SUPREME COURT
OF THE UNITED STATES

IN THE SUPREME COURT OF THE UNITED STATES

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HIKMA PHARMACEUTICALS USA INC.,)
ET AL.,)
Petitioners,)
v.) No. 24-889
AMARIN PHARMA, INC., ET AL.,)
Respondents.)

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Place: Washington, D.C.

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APPEARANCES:

CHARLES B. KLEIN, ESQUIRE, Washington, D.C.; on behalf of the Petitioners.

MALCOLM L. STEWART, Deputy Solicitor General, Department of Justice, Washington, D.C.; for the United States, as amicus curiae, supporting the Petitioners.

MICHAEL R. HUSTON, ESQUIRE, Phoenix, Arizona; on behalf of the Respondents.

C O N T E N T S

ORAL ARGUMENT OF:	PAGE:
CHARLES B. KLEIN, ESQ.	
On behalf of the Petitioners	4
ORAL ARGUMENT OF:	
MALCOLM L. STEWART, ESQ.	
For the United States, as amicus curiae, supporting the Petitioners	14
ORAL ARGUMENT OF:	
MICHAEL R. HUSTON, ESQ.	
On behalf of the Respondents	31
REBUTTAL ARGUMENT OF:	
CHARLES B. KLEIN, ESQ.	
On behalf of the Petitioners	64

P R O C E E D I N G S

(12:23 p.m.)

CHIEF JUSTICE ROBERTS: We'll hear argument next in Case 24-889, Hikma Pharmaceuticals versus Amarin Pharma.

Mr. Klein.

ORAL ARGUMENT OF CHARLES B. KLEIN

ON BEHALF OF THE PETITIONERS

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

Under Section 271(b) of the Patent Act, selling a product suited for both infringing and substantial non-infringing uses is lawful unless the seller actively induces the infringing use. Congress later passed -- Hatch-Waxman Section viii to ensure that one infringing use will not foreclose selling a generic drug for a second non-infringing use. So public statements entirely consistent with selling skinny-label generic drug products under Section viii cannot actively induce infringement.

Under our approach and the one advanced by the United States, "actively induced infringement" when dealing with

statements requires a clear message that necessarily promotes infringement. The Court applied this standard in Grokster and more recently in Cox.

Active inducement cannot depend on whether doctors might read infringing instructions into product descriptions that, on their face, are entirely consistent with non-infringing use. Amarin argues that generic drug companies must constantly discourage infringement with disclaimers that are explicit. But that turns the statute on its head.

Agreeing with Amarin, the Federal Circuit basically swapped the statutory term "active" for its antonym, "passive." And under the decision below, patent lawsuits filed after skinny-label product launches will routinely survive a pleading challenge. This shuts the Section viii pathway down. Generic companies won't choose that pathway if, at best, it means paying millions in legal fees and, at worst, a massive damages award.

Reversal is needed to harmonize Section viii with Section 271(b) and to

encourage legitimate competition that reduces drug prices.

I welcome the Court's questions.

JUSTICE THOMAS: Wouldn't it have been safe to just simply say that -- that the generic drug was -- was only approved for the SH indication and nothing more?

MR. KLEIN: Your Honor, Hikma did say that when it launched its product in the November press release, and it did say that on the accused website. But the law does not require that. In Grokster and Cox, the Court made clear that failure to take affirmative steps to prevent infringement is -- is not what the standard --

JUSTICE THOMAS: But what if you -- what if Respondent had engaged in a certain degree of self-adulation and said that this is a great product for this, that, or the other, and you merely quoted it? Wouldn't that almost be baiting people into inducement -- or inducing people into using the product more broadly than the unpatented use?

MR. KLEIN: The hypothetical is a -- is a little vague, but if -- if Hikma or a

generic were to send a clear message that --

JUSTICE THOMAS: Well, not using your language but using their language. They have patented uses that they think are great, but you could -- why didn't you -- you simply quote them. Wouldn't that be a way to induce?

MR. KLEIN: If -- if Hikma quoted Amarin --

JUSTICE THOMAS: Yeah.

MR. KLEIN: -- with regard to its cardiovascular use --

JUSTICE THOMAS: Yeah.

MR. KLEIN: -- that could plausibly state a claim if -- if it's a clear message that necessarily promotes infringement.

The -- the Grokster Court addressed a similar type of situation when distinguishing the Sony case and -- and -- and distinguished statements like "record favorite shows on your Betamax" and said that does not encourage conduct that necessarily infringes, and, therefore, that's not actively induced infringement.

And if you don't actively induce infringement, you fall under Section 271(c) --

JUSTICE THOMAS: I'm -- I think what I'm asking you is, is the only way to actively induce infringement is -- overstating or your own statements sound as though the patented use is covered by your product, as opposed to simply quoting the Respondent's website or statements about its product, which is patented?

MR. KLEIN: I -- I'm not saying there is any kind of magic words standard. And if -- if the generic basically adopts by reference statements by the -- the -- the brand that would -- that would encourage the infringing use, then that could plausibly state a claim.

JUSTICE SOTOMAYOR: Do you need any of the special rules that you're claiming we have to announce to win this case? Does this pass Twombly and Iqbal?

MR. KLEIN: It does, and -- and our --

JUSTICE SOTOMAYOR: It passes Twombly and Iqbal?

MR. KLEIN: Our case, yeah.

JUSTICE SOTOMAYOR: Yeah, meaning --

MR. KLEIN: Easily.

JUSTICE SOTOMAYOR: -- the complaint

here --

MR. KLEIN: The complaint --

JUSTICE SOTOMAYOR: -- is adequate under Twombly and Iqbal?

MR. KLEIN: Oh, I'm sorry. I'm sorry. I thought you -- I -- I misunderstood the question. The -- no, the -- the complaint does not pass the standard for plausibility under Twombly and Iqbal. Our argument --

JUSTICE SOTOMAYOR: That -- that -- that's the point --

MR. KLEIN: Yes, yes.

JUSTICE SOTOMAYOR: -- which is you're asking us to announce --

JUSTICE THOMAS: Yeah.

JUSTICE SOTOMAYOR: -- rules that -- that -- almost impossible in this area because determining whether or not there's active inducement is always contextual.

I think Grokster said that one of the factors it used was that the name that the infringer was using was suggestive of the infringement. So that wasn't a express statement of any way to infringe. It was a -- suggestion. But, in context with other things,

it reached active inducement.

I'm asking a very simple question. You don't need all of the things you've been arguing about to win under Twombly and Iqbal, correct?

JUSTICE THOMAS: No.

MR. KLEIN: That is correct. I -- the statements here, as the government called them, were anodyne. They -- they -- they were unoffensive. They were totally consistent --

JUSTICE SOTOMAYOR: Now I do know that we make life hard because we say we're not going to take on error correction, so you had to make up a rule of some sort, but it seems like everything you say, like somehow you need express statements as opposed to what we have said, you need active inducement.

You want to change the words, but do we need to change any of our standards for you to win?

MR. KLEIN: No, Your Honor, because there are obvious alternative explanations in view of the anodyne statements. Every single accused statement has an -- has an explanation that is entirely consistent with

non-infringement.

JUSTICE SOTOMAYOR: All right. Thank you, counsel.

JUSTICE JACKSON: Can I ask you a similarly straightforward question? With respect to Amarin's allegations concerning the label, I had understood that by statute, generics have to have a label that essentially, in all relevant circumstances, mirrors the brand label, except for just admitting the patented indication. Is that correct?

MR. KLEIN: That is correct. It's called the sameness requirement. That's by statute. Now --

JUSTICE JACKSON: So it's -- it's -- it's -- so even if Amarin is right that it thinks that -- that Hikma could have or should have excluded a certain study or included the -- some other information, if those aren't on the original label, Hikma can't do that?

MR. KLEIN: Hikma cannot change the label, but I want to be clear about something because Amarin supplied to the FDA the sections that Amarin thought pertained to its patent.

And then the way the FDA, they --

the -- the skinny-label process works is the FDA compares what Amarin says is patented in the label to the proposed skinny label, and it's a ministerial role. If -- if the generic carved out everything that the brand said is patented, then the skinny label can be approved. And the generic can't add new disclaimers or -- or new language.

JUSTICE JACKSON: Or anything else. And it can't be accused of inducing infringement by refusing to put things on the label that the brand didn't have, right?

MR. KLEIN: That's true because of the statutory scheme. That's true because Grokster and Cox says there's -- they're -- the statute doesn't require active discouragement of infringement and for all of those reasons.

