENT: It -- it -- I assume the 26 were -- must have been representative of the 384, right? Otherwise, why not make one of those other 384, one -- the ones you do by amino acid sequence.

So, if you look at the 26 that they give you the amino acid sequence, they look structurally nothing like the four antibodies that were independently developed by other companies. That is very striking to me.

JUSTICE GORSUCH: Thank you.

CHIEF JUSTICE ROBERTS: Justice Thomas?

Justice Alito?

Justice Sotomayor? No?

JUSTICE KAGAN: Mr. Clement, can I ask you to address Professor Lemley's brief? He has a -- seems to have a very strong view that these antibody genus claims are valuable -- patents are valuable or potentially so and that the Federal Circuit's test is going to pretty much wipe them out across the board.

So why -- why is it that Professor Lemley is wrong in your view?

MR. CLEMENT: So I think he's wrong on a number of levels. I think he's wrong that the existing Federal Circuit precedent is going to foreclose all genus claims. I mean, there's the Bayer case that we cite in our brief that's an example of the genus claim that the Federal Circuit recently upheld.

Now it may be that in this particular area of antibody science, given the current state of the science, that you may not have an ability to functionally claim a genus, and

that's kind of -- at -- at some level nobody's fault. It's just the way the science works.

And, personally, I think that's great, and -- because what it does is it allows different companies to independently develop different large molecule therapies to deal with the same malady.

And if you look at the Fish & Richardson brief, it goes through and shows that there are number of situations where there's one antigen or pathogen that people are trying to target and they target with different multiple large molecules, and that can be hugely important.

I mean, I -- I -- I want to make clear my friend and I do disagree on a factual matter. He wants you to believe that everything in this genus is fungible. And, of course, it's fungible with respect to the two functions claimed by definition, but it's not -- they're not functional. They are different compositions of matter. They can work very different ways. Somebody can tolerate one and not the other.

And the best evidence of that is the Pfizer experience, right? The Pfizer antigen --

antibody is in this genus, and when it went into clinical testing, it fell down.

So, if -- if Amgen's had fallen down for the same reasons that -- that -- that Pfizer's did, we'd be without the treatment because it claimed the whole genus and --

JUSTICE KAGAN: So -- so --

MR. CLEMENT: -- they wouldn't enable it.

JUSTICE KAGAN: -- so -- so tell me if this is wrong. As I understand, what -- Professor Lemley could be wrong for one of two reasons, right? He could be wrong to say that the Federal Circuit test is going to basically invalidate all these patents, or he could be wrong in thinking that these patents are valuable.

I hear you saying that he might be right about the Federal Circuit's test invalidating most of these patents, but that's okay because we shouldn't want these patents around.

MR. CLEMENT: You know, the truth has a way of leaking out. I mean, yeah, I mean, I am saying that --

(Laughter.)

MR. CLEMENT: -- because -- because -- because I think functional genus claims are terrible. I think they retard the science. And I don't think you have to look beyond this Court's cases.

The eighth claim in Samuel Morse's claim, the other ones were nice species, structure, good stuff. The eighth one was a functional genus claim for everything that allows letters to print somewhere else through the use of electricity. This Court deep-sixed it and thank goodness, because Samuel Morse is brilliant, but he didn't invent the fax machine.

And look at the Lamp case. I mean, they claimed the entire genus of all fibrous text -- textiles. Turns out the one that they discovered didn't work very well and was a lousy lamp. And Edison had to go through all this different work to find out that there actually is like a subgenus. It's called bamboo. That stuff all works and it all has the same structurally common feature of really parallel fibers. And that's the way -- I'm not against all genus claims, but you got to get some

structure in there.

And as this Court's cases teach, it's got to be structure that unifies the genus. And what's -- and I love Lemley, but what -- you know, I -- I take Sir -- Sir Gregory Winter on the science, and what he tells you is, in this area of science, there -- you just can't get that structural commonality. It just doesn't work. It's -- I mean, maybe somebody will discover it and they will get another Nobel Prize for discovering it.

JUSTICE KAGAN: Thank you.

CHIEF JUSTICE ROBERTS: Justice Gorsuch?

Justice Kavanaugh?

Justice Barrett?