I -- I also want to point out how Grokster warned against trenching on regular commerce, and that is exactly the situation here because the regular commerce we're talking about here is commerce that's encouraged by Congress. It's -- it's Section viii skinny-label products.

And as a practical matter, under the

decision below, you can get of -- FDA approval of your skinny product label, but as soon as you put that product into commerce and you say anything about that product, anything, you call it a generic version, even if you have disclaimers, you can be sued.

And that lawsuit will survive a pleading challenge. And that sends a -- a terrible message to the generic industry. Hatch-Waxman was designed to resolve patent disputes before a product launch for the -- for the reason that it's the -- it's an economic reason.

Once a generic launches its product, its profits will be much, much lower than the brand's profits. And so, if the generic gets hit for a lost profits damages award, it's devastating.

This happened in the GSK case with Teva, and Teva got hit for hundreds of millions of dollars that dwarfed its actual profits. And that is what the decision below is encouraging, and that's why we -- we are urging the Court to reverse.

CHIEF JUSTICE ROBERTS: Anything else?

Anything else? No?

Thank you, counsel.

Mr. Stewart.

ORAL ARGUMENT OF MALCOLM L. STEWART

FOR THE UNITED STATES, AS AMICUS CURIAE,

SUPPORTING THE PETITIONERS

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

I'd like to begin with two very brief observations. The first point is that although the Federal Circuit appropriately said that the label itself was not sufficient to get the -- Amarin past 12(b)(6) in this case, we think the court of appeals erred in giving any weight at all to the label.

The contents of a Hatch-Waxman skinny label are largely dictated by federal law, and to treat the generic manufacturers' compliance with those requirements as any evidence of intentional inducement to infringe would be wrong.

The second thing is, when Respondents explain in their brief why they sued Hikma but haven't sued any of the other generic manufacturers of -- icosapent ethyl, their

explanation is all of those other manufacturers included in press releases express disclaimers to the effect that their product is not authorized for use to treat the CV indication. But it's a bedrock principle of inducement law that active inducement to infringe is required. The question is not whether the defendant has adequately warned people away from infringement.

I welcome the Court's questions.

JUSTICE THOMAS: What would Respondent have to have alleged to survive a motion to dismiss?

MR. STEWART: I think they would have had to --

JUSTICE THOMAS: In your world, not the Fed Circuit's world.

MR. STEWART: In -- in our world, the -- the Respondent would have had to -- to identify statements or actions that had the clear purpose of induce -- of causing others to infringe as something that the -- the brand wanted to bring about.

The Court in Grokster said it was with reference to copyright, but it was drawing on

copyright -- on patent law principles.

The Court said one who distributes a device with the object of promoting its use to infringe copyright, as shown by clear expression or other affirmative steps taken to foster infringement, is liable for the resulting acts of infringement by third parties. And so they would have needed to point to statements or actions that clearly revealed a purpose to induce infringement.

JUSTICE THOMAS: What role -- what impact is it that occurs in states that encourage the use of the generics for the patented use? What does that have on the problem that the Respondent is having?

MR. STEWART: I mean, I -- I -- I think one of the principles that emerges from this Court's cases and from Cox most recently --

JUSTICE THOMAS: No, I don't mean on this. I mean with the problems of the -- of the unpatented -- the generic being used for uses that are still patented by Respondent.

MR. STEWART: I mean, the preliminary point I would make is the perceived difficulty

or the actual difficulty of going after the direct infringer or getting the direct infringement to start -- to -- to stop is not a justification for watering down inducement principles.

JUSTICE THOMAS: Yeah.

MR. STEWART: Now there are other things that Respondents could try to do and some of them they have tried to do. They sued Health Net in this case, and they separately alleged that the health insurer, through its reimbursement policies, was encouraging pharmacies to fill the drug fully.

JUSTICE THOMAS: But aren't some states doing that too?

MR. STEWART: I mean, states certainly have these generic substitution laws. And I'm not sure to what extent states are regulating the health insurers, but, certainly, Amarin and similarly situated companies could urge state legislatures to take measures to prevent this from happening.

The other thing they could do, I understand they don't want to sue the doctors, but they could attempt informational campaigns

to doctors and tell the doctors our product is the only one that is authorized to be used for the CV indication. It would be infringement of patent to administer icosapent ethyl for the purpose of reducing cardiovascular risk.

And the doctor really is in the best position of any other -- any single actor to say for what purpose am I prescribing the drug and at least in theory could figure out is there a patent on one method of use and adjust prescribing practices accordingly.

CHIEF JUSTICE ROBERTS: I understood that the test that you articulated is that the -- what was required -- is that the generic person clearly reveal a purpose of infringement, is that --

MR. STEWART: Act -- acts or messages that reveal a clear intent to encourage infringement.

CHIEF JUSTICE ROBERTS: That's a pretty broad safe harbor. I mean -- really just have to have, you know, a seminar on your first day of work and say whatever you do, don't -- don't do that. It's a pretty easy -- it -- it's a pretty high threshold -- or low

threshold.

MR. STEWART: I -- I mean, it is supposed to be a -- a difficult standard for the pleader to -- satisfy, but I think that's for design. That is, the Court has said in various contexts that when a product is capable of both infringing and non-infringing use -- uses, it's important that a patent on one method of use not become a de facto monopoly on the product as a whole.

And so it's supposed to be feasible for people in Hikma's position to market their product for the unpatented use without running afoul of liability for third parties who choose to use the product in infringing ways. Unless they have affirmatively encouraged that to be done, the -- the mere knowledge that it will be done or the expectation that some people will infringe is not enough.

JUSTICE JACKSON: And the risk of liability and what it could do to a generic, I would think, would be pretty significant.

MR. STEWART: It -- it's very substantial in part because the generic is charging a lot -- typically, a lot less for the

drug than the brand-name manufacturer is. And so, if the generic has to pay lost profits to the -- the brand name, the profits that the brand name would have earned on a particular volume of sales would -- would be much more than the generic has actually earned.

JUSTICE JACKSON: And the product is substantially similar. I mean, that's why it's a generic. So -- in other words, there's no defense that, well, we really have a different product here. We -- they -- it's -- it's the generic of the drug, and so, if they're also liable absent active inducement for people taking their generic and using it in an infringing way, you would think that could happen a fair amount, and it would really be a risk to the bottom line of this generic company.

MR. STEWART: Yes. I mean, there -- there is an intimation -- more than an intimation in the Respondents' brief that Hikma was doing something wrong by describing its drug in press releases as a generic version or a generic equivalent of Vascepa.

But, in fact, that's a -- a -- a

normal thing to say. It really refers to two different things. One of them is, under the abbreviated new drug application process, the generic comes on the market not by conducting independent studies of safety and efficacy but by showing that it is equivalent to a drug that's already been found safe and efficacious.

And so, when Hikma says we're the generic version of Vascepa, they just mean Vascepa is what's called the reference listed drug. It -- it is the drug as to which we've established equivalence in order to get approval.

The second thing is that the patents in these cases refer to methods of reducing cardiovascular -- risk of cardiovascular events or cardiovascular death, and the method they describe is the use of what the patent refers to as ethyl icosapent in various ways, a -- a series of steps with certain types of patients.

And everybody agrees, if Hikma's drug is used to reduce the risk of cardiovascular death or events through the performance of those steps, infringement will occur. The reason that's so is that Hikma's drug is ethyl

-- icosapent. It's the same stuff. And it's the same stuff for infringement purposes, but it's also the same stuff for describing the product.

JUSTICE KAVANAUGH: Can you explain the United States' concerns about the broader market implications of the decision?

MR. STEWART: I -- I mean, I think we would divide the -- the -- what the Federal Circuit relied on into three categories. The one we were most concerned with was the skinny label because all of the things that Amarin is complaining about are things that were on the brand name's label, and the rule is the generic is supposed to use the same label as the brand unless there's a good patent-specific reason to take things off.

And so the Federal Circuit, I think, thought it was being limited by saying the label by itself is not enough to get past 12(b)(6), but the flavor of its opinion was this is almost enough, and if you have some pretty ethereal stuff at the -- in addition, that will be enough to get you over the hump. And we think it shouldn't have attached any

weight to the label. Hikma just did what it was supposed to do.

And then the second thing is the description of the -- Hikma's generic product as the generic version --

JUSTICE KAVANAUGH: I understand that, but the interest -- the implications of the decision in the marketplace at large, I understood -- do you want to speak to that or not speak to that?

MR. STEWART: Yes. I mean, I -- I think the FDA's view is it -- it is too soon to tell exactly what the effects of the Federal Circuit's decision would be on the willingness of other generic manufacturers to enter the marketplace. And, in part, I assume that generics are waiting on this Court's decision in this case, but we certainly think that if the Federal Circuit's analysis were affirmed, that it would create a substantial disincentive to entering the generic market.

JUSTICE ALITO: What if --

JUSTICE KAGAN: Your point -- no, go ahead.

JUSTICE ALITO: What if Hikma -- Hikma

had -- had not just said its drug is generic Vascepa but went on to say that Vascepa is approved to treat cardiovascular risks?

MR. STEWART: I think if it had said those two things in the -- in the same breath that you would have a pretty strong case of active inducement, that it would not take much work to connect the dots that this is something Vascepa has been approved for and ours is the same stuff.

JUSTICE ALITO: What if it had said studies have shown that icosapent ethyl, the active ingredient in our drug, reduces cardiovascular risks?

MR. STEWART: I think that would be problematic as -- as well, although probably closer to the line, but one thing I would say about the label is, when Hikma prepared its skinny label in conformity with the rules, kind of the most obvious thing it took off of Amarin's label was the indication at the beginning.

But a second thing that it took off of Amarin's label was, in the clinical studies section of Amarin's label, Amarin -- summarized

the results of what they call the REDUCE-IT study, which was designed to test the efficacy of the product for reducing cardiovascular risks, and the study concluded that Vascepa was efficacious for this purpose. And --

CHIEF JUSTICE ROBERTS: I -- I see your red light is on. Thank you.

MR. STEWART: Okay.

CHIEF JUSTICE ROBERTS: Justice Thomas?

JUSTICE THOMAS: No.

CHIEF JUSTICE ROBERTS: Justice Alito?

Justice Sotomayor?

JUSTICE SOTOMAYOR: I ask the same question of you that I asked of Petitioners' counsel. Do we need your new definition that you gave the Chief or saying again that following the label alone, exactly what the Federal Circuit said, is not enough? Do we need any special rules --

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

JUSTICE SOTOMAYOR: -- for Petitioner to win?

MR. STEWART: I -- I -- I don't -- think you need special rules. I -- the -- you

are interpreting Section 271(b), which is not specific to Hatch-Waxman. It's just the general inducement provision. And we think application of the general rules is sufficient.

JUSTICE SOTOMAYOR: Is enough? Okay.

MR. STEWART: Yes.

JUSTICE SOTOMAYOR: And then, finally, there's a whole lot of discussion about congressional policy, both in your brief and in Petitioners' brief, that they wanted to encourage this, and we should rule that what active infringement means in patent law is very narrow because of that.

I always have problems when we use policy reasons to set a standard.

MR. STEWART: Right.

JUSTICE SOTOMAYOR: That's not our job. If they're infringing a patent, they're infringing a patent. If they're not infringing a patent, they're not. But why should we change our rules, narrow them or expand them --

MR. STEWART: I don't --

JUSTICE SOTOMAYOR: -- to avoid either result?

MR. STEWART: I -- I -- I basically

agree. I don't think it's a main -- matter of changing the rules. We have described the Hatch-Waxman scheme at some length because it's pretty complicated. But, in the end, Hatch-Waxman embodies the same basic principles as the Patent Act generally; namely, if you sell something that can be used either in an infringing or a non-infringing way, then you still won't be held liable for others' infringement unless you've actively encouraged them to infringe.

JUSTICE SOTOMAYOR: That's the bottom line, correct? Thank you.

CHIEF JUSTICE ROBERTS: Justice Kagan?

JUSTICE KAGAN: Mr. Stewart, your point about not looking to the skinny label in a suit like this, I -- I guess the reasonableness of that depends on how much patent review the FDA is doing when it approves the skinny label.

So what's the answer to that question?

MR. STEWART: I -- I mean, I think the -- the Court discussed this in Caraco. The FDA has disclaimed patent expertise, and so it doesn't purport to read patents and determine

what conduct would infringe them.

But -- Respondents suggest that the result is we take the generics' word for what is and isn't infringing. And I think that that's not correct. As the Court -- explained in Caraco, the brand-name manufacturer will provide for the Orange -- Book what's called a use code, which will describe what it believes its patents cover, and the FDA considers itself bound by the use code.

And so, if the brand name is saying this wide range of uses would be patented, the FDA won't look behind that. There is a counterclaim mechanism by which the -- the generic can obtain judicial review of that determine -- of the brand's behavior in a suit between the two private parties.

But the -- kind of the bottom line is, here, there was really no dispute if the -- about what was patented. If there had been a dispute, FDA would have deferred to the brand's own description of what its patent covered, and then the question would just be, has the generic carved out enough of the label to excise references to the patented use?

And what I was saying before about the clinical studies, although Amarin's label had a description of the REDUCE-IT study that was about efficacy of the drug for treating -- or preventing cardiovascular events, Hikma omitted that from its own label. So it didn't just omit the indication. It omitted another part of the label that referred to the efficacy of the drug for that purpose because the purpose was still patented.

JUSTICE KAGAN: Thank you.

CHIEF JUSTICE ROBERTS: Justice Gorsuch, anything further?

Justice Kavanaugh?

Justice Barrett?

Justice Jackson?

JUSTICE JACKSON: Can I just ask you, what -- what is the relevance of the state laws that you cite permitting or requiring substitution of generics for brand-name drugs in this context? I would think those would be relevant to an Amarin lawsuit maybe against a third party, but I don't know why they matter here.

MR. STEWART: I -- I mean, I think the

Court can decide the case without referring to them. The -- we -- we had two basic reasons for including some discussion. The -- the first was we didn't want the Court to decide the case based on a misimpression of the facts or the way the world works. And I think portions of the court of appeals opinion are written as though, in -- in each case, the doctor who's writing the prescription determines which version of the drug will be dispensed and that will carry the day.

And we wanted to explain, in the real world, it's more complicated than that. And -- and kind of conceivably in some future case, that could matter given the way it was pleaded because you'd have to show, in light of these laws, how is it plausible that what we said would cause somebody to infringe.

JUSTICE JACKSON: I see.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

MR. STEWART: Thank you.

CHIEF JUSTICE ROBERTS: Mr. Huston.

ORAL ARGUMENT OF MICHAEL R. HUSTON
ON BEHALF OF THE RESPONDENTS

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

The implications of this Court's ruling in this case will go far beyond the pharmaceutical industry. This is not really a Hatch-Waxman case at all. It's not really a skinny-label case.

Hikma got the full benefit of the Hatch-Waxman compromise when it was permitted to sell its product for FDA -- with an FDA approved skinny label as a treatment for severe hypertriglyceridemia. But, in exchange, Hikma was required to promise not to promote its product for any still patented use of Amarin's branded drug.

That limitation on generic marketing of their products is absolutely vital. It is the only thing that makes it economically rational for a branded company like Amarin to spend the $300 million that Amarin spent in the REDUCE-IT trial to discover that an existing drug, Vascepa, actually had life-changing implications to treat cardiovascular risk. And

that rule of induced infringement liability is not unique to pharmaceuticals.

This Court's interpretation in this case will be of Section 271(b) of the Patent Act. That is the statute that protects all patented innovations in this country of whatever kind.

The standard for induced infringement liability is settled. In most cases, the key dispute is going to be whether the defendant had the requisite intent to infringe. But Hikma has not contested its intent as this case comes to the Court because the case is at the pleading stage.

Nor has Hikma disputed that there was substantial direct infringement of Amarin's patents using Hikma's product. So the only element that's in dispute here today is whether it is plausible that Hikma took active steps to encourage that infringement.

It is plausible. There are seven other generic manufacturers of icosapent ethyl on the market, but Hikma alone was the one who described its product as AB rated for "hypertriglyceridemia," even though that

product is not approved for that distinct medical condition.

Hikma alone repeatedly used Amarin's brand name, Vascepa, just at the moment when that name was synonymous in the market with treating cardiovascular risk. Those statements and more by Hikma that other generics did not use state a plausible claim.

I welcome the Court's questions.

JUSTICE THOMAS: Was there anything inaccurate about that statement?

MR. HUSTON: Yes, there absolutely was, Your Honor. And I want to just say for -- I -- there -- it was inaccurate. I also don't think, frankly, it matters whether it was inaccurate. A statement can be absolutely true. Imagine a statement that Hikma said you can use and should use our product to accomplish exactly the same medical purposes as Vascepa, including cardiovascular risk, the kind of example that I think Justice Alito gave to my friend, Mr. Stewart.