Justice Jackson?

JUSTICE JACKSON: So there are some fields where there is a degree of unpredictability or randomness, and I guess I'm just a little worried that your view on this would mean that we would not be able to have patents where some experimentation was required.

Can you just speak to that a little bit more? I mean, again, I hear you in some

ways suggesting that the specification has to absolutely get a skilled artisan to the endpoint of every species in the genus a hundred percent of the time exactly as indicated.

And I'm just concerned because there are going to be some areas, and perhaps this is one of them, where there's a -- a -- a reasonable degree of unpredictability in terms of the outcome, but you're sort of in the ballpark enough that we would want to make sure that there was innovation in this area with -- with these kinds of companies investing in -- in patenting these kinds of developments.

MR. CLEMENT: So I -- I think what I would say is I do think the test should be undue experimentation. It should not be zero tolerance, no experimentation.

JUSTICE JACKSON: Okay.

MR. CLEMENT: But I also do think, if you're going to start with the text, which I assume you always do, then what you would say is you start with the idea that you have to make and use the invention, and the invention is defined by the full -- by the -- by the claims in the invention, and -- and, in that sense,

Amgen's the master of their own claims, the master of their own patent. And then you look at those, and if they claim a lot, I mean, you -- you have to enable the full scope of what you claim.

And then, from that starting proposition, which might get you to the idea that there's no experimentation, then I think it's a little bit of, you know, de minimis non curat lex reasonableness, a little bit of play in the joints, but this is where Mr. Lamken and I just see the facts completely different.

He wants to say, oh, well, this -- these are just hypothesized things that couldn't be invented here given the current state of the science.

With all due respect, balderdash. I mean, there are four disclosed patents here with anti -- amino acid sequence that the competitors have made that are on the chart.

Now, if you are a skilled artisan in the field and you want to produce the 15 binder that Pfizer did, you can produce it a hundred percent of the time by duplicating the amino acid sequence.

But, if you want to use their roadmap to get a 15 binder so you can test to see whether his claim that all of this is fungible is really right and it's no better than the 7 binder, I mean, get a big cup of coffee because it is going to take forever to run all of the tests that are going to be necessary --

JUSTICE JACKSON: All right. One --

MR. CLEMENT: -- and you could you run them all, and you might not get a 15 binder and then you have to start over.

JUSTICE JACKSON: One last question on the facts. I understood that Amgen had trial testimony in this case that the roadmap is certain to make all of the claims' antibodies, including Sanofi's, Pfizer's, and Merck's.

And I had understood, in terms of the way the -- the burdens work, a little complicated, but that you had to have evidence disproving that by clear and convincing evidence.

So do you? And, if so, what is your evidence?

MR. CLEMENT: So I -- I appreciate the question, and this really goes back to the

suggestion that there is sort of a lurking legal difference here, because the reason I don't have evidence that says that that claim is not true is because it implicitly says if you take forever. I can't tell you that if you run these experiments, you won't eventually get Praluent, Pfizer, the Merck embodiments, but, unlike the paint, where you can start and say, all right, I want -- I want to test that, so I'm going to -- I'm going to reproduce that. You can't do that.

So the -- the -- the twin claims that my friend keeps making and he seems to think are legally sufficient, and I definitely disagree, are, if you run the test, you're always going to get something in the genus.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

MR. CLEMENT: Thank you.

CHIEF JUSTICE ROBERTS: Ms. Sinzdak?

ORAL ARGUMENT OF COLLEEN R. SINZDAK

FOR THE UNITED STATES, AS AMICUS CURIAE, SUPPORTING THE RESPONDENTS

MS. SINZDAK: Mr. Chief Justice, and may it please the Court:

I think I want to pick up where

Respondents' counsel left off with a very important fact, and that is that if an antibody has already been created, a scientist who wants to make that antibody is not going to go into a laboratory and inoculate a mouse.

They're going to use the amino acid sequence. That is the recipe for making an antibody. That is why the government says that for the 26 exemplars within the patents, that actually let -- where they -- where Amgen has actually listed the amino acid sequence, those -- those antibodies are enabled because, if a scientist wants to go into the lab and it wants to make an -- that antibody, it has the recipe, it has the amino acid sequence.

And I also do not want you to take my -- my word on the science, but I do want you to take the expert testimony on the science. And I think that if you look at Trial Transcript 20 -- 225, you will see that -- that Respondents' expert explained that the amino acid sequence is the recipe.

If you look at the Winter brief at 14, it explains that the amino acid sequence is the recipe.

And if you look at Amgen's own brief at 13, it says, how should you start their roadmap. You should go in and you should use the amino acid sequence of the antibodies that they actually invented and make those antibodies, and then you should go through this whole elaborate mouse inoculation process.

So the reason here, just on the -- on the clear facts that this is not an enabled genus, is that they have not given the information that a person skilled in the art would need to make and use all of the antibodies within the genus. It really is that simple.

And I think that we need to be very careful about when we hear claims that this is complicated science, and we need to start going beyond the sort of -- the basic text that says you have to be able to make and use the invention. We have to start relaxing the rules, and we have to say not can you make and use every antibody within the genus, but, oh, do you really need a particular antibody? You know, does it really matter, I think, is what Petitioners' counsel said.

It is very dangerous, I think, to

start asking those kinds of questions because the truth is we don't know if it matters. This is an unpredictable field. This is a field where developments are getting made every day. And they haven't made certain antibodies within this genus. We don't know if one of those antibodies is going to be the one that really works to beat the cholesterol problem that causes heart attacks, that works better than everything else, or the one that's going to be tolerated by more patients or the one that's going to be cheaper to manufacture.

We don't know that, and so we can't say, oh, does it matter? What we have to ask is, is it different? And this isn't some new rule that I'm coming up with. Under the patent law, it has never been the case that you say, oh, is this better? Do you have -- you don't have to build a better mousetrap; you have to build a different mousetrap.

And, here, we know that the Respondents, they built a different mousetrap, right? That their antibody, it binds to different parts of the antigen. So it is different. It is not simply the same.

And I actually think you -- you see in the reply brief that even Amgen knows it's not the same, because the government explained that there is a doctrine out there that prevents copyists, that prevents someone from making a great invention and then having someone else just make a tiny change and knock it off, and it's called the doctrine of equivalents, and it's been in this Court's cases for two centuries.

And Amgen says we can't use the doctrine of equivalents here, and the reason is because they're not equivalent, and because they're not equivalent, you have to enable all of the different antibodies.

So, again, this is just the basic principles. It is the enablement requirement that has been in the law since the beginning.

And I think, Justice Kagan, you said, well -- well, actually, Professor Lem -- Lemley is very worried that this enablement requirement is going to harm innovation.

But Professor Lemley has a new article from 2023, Yale Law Journal, which is called "The Antibody Patent Paradox." And in that, he

says, you know, it doesn't look like these antibody patents -- it doesn't look like these genus patents are enabled, but there is this doctrine of equivalents, and maybe it would take care of all of these innovation problems.

And I think, honestly, even if you look at Footnote 399 of that original Lemley article, "The Death of the Patent Genus," in that footnote, it says, now there is a case happening right now, it's -- it's Amgen versus Sanofi, and it doesn't really seem like that genus is enabled, but, you know, it's -- it's not enabled for a different reason.

So I think there are some concerns going on with -- with the enablement requirement. I still actually think that the -- the concerns that Lemley is expressing can be dealt with through the doctrine of equivalents, and I can explain a little more, I -- what I think is happening there with respect to chemical genuses. But, whether you think that's true or not, it's simply an entirely different question.

I think, Justice Jackson, you were talking a little bit about the predictability

and this is an unpredictable area of -- of -- of -- of science and how are we going to deal with those sorts of things.

I think it is correct this is an undue experimentation question, and we're going to say, like, is this something that a person skilled in the art is going to be willing to do? And, quite honestly, at the time of Wands, I think that people were a lot more comfortable doing the mouse inoculation process, and the reason for that -- and I hate to bring in yet another complicated area of science -- but recombinant DNA technology was in its infancy. So I don't know that you really could use an amino acid sequence to go into a -- a lab and just make a particular antibody. So, at that time, actually, if you wanted to claim a particular antibody, what you would do is deposit that antibody -- or it's called a hybridoma of an antibody. You would deposit a hybridoma in a depository, and then, if another scientist or if another company wanted to make that antibody, they could sort of check it out and clone it, and that's how you would make that particular antibody.