And I heard Mr. Stewart say that would state a claim for -- a strong claim for induced infringement. I agree with that. So truth is

not a defense to liability in an induced infringement situation.

JUSTICE THOMAS: So what if they simply quote you?

MR. HUSTON: I think they can't -- they cannot do that, Your Honor, because the whole point of the compromise is that Hikma is allowed to market its product but only for the unpatented use, only as a treatment for severe hypertriglyceridemia.

If Hikma comes on and quotes Amarin's marketing of its product to treat the -- for the patented purpose, that's the most classic case of induced infringement. That's like the literal textbook definition of induced infringement.

I -- I also do think it's important to say, though, that -- the -- the key statement on which we rely here, the statement on Hikma's website where it described what its drug is for, was not accurate. Hikma said its product was for treating hypertriglyceridemia. That's misleading, if not false, because Hikma's product was approved by FDA only to treat severe hypertriglyceridemia, and that's a

distinct medical condition that presents distinct medical risks.

JUSTICE GORSUCH: Well, if that's your best piece, and I think it probably is, that website, what do you do with -- there was a further disclaimer on the website saying that the product was -- Hikma's generic version is indicated for fewer than all approved indications of the reference listed drug?

MR. HUSTON: Sure, Your Honor. So two points about that disclaimer, which is at JA 195. First, as you can see even on the blown-up version in the Joint Appendix, it really appears in quite tiny print, but even if the -- even if somebody read it, even if they saw the disclaimer, just as Your Honor read, all it says is Hikma's product is approved for fewer than all uses of Vascepa.

It doesn't disclaim that Hikma's product can and should be used to treat the most famous use of Vascepa, the billion-dollar use, which is -- saving patients' lives by treating cardiovascular risk.

So there's nothing -- the disclaimer is, I think, at best, carefully worded, it's

sort of written by a clever lawyer to try to minimize Hikma's liability while still sending the fundamental message that is coming across by all the collection of Hikma's statements that says doctors can and should prescribe Hikma's product anytime they would prescribe Vascepa, including to treat cardiovascular risk, in a way that infringes Amarin's patents.

So I --

JUSTICE BARRETT: Oh, go ahead.

MR. HUSTON: I just think having rang the bell, Your Honor, having repeated -- when Hikma has come on to the market repeatedly and said we are generic Vascepa, generic Vascepa, generic Vascepa, a billion dollars in sales, our product is for hypertriglyceridemia, having made all of those offensive statements that are calculated that have the intent to induce infringing sales, that tiny little sort of cleverly worded disclaimer I don't think is sufficient to pull that back.

JUSTICE BARRETT: Mr. Huston, I just wondered, if you -- you started in your opening talking about the impact of this case that would be more broad, that it would extend

beyond just the pharmaceutical industry.

It seems to me this is a pretty fact-bound case about the plausibility standard. I don't know that we have to -- to reach any kind of greater issue. So do you see the case that way? Is this just kind of applying Twiqbal to this particular complaint?

MR. HUSTON: I -- I do see the case that way, Your Honor. We -- we -- that's what we argued in our brief in opposition.

And I think that it's not this Court's typical practice to grant a case that asks merely whether the facts as pleaded under the -- you know, a settled legal standard states a claim.

All that said, you know, of course, we -- we -- we -- we continue to think, and I -- I -- I do want to think -- I do think it's very important to say, it is important, as I think the -- was the premise of Justice Sotomayor's questions, that the Court not adopt a new induced infringement standard with words like express promotion is required.

I -- I -- I can't -- I just can't understate the extent to which that would be a

transformation of the scope of patent law. So, if the Court is going to simply apply Twombly and Iqbal to the facts of this case, and I -- I do think that's the right approach to the case, then I continue to think that the key question in the case is in -- in -- as in most cases of induced infringement, what was the message that the doctors who read these Hikma statements took away? And that's a -- typically a fact question.

JUSTICE BARRETT: I -- I agree that's the key question, it is a fact question, and, you know, Justice Alito observed the other day, I'm not sure why this case is here except four of my colleagues wanted it to be.

But, if it is a fact-bound question, what I'm asking is, if the case is as you just described it, what's the broader impact? You know, in the -- in your -- are you talking about broader impact solely if we reached some new rule?

MR. HUSTON: Yeah. No -- I -- I -- I'm totally --

JUSTICE BARRETT: Okay.

MR. HUSTON: Let me -- I appreciate

the opportunity to clarify.

If the Court says that even though this case is at the pleading stage, even though it's only a plausibility pleading standard, these allegations of intentional -- intentional statements by Hikma where intent is undisputed, that that doesn't even state a claim for relief, I do think that's going to have serious implications. It's going to make it much, much harder to plead induced patent infringement.

And I think that's going to have implications both in the patent space more generally but even in the pharmaceutical space because, as I mentioned, if -- if -- if a -- if a branded drug like Amarin cannot get any kind of protection for a new -- this newly discovered use of its existing drug, it would just be economically irrational to make that kind of investment that discovers a lifesaving cure.

And I think that's what we are really fighting for in this case, is the opportunity to say: We spent five years, we spent $300 million, and we discovered something that is literally saving people's lives. Hikma wants

to come and, having spent no money basically at all -- and try to capture all of those gains.

The patent law doesn't allow them to do that. They are allowed to sell their product for the unpatented use. But -- when we have discovered this game-changing "new use," Hikma can't come in and try to capture those -- those -- those sales. That's what it did with its repeated statements by calling itself generic Vascepa over and over again by --

JUSTICE KAGAN: Would -- would --

JUSTICE KAVANAUGH: What --

JUSTICE KAGAN: -- would you contest, Mr. Huston, that these press releases were really issued for investors, that they had nothing to do with -- this was not the way the company marketed itself to doctors?

MR. HUSTON: I -- I would contest that, Your Honor, I -- especially because we're at the pleading stage, where all inferences that are fair have to be taken in our favor.

I think Hikma's claim that these were directed at investors is really just grounded in the fact that there's a "Contact Us" section of the press release that allows you to get in

touch with the investor relations team, in addition to other kinds of, you know, phone numbers provided. So they're not consciously directed at investors, not expressly directed at investors.

And I think two other points about that. First, Hikma spread these messages far and wide. It wanted --

JUSTICE KAGAN: I mean, is there any evidence at all that Hikma directed these to -- to the medical community, that Hikma gave these press releases to doctors?

MR. HUSTON: So I -- I think the answer is yes in the sense that these -- this is advertising, Your Honor, which is, as Grokster said, a classic form of induced infringement since common law. Hikma, the -- the -- our allegations are -- we don't have evidence; we're at the pleading stage -- but the allegations we have are that Hikma took these press releases and intentionally attempted to make them get distributed as far and widely as possible. It did want doctors to see these things.

And evidence has come in in other

cases where doctors have testified that they do pay attention to press releases and that they do pay attention to the announcements of when generics are coming online, and those kinds of announcements do affect doctors' prescription decisions.

So that's all evidence that, you know, we're going to put on -- you know, that -- those -- we're going to use the Federal Circuit's established standards for pleading -- or for proving induced infringement claims. It only has to be plausible at this stage. And I don't think it's a fair inference -- I don't think you can say the only fair inference from Hikma's statements is that they were directed solely at investors and were not going to reach doctors.

JUSTICE KAVANAUGH: But I guess, to your initial statement when you started out saying this is not a Hatch-Waxman case at all, I think you said that, and to why this case is here, because I'm glad it's here, the federal -- Congressman Waxman filed an amicus brief. And I don't want to put too much faith in a former Congressman's brief about his own

statute, but it says, "the Federal Circuit's decision threatens to decimate the compromise at the heart of the Hatch-Waxman Act, which, in turn, threatens to undermine the generic pharmaceutical -- industry if this kind of complaint's good enough." And points out, you know, "generics have saved 3.4 trillion over the past 10 years, but the Federal Circuit's decision here leaves generic drug companies in the dark about what might expose them to liability."

All of which just to say I think the question is, you know, if this is good enough, then that's going to have some serious implications market-wide.

MR. HUSTON: So, Justice Kavanaugh, maybe two or -- maybe three points if I might in response to that.

First, when we say "if it's good enough," all we mean is good enough to get out of the starting gate, to get into discovery, where we're going to have the opportunity -- we're going to be held to the burden to prove everything that we allege. That's the first point.

The second point about Hatch-Waxman is that the reason it's named Hatch-Waxman, of course, is that it was a fundamental compromise, and on the other side of that compromise was about protecting the need to encourage branded drugs to take existing products and -- invest massive resources to discover how those drugs can be used for new cures.