But, if you wanted to kind of just go into a lab and make an antibody de novo, you really would have to inoculate a mouse and hope. But you don't have to do that anymore, right? At this -- now we -- we have a recipe. And because we have that recipe, I -- I think the idea that you would tell scientists, well, just go and run that mouse process until you get what you're looking for is -- is -- is really absurd.

And I would also caution, again, this idea, which I think run -- under -- under -- undergirds a lot of the arguments here on Petitioners' side, that we need to make new rules for new science. It's a -- it's a dangerous idea. And -- and, you know, you think about Consolidated Edison, where the first people who invented that light bulb with carbon filter paper, they really thought they had the best light bulb. They did, but they were wrong. They were simply wrong.

And when we kind of make these predictions, you can stifle innovation. And I think this is another sort of response to the Lemley brief. What happens when you allow a genus patent that will -- that -- that -- that

-- that will -- will cover not just something that has been invented but also things that have not yet been made and used is that nobody else has the incentive to go out and make and use them.

So let's say you're look -- you have this 15 binder, right? And if you look at Amgen's patent and you look -- the only thing you're going to be told to do is to go and inject a mouse or there's another process, which I do want to mention briefly, but you're going to go inject -- inject a mouse -- a mouse and hope for the best, right? But, if a scientist goes into a lab and it takes all of the hard time and effort and it goes through and it finds a 15 binder, that 15 binder belongs to Amgen. And that's just not the basic patent quid pro quo.

JUSTICE GORSUCH: Counsel, can I just ask you a question about the legal standard?

MS. SINZDAK: Sure.

JUSTICE GORSUCH: You -- you -- you -- you've emphasized full enablement, and that's certainly what Wood, for example, says from this Court. But at -- at least your -- your

colleagues both seem to suggest that there might be some elbow room, non curat lex room in there somewhere, reasonableness. What do you think? What does the government think?

MS. SINZDAK: I think there is always room for reasonableness, but I do think that -- that the need to be reasonable needs to be tempered with the need not to accept sort of pronouncements about -- about what is and is not different. So I -- I -- I -- or what does -- what embodiments do and do not matter. So I think, again, the doctrine of equivalents is really, I think, where a lot of this reasonableness concern gets taken care of.

I would also say that -- that -- that -- that the Federal Circuit has -- and I think quite correctly -- said that, you know, if you claim a genus of wooden baseball bats and every person skilled in the art knows that you can't make a baseball bat out of -- out of pine, then you don't have to say except pine because the -- the -- the strict -- the plain text of the statute says a person skilled in the art.

JUSTICE GORSUCH: Okay.

MS. SINZDAK: So I think there you

would have a little bit of reasonableness.

JUSTICE GORSUCH: And then a similar question with respect to cumulative efforts. There was some discussion about that and -- and maybe some -- some agreement that -- that cumulative effort may not be the -- the right -- it may be a consideration, but it's not -- surely not a dispositive one if the patent did clearly specify every single time you're going to produce a winner.

And the problem here, as I understand Respondent, is that that's no guarantee. There's no -- you're -- even if you do everything right and you follow all of it, conservative substitution, you're going to have some winners and you're going to have some losers.

But, if -- if you could, for example, every single time get a winner, then the fact that it would require a long time to get them all wouldn't -- wouldn't necessarily defeat a patent, would it?

MS. SINZDAK: No.

JUSTICE GORSUCH: Okay.

MS. SINZDAK: It -- it certainly would

not. I do agree with Respondent it can be relevant, and I think it can particularly be relevant if, for example, you figure out that 10 of a million types of a -- there's a million types of ammonia in the world and 10 of them are going -- can be used instead of gasoline to run superefficient cars, right? But you don't know which 10, so you just claim the genus of ammonia that can be used to run cars, and then what you're saying is you have to go out there and try them. And you may actually have to try all a million of them so -- to get to those 10. And so there the cumulative effort is relevant because you're going to be there testing and testing and testing.