The dark green briefs are replete with examples of situations where that has happened. It can only happen, it's only economically rational to occur, if they can get patent protection for that subsequent use.

JUSTICE KAVANAUGH: Yeah.

MR. HUSTON: And then I think the last --

JUSTICE KAVANAUGH: I don't dispute that there's a compromise. I was just making the point that, you know, I take it seriously when someone says this is upsetting the compromise.

MR. HUSTON: Well, I -- I think the -- the -- the last reason why the Court can have confidence that that is not going to come to

pass, Your Honor, is the example of the many other generics who sell the very same product that Hikma does, and we haven't sued any of them.

And you can look at what they say on their press release to know that generics have a ready roadmap to avoid -- induced infringement liability. All they have to do is accurately describe the limited purpose for which their drug is approved.

So, for example, Camber, one of the other generic manufacturers, it says, "Camber's press release is indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia." It doesn't talk about generic Vascepa. It doesn't talk about the volume of sales of Vascepa and say this is a billion-dollar revolutionary drug. It doesn't say that it is in a therapeutic category of hypertriglyceridemia. And, again, that's a different medical condition. So Camber, Zydus, Dr. Ready's, they all -- none of them do the things that Hikma did.

JUSTICE JACKSON: Well, counsel --

JUSTICE ALITO: Are you just saying --
JUSTICE JACKSON: -- can I --
JUSTICE ALITO: -- just -- are you just saying generic Vascepa would be enough?
MR. HUSTON: I do not think, Your Honor, that merely saying one time generic Vascepa is enough to state a claim for liability. And that's not our allegation. Our allegation is that Hikma said it over and over and over again and that they did it at just the key moment where there was a market -- a market -- key market association between Vascepa and treating cardiovascular risk.
That was the context. Grokster says, of course, that induced infringement is a context-dependent analysis. That was the context into which Hikma launched these statements over and over and over again.
But I -- I take the point. I'm certainly not here to say that a company that one time says generic Vascepa is going to be held liable. As the Federal Circuit held, Hikma did much, much more. It made statements that no other generic manufacturer --
JUSTICE JACKSON: But, counsel, I

guess it -- it seems to me you -- you do emphasize that we're talking about plausibility and this is early in the case and we're at the motion-to-dismiss stage. But that does highlight what has to be plausible, what is the focus of this.

And the government here, the SG, says what we're looking for is an intent on the part of this manufacturer to be inducing people or to have doctors be using this drug for the patented purpose.

Your standard, as far as I can tell, is more just what message would the doctors have taken away from the marketing materials. And, as Justice Kagan pointed out, at least some of these marketing materials, I think, were directed to investors.

So the -- if the intention of the generic is to mention Vascepa and the size of the market, et cetera, et cetera, for the purpose of getting investment, not for the purpose of inducing doctor infringement, what do we do with that in terms of understanding whether active inducement liability lies?

MR. HUSTON: A couple points about

that, Justice Jackson. I think the first is that, of course, at this stage of the case, your own -- your -- you can't just take Hikma's assertion that, oh, we put out that press release for the purpose of talking to our investors.

JUSTICE JACKSON: No, but it's your burden if we are supposed to be looking for intent. And I guess that's why I think we do have to kind of focus on what the legal standard is here. If -- if -- if we are looking for intent to induce infringement, then I would think it's your burden to actually have statements and evidence that go to that.

And if we look at those statements and we say, yes, we see them, but, really, those statements that you point to are indicative of an intent to encourage investors, then why have you stated enough of a claim in this circumstance?

MR. HUSTON: I understand the question, Your Honor, but I -- I -- I want to stress the Federal Circuit found that it was undisputed -- that's their word -- that in -- Hikma did not contest the requisite intent.

That's at Pet. App. 15a.

Hikma's motion to dismiss in this case did not say, unlike most other skinny-label cases where intent, along the lines of Your Honor's question, would very much be the focus and where I'm sure Hikma at trial will attempt to -- to prove exactly the kinds of things that Your Honor --

JUSTICE JACKSON: But is -- is the Federal Circuit right about that?

MR. HUSTON: Yes --

JUSTICE JACKSON: I don't know that we can disaggregate. I mean, they've -- they -- they might have -- Hikma might have said, we're not really focused on our intent to induce something or our intent to have people buy more of this product.

But, if the active inducement element of this is what we're all focused on and active inducement requires an intent to induce doctors to use this product, then I don't know that their concession about intent really covers this particular circumstance.

MR. HUSTON: So, Your Honor, I -- I mean, the Court has always talked about those

as distinct elements of induced infringement. There are three elements. There has to be direct infringement. Somebody has to do the infringing. And then the inducer has to both have the intent that that happen and take active steps.

JUSTICE JACKSON: I understand, but the United States today said the active inducement -- active steps prong of this is statements and acts that are -- that demonstrate an intent to induce the doctors. So they brought intent into the very element we're talking about here.

MR. HUSTON: There's no way to reconcile that conception of the -- of the standard with this Court's case after case after case --

JUSTICE JACKSON: So they're wrong about that?

MR. HUSTON: They're wrong --

JUSTICE JACKSON: All right.

MR. HUSTON: They're just distinct elements --

JUSTICE GORSUCH: Well, how --

MR. HUSTON: -- and the intent element

isn't part of this case at this stage.

JUSTICE GORSUCH: I -- I -- I'm sorry to interrupt. Go ahead and finish.

MR. HUSTON: I -- I'm just -- I -- I'll -- I just want to say that, I mean, the Court has always talked about them as distinct elements. The Federal Circuit found that Hikma had not contested the intent element. I think -- actually, I thought it was common ground between all of the parties that we're only here talking about what constitutes active steps. These are active steps in the sense that Hikma put out statements.

And then I think the only question we're left with is the one Justice Barrett flagged, which is how is a listener going to understand those statements? That's a fact question that's typically not suitable for resolution on summary judgment. That's the crux of our case.

Justice? I'm sorry.

JUSTICE GORSUCH: I'm not even sure I want to ask my question anymore, Mr. Huston.

(Laughter.)

JUSTICE GORSUCH: Let me come at it

this way. I understand your -- your -- your point about this case being a little different, but, you know, Twombly/Iqbal talking about whether you have an antitrust conspiracy versus maybe what is entirely rational independent conduct, right?

MR. HUSTON: Yes.

JUSTICE GORSUCH: The Baby Bells, right?

MR. HUSTON: Yes.

JUSTICE GORSUCH: Are not to compete in one another's territory.

MR. HUSTON: Yes.

JUSTICE GORSUCH: It seems like a whole different world.

At any rate, there, the question was, hey, everybody knows that they're not going into each other's territory, but it could be explained by two possible intents, and it was the burden of the plaintiff to rule out, plausibly rule out, the non-problematic intent.

And I -- I think what Justice Jackson is getting at is, why isn't this case just like that? The -- why isn't that the question? I understand your point that, well, they didn't

contest it, but it is your burden on -- on a motion-to-dismiss stage to -- to rule out that lawful intent, hey, this is puffery for investors, and this can be plausibly explained by -- by that rather than infringement.

MR. HUSTON: I -- I think I would say two things, Your Honor. The first is that it -- it's -- it's very hard for me sitting here in the Supreme Court of the United States to put myself in what arguments we would have made if Hikma in a motion to dismiss had said we want to contest our unlawful intent the same way the defendant in Twombly contested its intent.

You're absolutely right. Twombly was an intent case. That was where all the action in the case was. Did the defendants have an unlawful intent? Hikma did not contest its unlawful intent at this stage.

JUSTICE GORSUCH: Okay. I got you.

MR. HUSTON: So I just think it's a different -- but, I mean, the other -- the other point I would make is, though -- even that kind of intuition, even a -- if you -- if you think, okay, there's a -- there's an

alternative explanation for the press releases, which is what -- that they were aimed at investors, that cannot explain Hikma's website, where it's described its -- it describes its product as a treatment for hypertriglyceridemia, the infringing use, instead of, as all the other generic companies do, as a treatment --

JUSTICE GORSUCH: Got you.

MR. HUSTON: -- for severe hypertriglyceridemia use.

JUSTICE GORSUCH: I got you.

MR. HUSTON: So here again, I think you're -- you can't -- even that conception of the case cannot carve out all of the allegations we have made, all of which add up together to support Hikma's unlawful intent and their active steps that have the effect of inducing infringement. And that is fundamentally what we're going to be held to the burden to prove, as in all other cases of induced infringement.

We're going to show that the infringing sales of our product happened faster and to a greater degree than would have

occurred had Hikma not made these statements. And so, again, I -- I understand the Court's -- concern about the idea that, you know, and I think my friends have attempted to say this is going to devastate the generics market. Nobody wants to devastate the generics market. But it's just factually not true.

And the surest reason you can know it's not true is because there's seven other generics in this market selling this product who know how to market their product lawfully. And all that Hikma needed to do was follow that path and they wouldn't be here, just like the other generics aren't here.

JUSTICE KAGAN: Mr. Huston, my sense of your papers in this Court as compared maybe to your papers below is that you've really dialed down your reliance on the skinny label.

So could you tell me why that is if I'm right about that, and -- and more to the point maybe, what is your view of the relevance of the skinny label? Would you go -- would you accept Mr. Stewart's proposition that that label has no relevance? And, if not, why not?

MR. HUSTON: Sure. So, Justice Kagan,

I would not accept Mr. Stewart's proposition that that has no relevance, and I think the -- I think the reason for that is that this Court is not accustomed in pleading cases and in Section 271(b) cases to saying there's a category of evidence that's sort of fundamentally off the table. That to me sounds like the creation of a safe harbor, and I think that's a legislative task fundamentally.

Now, to be sure, Hikma has -- you know, I -- I don't think Hikma could be held liable -- or, you know, I -- I -- I -- I think that there is a protection in the statute in Hatch-Waxman for -- for Hikma to -- prepare a skinny label.

That's why, as the Federal Circuit said, the skinny label is not the heart of our case by any means. It is one piece of evidence.

JUSTICE KAGAN: Well, why should it be one piece of evidence?

MR. HUSTON: Sure. Because, again, I don't think that the Court has generally said there's sort of evidence that's off the table. But the way I think about the label in this

case, because keep in mind the label comes factually later in time.

So it's really at the moment that Vascepa is all -- getting all of this amazing press attention that doctors are prescribing it en masse to -- for -- to -- for the first time really effectively treat patients with severe cardiovascular risk. It's into that market that Hikma launches all of its offensive statements about generic Vascepa, billion dollars in sales, hypertriglyceridemia and the like.

Then it comes out with its label. And the way I think about the label is the label was an opportunity for Hikma to try to -- to sort of mitigate the damage from its unlawful statements and it didn't take it. And in that sense, I think the -- the Hikma label maybe -- you know, probably, arguably, exacerbated our harm.

But that's the way I think about the label. It's -- it is definitely not the -- the key contention that we rely on because, again, it's not the thing that distinguishes Hikma from all the other generic manufacturers.

They were -- it was -- those generics made all of these statements that Hikma did not make, and I think that's why they're here -- that's why they're not here and Hikma is. The label just was an opportunity missed by Hikma to try to control the extent of the infringement after they had already rang the bell.

I think I just want to spend one moment if I might talking about where the Court would go from here if it found that this is a Twombly/Iqbal case and that the allegations in the current complaint did not suffice to state a claim for relief.

I think, as we described in our brief, the Court's far and away most common practice in that situation would be to vacate the Federal Circuit's opinion and remand. It would not be to enter the form of judgment in this Court that Hikma requests, which would be to sort of declare the case over.

And I think that disposition, again, I -- you know, I -- obviously, we -- we hope that you will agree that the -- the -- the -- the complaint here does state a claim, but in

the event the Court didn't, it would be especially important for the Court to allow the case to proceed back on remand because, since the Federal Circuit remanded the case and since Hikma did not stay the mandate, extensive discovery has occurred. Millions of documents have been exchanged, 12 depositions have -- have -- have come -- have been taken, and that has revealed substantial new evidence of Hikma's intent to infringe and the effect.

JUSTICE BARRETT: So are you saying you'd amend your complaint?

MR. HUSTON: Absolutely, Your Honor. We would -- we very much want the opportunity to amend. That would normally be the course under the Federal Rules of Civil Procedure, and all I'm trying to say is I think the case for our opportunity to amend is even stronger here given that there -- the -- you know, there's been a material change in the case since the Federal Circuit's opinion. We've uncovered all of this new evidence.

JUSTICE KAVANAUGH: Well, Judge Andrews granted a motion to dismiss, right?

MR. HUSTON: Yes, Your Honor.

JUSTICE KAVANAUGH: Okay.

MR. HUSTON: But -- and we successfully appealed that judgment, so --

JUSTICE KAVANAUGH: I understand. I'm just talking about what happened in the district court.

MR. HUSTON: That's right. And so, yeah, again, the case has the same posture as all the cases cited on, I think, page 51 of our brief. A district court judge grants a motion to dismiss. We elect to appeal that judgment. We successfully appeal it. The Federal Circuit reverses. There is no stay of the mandate by my friends on the other side. The case returns to district court. Judge Andrews opens discovery.

And we take substantial discovery, and discovery does its job. It reveals that exactly what we allege about Hikma's intent and the effects of their statements is true.

And we haven't yet had an opportunity to bring that out, but, you know, obviously, in -- in this situation, we very much want that opportunity to bring that evidence. And what I don't think is supported is Hikma's sort of

very unusual ask that this Court would simply declare case over and --

JUSTICE GORSUCH: Well, we wouldn't -- we wouldn't enter judgment, but we would reverse and remand for further proceedings, consistent, and I would take it the Federal Circuit, that when -- that would then send it back to the district court. The district court would say, okay, the -- the motion to dismiss is granted, as I said many years ago now --

MR. HUSTON: Well --

JUSTICE GORSUCH: -- and -- and you could -- you could then file a motion for leave to amend. Is -- is that about right?

MR. HUSTON: I -- I think that -- I think -- I think that's about right, Your Honor, with a slight tweak. I think, actually, what would happen probably is the Federal Circuit would remand and we would then go to the district court and he would say, you know, there's -- I'm supposed to have further proceedings consistent with the Supreme Court's opinion. What should those proceedings be? Our proceed -- our requested proceeding is going to be an amended complaint.

JUSTICE GORSUCH: Yeah, yeah, of course. You'd move, yeah.

MR. HUSTON: And that's what -- all I'm saying is I think Hikma is trying to tell you --

JUSTICE GORSUCH: Yeah, no, right.

MR. HUSTON: -- we shouldn't have that right. And I just don't think anything in the law supports that.

JUSTICE GORSUCH: I just want to make sure the way I described it is -- how you'd foresee it.

JUSTICE KAVANAUGH: You agreed with Justice Gorsuch, right?

MR. HUSTON: I agreed -- I -- I -- I -- I agreed with -- I -- let me -- let me try to be as clear as I can. I --

JUSTICE KAVANAUGH: I shouldn't have asked it. I'm sorry.

JUSTICE BARRETT: I thought you agreed with Justice Gorsuch.

MR. HUSTON: I think I mostly agree, and I hope I -- I hope I don't -- I hope I agree in full. But I -- I think the right way to think -- I don't -- I don't -- I just want

to make sure that there would be an -- the district court judge would entertain a motion to amend the complaint.

JUSTICE KAVANAUGH: Right.

MR. HUSTON: That's what we want an opportunity to do. That's what Hikma is telling you we should not have the opportunity to do. But, as long as we're --

JUSTICE GORSUCH: Yeah. But this Court doesn't normally weigh in on whether --

JUSTICE KAVANAUGH: We're not going to weigh on in on that. We would just remand.

MR. HUSTON: That is your --

JUSTICE KAVANAUGH: You can argue to the district court, right, as Justice Gorsuch said?

MR. HUSTON: I think that is your typical practice. Again, I'm trying to, you know, oppose the sort of extraordinary requests that I think my friends on the other side are asking.

JUSTICE KAVANAUGH: I'm sure they'll address it on rebuttal. Okay.

JUSTICE GORSUCH: Thank you.

CHIEF JUSTICE ROBERTS: Anything

further?

JUSTICE THOMAS: No. No.

CHIEF JUSTICE ROBERTS: Anything further?

Is there anything further down there? No?

Anything further?

Okay. Thank you, counsel.

MR. HUSTON: Thank you.

CHIEF JUSTICE ROBERTS: Rebuttal, Mr. Klein.

REBUTTAL ARGUMENT OF CHARLES B. KLEIN
ON BEHALF OF THE PETITIONERS

MR. KLEIN: Thank you, Your Honor.