So I -- I -- just a -- a few minor factual points. First of all, I think that 400 number is misleading because, first of all, it's -- it's a -- or the 385 number. So that is, if you -- that's how many they got when they ran this mouse process once, but this is not a process -- a -- a product by process claim. They're not only claiming those, you know, 385.

And it's not even -- they're not only claiming antibodies made by mice; they're

claiming these antibodies that bind and block made through any process.

And I -- I also think that, you know, at least looking at their expert testimony, I'm not sure that all of the competitor antibodies can be made with that mouse process, and -- and I -- I say that only because I look at Trial Transcript 758, and if you look at that, their expert is talking about the various competitor antibodies, and it says, you know, you can run the mouse and we think you would get Praluent by running the mouse experiments. But, actually, you would need to -- to get this phage library to -- to find -- to -- to make another of the competitor antibodies.

To me, that looks like they're saying the mouse has some limitations, so you're going to need to use a different process. And I actually think use -- you heard Petitioners' counsel up here conceding that you're not going to be able to -- you know, there are -- you're not necessarily going to make everything with the mouse because you're going to have some of these conservative substitution -- you're going to make some -- some antibodies with

conservative substitution, that might -- I -- I think what he was saying is that, you know, that -- that's -- that's in addition to those 400.

So I -- I -- I -- I do think just as a factual point there -- there are -- we -- we need to be careful and precise. And what I would urge the Court is to look at the Winter brief but then to also just focus on the legal question here, and I think answering that legal question just means reiterating the enablement inquiry that this Court has been applying and applying and applying for 200 years.

CHIEF JUSTICE ROBERTS: Counsel, is there anything that Mr. Clement said this morning with which the government disagrees?

MS. SINZDAK: I did not hear anything.

CHIEF JUSTICE ROBERTS: Okay. And on the doctrine of equivalents, wouldn't that be less protective of the investment someone might make to pursue these in -- inventions in terms of its, I would say, maybe I'm not remembering right from earlier cases, but it suggest -- seems to me that that would be less protective and therefore less of an encouragement to

investment.

MS. SINZDAK: I -- I mean, to the extent that Petitioner is asking for protection for things that they have not made -- enabled people to make and use, I think you're right, because I don't think the doctrine of -- of equivalents is going to get them things they haven't invented yet.

But I also think that -- that -- that that's just the basic patent quid pro quo. You don't get a patent on anything that you haven't enabled people to make and use. So I guess I would say, yes, get -- not being allowed to have their patent is going to get them less -- less, but that's exactly what the law requires.

CHIEF JUSTICE ROBERTS: Justice Thomas?

JUSTICE THOMAS: Would you comment briefly on the relationship between the enablement -- enablement inquiry and the claim -- the invention, the claim?

It seems as though, as Mr. Clement said, that the broader -- the more you claim, the more on -- you must focus on the enablement analysis. And you -- I don't think you

commented on that.

MS. SINZDAK: I think that is often the case. You need to provide enough information to enable a person to make any given embodiment of your invention. And, you know, if -- if you've claimed a lot of different things, you may have to put in a lot more information.

I would say that sometimes I think it's going to be more -- you're not going to have to give a ton more information. My understanding is that, for example, with respect to a chemical genus, you might be able to say, I'm talking about this family of chemicals that have this helical ring structure, and, you know, this -- this -- this chemical group that hangs off of it can be one of these five things.

And -- and that's actually going to enable a chemist, not me, to make tons and tons and tons of different things, or you --

JUSTICE THOMAS: So the -- in this area, you -- I -- I think there's -- if -- if I understand your argument and Mr. Clement's, this area doesn't seem to have the same predictive quality that you would find in some of the other

areas. For example, his paint mixing would be relatively easy. But, as you move along to the other antibodies in this area, it seems as though there it's trial and error. It's more each one has to be assessed on its own terms.

So it would seem to me that the -- it would be -- it would be more difficult to achieve what you just said in this particular area.

MS. SINZDAK: I think that is exactly right, but I don't think that that means that you should bend the rules of enablement. And, in fact, I think that could be very dangerous, right, because one of the incentives right now for scientists to figure out the structure/function relationship in antibodies beyond the Nobel Prize, but another incentive is then you could claim broader genuses.