I want to start by addressing this -- this point with no specifics that somehow new evidence came up in discovery that supports a claim for active inducement. Just to be clear, there is no such evidence, no evidence that Hikma somehow intended its archived prelaunch litigation-related press releases to induce infringement or its online product catalogue to induce infringement. Zero evidence.

The dismissal below also was with prejudice, and it was with prejudice because

Amarin conceded to that judgment. And so, if -- if the Court were to remand, it -- it -- the only thing left -- or, if the Court were to reverse and remand, the only thing left would be a Rule 60 motion, and Amarin could file that if -- if -- if they wish.

I do want to address this argument that the conduct element turns on how a physician would understand vague and equivocal statements. That -- that is not the standard when there's an obvious alternative explanation. Twombly and Iqbal make it very clear, if there's an obvious alternative explanation, a complaint doesn't survive the pleadings stage just because maybe some physician out there might possibly read an instruction to infringe into an equivocal or vague statement like generic version of Vascepa.

And there are obvious alternative explanations for all the accused statements in this case. The -- the press releases that are accused were all archived as of the launch. They concern litigation victories. And -- and -- and they -- the only indication

mentioned is Vascepa's non-infringing indication. At the time of launch -- and this is in the record -- the November 2020 press release, so this is when the product's first available, makes it clear the product is only accused -- the -- the product is only approved for the non-infringing indication and not approved for any other indication. And it has all the labeling information in the press release itself. That -- there's no way that induces infringement.

I do want to talk about the web page because I don't think my friend accurately characterized the web page. The web page refers to an AB rating for hypertriglyceridemia, which is a lot of jargon, but the jargon is conceded and explained in the complaint and in the decision below, and it means therapeutically equivalent only as labeled to reduce high triglycerides. That's what it means. The label is linked to the web page.

So there is no plausible way to read that web page as somehow encouraging doctors to go off-label and -- and use the product for a

patented method that has been carved out. That is not plausible. The obvious alternative explanation is the plain reading of -- of the -- of the web page.

I see I'm out of time.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

The case is submitted.

(Whereupon, at 1:24 p.m., the case was submitted.)

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10 [1] **43:**8
12 [1] **59:**7
12(b)(6 [2] **14:**13 **22:**21
12:23 [1] **4:**2
15a [1] **49:**1
195 [1] **35:**12

2

24-889 [1] **4:**4
271(b [5] **4:**11 **5:**25 **26:**1 **32:**4 **56:**5
271(c [1] **7:**25

3

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5

51 [1] **60:**9

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ab [1] **32:**24
abbreviated [1] **21:**3
about [48] **8:**7 **10:**4 **11:**22 **12:**22 **13:**4 **15:**23 **22:**6,13 **24:**18 **26:**8 **27:**16 **28:**20 **29:**1,4 **33:**11 **35:**11 **36:**24 **37:**3 **38:**20 **41:**6 **42:**25 **43:**10 **44:**1,5 **45:**16,17 **47:**2,25 **49:**10,22,25 **50:**13,19 **51:**6,11 **52:**2,3 **55:**3,20 **56:**25 **57:**10,14,21 **58:**10 **60:**5,19 **61:**14,16
absent [1] **20:**13
absolutely [5] **31:**19 **33:**12,16 **53:**15 **59:**13
accept [2] **55:**23 **56:**1
accomplish [1] **33:**19
accordingly [1] **18:**11
accurate [1] **34:**21
accurately [1] **45:**9
accused [3] **6:**11 **10:**24 **12:**10
accustomed [1] **56:**4
across [1] **36:**3
act [5] **4:**12 **18:**17 **27:**6 **32:**5 **43:**3
action [1] **53:**16
actions [2] **15:**20 **16:**9
active [22] **5:**5,16 **9:**18 **10:**1,17 **12:**16 **15:**6 **20:**13 **24:**7,13 **26:**12 **32:**19 **47:**24 **49:**18,19 **50:**6,8,9 **51:**11,12 **54:**18 **64:**18
actively [7] **4:**14,21,24 **7:**22,24 **8:**2 **27:**10
actor [1] **18:**7
acts [3] **16:**7 **18:**17 **50:**10
actual [2] **13:**21 **17:**1
actually [5] **20:**6 **31:**24 **48:**13 **51:**9 **61:**17
add [2] **12:**7 **54:**16
addition [2] **22:**23 **41:**2
address [1] **63:**23
addressed [1] **7:**16
addressing [1] **64:**15
adequate [1] **9:**3
adequately [1] **15:**8
adjunct [1] **45:**13
adjust [1] **18:**10
administer [1] **18:**4
admitting [1] **11:**10
adopt [1] **37:**21
adopts [1] **8:**11
adult [1] **45:**14
advanced [1] **4:**24
advertising [1] **41:**15
affect [1] **42:**5
affirmative [2] **6:**13 **16:**5
affirmatively [1] **19:**16
affirmed [1] **23:**19
afoul [1] **19:**14
after [5] **5:**17 **17:**1 **50:**16,17 **58:**7
again [12] **25:**17 **40:**10 **45:**21 **46:**10,18 **54:**13 **55:**2 **56:**22 **57:**23 **58:**22 **60:**8 **63:**18
against [2] **12:**19 **29:**22
ago [1] **61:**10
agree [6] **27:**1 **33:**25 **38:**11 **58:**24 **62:**22,24
agreed [4] **62:**13,15,16,20
agreeing [1] **5:**14
agrees [1] **21:**21
ahead [3] **23:**24 **36:**10 **51:**3
aimed [1] **54:**2
alito [8] **23:**22,25 **24:**11 **25:**12 **33:**21 **38:**13 **46:**1,3
all [43] **10:**3 **11:**2,9 **12:**17 **14:**15 **15:**1 **22:**12 **31:**8 **32:**5 **35:**8,17,18 **36:**4,17 **37:**16 **40:**2,2,20 **41:**10 **42:**7,20 **43:**12,20 **45:**8,23 **49:**19 **50:**21 **51:**10 **53:**16 **54:**7,15,16,21 **55:**12 **57:**4,4,9,25 **58:**2 **59:**17,21 **60:**9 **62:**3
allegation [2] **46:**8,9
allegations [6] **11:**6 **39:**5 **41:**18,20 **54:**16 **58:**12
allege [2] **43:**24 **60:**19
alleged [2] **15:**12 **17:**11
allow [2] **40:**3 **59:**2
allowed [2] **34:**8 **40:**4
allows [1] **40:**25
almost [3] **6:**20 **9:**17 **22:**22
alone [3] **25:**18 **32:**23 **33:**3
along [1] **49:**4
already [2] **21:**7 **58:**7
also [6] **12:**18 **20:**12 **22:**3 **33:**14 **34:**17 **64:**24
alternative [2] **10:**22 **54:**1
although [3] **14:**10 **24:**16 **29:**2
always [4] **9:**19 **26:**14 **49:**25 **51:**6
am [1] **18:**8
amarin [16] **4:**5 **5:**9,14 **7:**8 **11:**16,23,24 **12:**2 **14:**13 **17:**19 **22:**12 **24:**25 **29:**22 **31:**21,22 **39:**15
amarin's [10] **11:**6 **24:**21,24,25 **29:**2 **31:**16 **32:**16 **33:**3 **34:**11 **36:**8
amazing [1] **57:**4
amend [5] **59:**12,15,18 **61:**14 **63:**3
amended [1] **61:**25
amicus [2] **14:**5 **42:**23
amount [1] **20:**16
an [27] **10:**24,24 **13:**12 **20:**14,20,20 **27:**7 **29:**22 **31:**12,23 **34:**1 **42:**23 **45:**13 **47:**8 **48:**18 **49:**20 **50:**11 **52:**4 **53:**16,17,25 **57:**15 **58:**5 **60:**21 **61:**25 **63:**1,5
analysis [2] **23:**19 **46:**16
andrews [2] **59:**24 **60:**15
announce [2] **8:**17 **9:**14
announcements [2] **42:**3,5
anodyne [2] **10:**9,23
another [1] **29:**7
another's [1] **52:**12
answer [2] **27:**21 **41:**14
antitrust [1] **52:**4
antonym [1] **5:**16
any [18] **8:**10,15 **9:**24 **10:**19 **14:**14,19,24 **18:**7,7 **22:**25 **25:**20 **31:**16 **37:**5 **39:**15 **41:**9 **45:**3 **52:**16 **56:**18
anymore [1] **51:**23
anything [12] **12:**9 **13:**4,4,25 **14:**1 **29:**13 **33:**10 **62:**8 **63:**25 **64:**3,5,7
anytime [1] **36:**6
app [1] **49:**1
appeal [2] **60:**11,12
appealed [1] **60:**3
appeals [2] **14:**14 **30:**7
appears [1] **35:**14
appendix [1] **35:**13
application [2] **21:**3 **26:**4
applied [1] **5:**3
apply [1] **38:**2
applying [1] **37:**7
appreciate [1] **38:**25
approach [2] **4:**23 **38:**4
appropriately [1] **14:**11
approval [2] **13:**1 **21:**13
approved [10] **6:**6 **12:**7 **24:**3,9 **31:**13 **33:**1 **34:**24 **35:**8,18 **45:**10
approves [1] **27:**19
archived [1] **64:**20
are [36] **5:**8,11 **7:**4 **10:**22 **13:**23 **14:**17 **16:**23 **17:**7,18 **22:**13 **23:**17 **26:**1 **30:**7 **32:**21 **36:**14,17 **38:**19 **39:**21 **40:**4,21 **41:**18,20 **42:**4 **44:**10 **46:**1,3 **48:**8,11,17 **50:**2,10 **51:**12 **52:**11 **57:**5 **59:**11 **63:**20
area [1] **9:**17
aren't [3] **11:**19 **17:**14 **55:**14
arguably [1] **57:**19
argue [1] **63:**14
argued [1] **37:**10
argues [1] **5:**9
arguing [1] **10:**4
argument [6] **4:**4,7 **9:**9 **14:**4 **31:**1 **64:**12
arguments [1] **53:**10
articulated [1] **18:**13
as [58] **8:**4,5 **10:**8,16 **12:**25 **13:**2,2 **14:**5,19 **15:**22 **16:**4 **19:**10 **20:**23 **21:**11,19 **22:**15 **23:**5 **24:**16,16 **27:**6 **28:**5 **30:**8 **31:**13 **32:**12,24 **33:**19 **34:**9 **35:**12,16 **37:**13,19 **38:**6,17 **39:**14 **41:**15,22,23 **45:**13 **46:**22 **47:**12,12,15 **50:**1 **51:**6 **54:**5,7,8,21 **55:**16 **56:**16 **58:**15 **60:**8 **61:**10 **62:**17,17 **63:**8,8,15
ask [5] **11:**4 **25:**14 **29:**17 **51:**23 **61:**1
asked [2] **25:**15 **62:**19
asking [5] **8:**2 **9:**14 **10:**2 **38:**17 **63:**21
asks [1] **37:**12
assertion [1] **48:**4
association [1] **46:**12
assume [1] **23:**16
at [40] **5:**21,22 **14:**14 **18:**9 **22:**23 **23:**8 **24:**21 **27:**3 **31:**8 **32:**13 **33:**4 **35:**11,25 **39:**3 **40:**1,20,23 **41:**4,5,10,19 **42:**12,16,20 **43:**3 **45:**5 **46:**10 **47:**3,15 **48:**2,15 **49:**1,6 **51:**1,25 **52:**16,23 **53:**19 **54:**2 **57:**3