If somebody is able to figure out, oh, well, when I identify this antigen, oh, I can figure out what amino acid sequences for every single different antibody that could bind to that antigen, then they would -- that -- they would have a much better case for enablement.

But, if you say, no, it doesn't

matter, you can claim all of those anyway, there's less incentive to find that, sort of that -- that magic key, which I should not say magic, it's science.

(Laughter.)

CHIEF JUSTICE ROBERTS: Justice Alito?

Justice Sotomayor?

JUSTICE SOTOMAYOR: A simple question, maybe not so simple. Mr. Clement at one point in response to Justice Gorsuch said you should DIG this case. If we didn't want to, what could we say to help the Federal Circuit or anyone else who's -- who's interested in this area?

MS. SINZDAK: So --

JUSTICE SOTOMAYOR: What could we say that they didn't say? What could we explain? Your -- Petitioners' counsel has told us what he wants us to say. What would you want us to say?

MS. SINZDAK: So I -- I think, first of all, you -- you could DIG the case. We do not think that the Federal Circuit said anything wrong here. I think that some of the arguments that we're hearing from Petitioners suggest that it might be useful to clarify that you really do need to enable each of the different embodiments

that you're claiming, that you can't say these ones don't "matter," because that's simply not the -- not -- first of all, it's -- it's hard to know what that means other than if you're invoking the doctrine of equivalents, which Petitioner said he -- he can't invoke, but that requires sort of a predictive judgment that could really freeze innovation by saying, oh, don't worry, don't -- don't find that 15 binder, it doesn't matter.

And -- and any -- and -- and, of course, what they're saying is it doesn't matter, but, by the way, if you do find it and it does something truly amazing, we own it.

CHIEF JUSTICE ROBERTS: Justice Kagan?

Justice Gorsuch?

JUSTICE KAVANAUGH: I guess, in response to what you said to Justice Sotomayor, it would be important for this Court to say it essentially agrees with the Federal Circuit because there's been, as Justice Kagan points out, a lot of critiques of the Federal Circuit's approach, and if billions of dollars were on the line, this Court saying as much with -- along the lines that you proposed would eliminate that

uncertainty about the legal standard, and then everyone would know it's up to Congress.

MS. SINZDAK: I -- I -- I -- I agree with that completely. And I think also, with that final point, which is I -- I think an important one that maybe hasn't been discussed here, that to the extent you did think that the Petitioner had a good point that antibodies are just different and basic patent rules don't -- don't work, then the person -- then -- then -- then the body that needs to -- to make a special antibody exception is going to be Congress, not this Court.

I also completely agree that I do think it would be helpful -- to the extent there are scientists still out there making these broad genus claims that are going to stifle innovation, I -- I do think that that's a -- a danger to an innovation, especially in the medical field, where as -- from what people who know better than me tell me, anti -- antibody innovation is key, and -- and -- and we don't want people claiming more than they've really invented.

JUSTICE KAVANAUGH: Thank you.

CHIEF JUSTICE ROBERTS: Justice Barrett?

Justice Jackson?

Thank you, counsel.

Rebuttal, Mr. Lamken?

REBUTTAL ARGUMENT OF JEFFREY A. LAMKEN
ON BEHALF OF THE PETITIONERS

MR. LAMKEN: Thank you.

A key fact for this case is that Sanofi has not identified one antibody that would require undue experimentation to make. Sanofi likes its chart. We like that chart as well because the whole purpose of that retrial was so that they could prove that those competitor antibodies aren't made using the roadmap. And the jury disagreed.

There was no evidence of anybody ever saying, gee, I tried to make one of those competitor antibodies, it didn't come out the first time. I know the government points out that you might use a phage display from -- for one, but the patent's disclosures explain that you can use the mice and you can use phage displays and this is how you would get them.

And all this tells me that the bottom

is there's a reason out there why we have trials, why we have juries, and why we have patent examiners, so that we're not retrying all the elements of the case before this Court.

Before this Court, the question is did they prove that there's something you can't make or it takes undue experimentation to make, and that evidence -- that proof is simply absent.

In terms of Winter, I think it's very interesting to get the functional equivalent of an expert report when you're in the Supreme Court. If the Court's interested in a response to that, it so closely parallels Sanofi's brief in the court of appeals that I would commend the Court to look at our reply brief there and it will have the answers to virtually everything that Mr. Winter has.

And turning -- turning to the issue of millions, the quest -- question of millions matters only if you're looking at the cumulative effort to get to the millions. If each one is individually enabled, you know how to get there because you can do amino acid substitutions through this conservative substitution, you can get to any one you want, that's enablement.

Each of those is enabled.

The -- the question of millions becomes not enablement only if you're going to look at the cumulative effort to make each and every one, and I think that is a fundamental point of disagreement. Is it even relevant how hard it is to make all of them as opposed to how hard is it for the skilled artisan to do what skilled artisans do, which is make one that they want.

And, in this sense, I would like to respond to Mr. Clement's point that somehow it makes it hard -- our roadmap makes it harder. No, the roadmap makes it much easier because, if you know that it's going to bind to the sweet spot and we give you those two antibodies, those two anchor antibodies that help you figure it out with high throughput testing, quick and easy according to the testimony, if it binds there, it blocks. That's it. You're done. You have an antibody that works.

With respect to Morse's eighth claim, yes, everybody forgets about Morse's seventh claim, and Morse's seventh claim was, in effect, you use electromagnetism using -- to produce the

motion of the machinery at distance to reproduce letters. We're just like Morse's seventh claim because we have a structure, you're using monoclonal antibodies, and we tell you how to produce them, and these are all monoclonal antibodies that have a characteristic that you can observe, that they bind to a particular place, and by binding in that place, they produce the function you want, blocking.

There's a lot of going -- a lot about criticizing functional claiming here. But, in terms of functional claiming, that's not a 112(a) question of enablement. That's a 112(b) question, which describes what you have to do to claim. If people don't like functional claims, that's where it goes.

And this claim really isn't functional in a relevant sense. The binding is a characteristic you can observe, like what the government called water absorb -- absorptivity, when it was talking about the -- the Holland Furniture case. It's something you can observe. And if you have that characteristic, you bind and, therefore, you block and you're exactly within the claims.

As to the doctrine of equivalents, if you have an antibody that has a different amino acid sequence, that isn't protectable under the doctrine of equivalents because it's not equivalent. Because it has the same effect, it may also block, doesn't make it equivalent. It's only equivalent if the limitations, the requirements, are equivalent. And so you can swap out maybe one amino acid for one that's very similar, but if an amino acid in your claimed structure is just missing, you just clipped it out, then you would be around, and you would provide no protection whatsoever for people who are creating the antibodies.

You invest $2.6 billion investing and -- and determining that there's a sweet spot that if you bind to you will block and you will be saving lives. And the protection is listed to -- limited to what? The 26 you describe by amino acid sequence? That provides no protection at all because you can always come up with a 27th, and that's the whole point of the roadmap.

The roadmap is fully enabling because you can come up with that 27th, the 28th, or the

29th, whatever is out there. The testimony was the roadmap will allow you to get to them all. And it's not an infinite test because the evidence in this trial, in this art is there's just nobody who testified and said, gee, I ran the roadmap, I tried, I didn't get what I wanted, something was missing. No evidence that Sanofi on its first panel didn't come up with its -- its antibody, Praluent. No evidence that Amgen on its first trial failed to come up with its antibody. Or any of the other competitors. When you run the roadmap, you get them. The 15 binder, if a 15 binder, it exists, it's going to come out and it's going to be there.

If I could turn just very quickly to the -- issue -- issue of DIG, please?

CHIEF JUSTICE ROBERTS: A minute.

MR. LAMKEN: Thank you so much.

This case, you should make no mistake, has incredible impacts. We have two decisions from the PTAB, both characterizing it as a cumulative effort to make all the embodiments test. Nobody can invest billions of dollars with this decision out there. Nobody can invest billions of dollars if it's even relevant.

There's a legal dispute about the relevance of that cumulative effort test, and this Court should address it and excise it from the law.

Thank you, Your Honor.

CHIEF JUSTICE ROBERTS: Thank you, counsel. The case is submitted.

(Whereupon, at 11:44 a.m., the case was submitted.)

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