attached [1] **22:**25
attempt [2] **17:**25 **49:**6
attempted [2] **41:**22 **55:**4
attention [3] **42:**2,3 **57:**5
authorized [2] **15:**4 **18:**2
avoid [2] **26:**23 **45:**7
award [2] **5:**23 **13:**17
away [4] **15:**8 **38:**9 **47:**14 **58:**16

B

b [2] **4:**7 **64:**12
baby [1] **52:**8
back [3] **36:**21 **59:**3 **61:**8
baiting [1] **6:**21
barrett [8] **29:**15 **36:**10,22 **38:**11,24 **51:**15 **59:**11 **62:**20
based [1] **30:**5
basic [2] **27:**5 **30:**2
basically [4] **5:**15 **8:**11 **26:**25 **40:**1
be [63] **6:**21 **7:**6 **11:**22 **12:**6,10 **13:**6,15 **14:**20 **18:**2,3 **19:**3,11,16,17,22 **20:**5,16 **22:**24 **23:**14 **24:**15 **27:**7,9 **28:**12,23 **29:**21 **30:**10 **32:**4,10 **33:**16 **35:**20 **36:**25 **37:**25 **38:**15 **39:**18 **40:**21 **42:**12 **43:**23 **44:**8 **46:**4,21 **47:**5,9,10 **48:**8 **49:**5 **50:**2 **52:**18 **53:**4 **54:**20 **55:**13 **56:**10,11,20 **58:**17,19,20 **59:**1,15 **61:**23,25 **62:**17 **63:**1 **64:**18
because [25] **9:**17 **10:**12,21 **11:**23 **12:**13,14,21 **19:**24 **22:**12 **26:**13 **27:**3 **29:**9 **30:**16 **32:**13 **34:**6,23 **39:**14 **40:**19 **42:**22 **55:**9 **56:**22 **57:**1,23 **59:**3 **64:**25
become [1] **19:**9
bedrock [1] **15:**5
been [8] **6:**4 **10:**3 **21:**7 **24:**9 **28:**20 **59:**7,8,20
before [2] **13:**11 **29:**1
begin [1] **14:**9
beginning [1] **24:**22
behalf [3] **4:**8 **31:**2 **64:**13
behavior [1] **28:**16
behind [1] **28:**13
being [3] **16:**22 **22:**19 **52:**2
believes [1] **28:**8
bell [2] **36:**12 **58:**8
bells [1] **52:**8
below [5] **5:**17 **13:**1,22 **55:**17 **64:**24
benefit [1] **31:**10
best [4] **5:**21 **18:**6 **35:**4,25
betamax [1] **7:**20
between [3] **28:**17 **46:**12 **51:**10
beyond [2] **31:**6 **37:**1
billion [2] **36:**15 **57:**10
billion-dollar [2] **35:**21 **45:**18
blown-up [1] **35:**13
book [1] **28:**7
both [5] **4:**12 **19:**7 **26:**9 **39:**12 **50:**4
bottom [3] **20:**17 **27:**12 **28:**18
bound [1] **28:**10
brand [11] **8:**12 **11:**10 **12:**5,12 **15:**22 **20:**3,4 **22:**14,15 **28:**11 **33:**4
branded [4] **31:**17,21 **39:**15 **44:**6
brand-name [3] **20:**1 **28:**6 **29:**20
brand's [3] **13:**16 **28:**16,21
breath [1] **24:**5
brief [10] **14:**9,23 **20:**21 **26:**9,10 **37:**10 **42:**24,25 **58:**15 **60:**10
briefs [1] **44:**10
bring [3] **15:**23 **60:**22,24
broad [2] **18:**21 **36:**25
broader [3] **22:**6 **38:**18,20
broadly [1] **6:**23
brought [1] **50:**12
burden [6] **43:**23 **48:**8,13 **52:**20 **53:**1 **54:**21
but [67] **5:**12 **6:**11,16,25 **7:**3,4 **9:**25 **10:**14,18 **11:**22 **13:**2 **14:**23 **15:**5,25 **17:**14,19,25 **19:**4 **20:**25 **21:**5 **22:**2,21 **23:**7,18 **24:**2,17,23 **26:**20 **27:**4 **28:**2,18 **29:**23 **31:**14 **32:**11,23 **34:**8 **35:**14 **38:**16 **39:**13 **40:**5 **41:**19 **42:**18 **43:**1,8 **46:**19,25 **47:**4 **48:**7,16,22 **49:**9,18 **50:**7 **52:**3,18 **53:**1,22 **55:**6 **56:**25 **57:**21 **58:**25 **60:**2,22 **61:**4 **62:**24 **63:**8,9
buy [1] **49:**16
by [34] **4:**24 **8:**5,11,12 **11:**7,13 **12:**11,22 **14:**17 **16:**4,7,23 **20:**22 **21:**4,6 **22:**19,20 **28:**10,14 **33:**7 **34:**24 **35:**22 **36:**1,4 **39:**6 **40:**9,10 **52:**19 **53:**5,5 **56:**18 **58:**5 **60:**13 **64:**15

C

c [1] **4:**1
calculated [1] **36:**18
call [2] **13:**4 **25:**1
called [4] **10:**8 **11:**13 **21:**10 **28:**7
calling [1] **40:**9
camber [2] **45:**11,22
camber's [1] **45:**12
came [1] **64:**17
campaigns [1] **17:**25
can [27] **11:**4 **12:**6 **13:**1,6 **22:**5 **27:**7 **28:**15 **29:**17 **30:**1 **33:**16,18 **35:**12,20 **36:**5 **42:**14 **44:**8,12,13,24 **45:**5 **46:**2 **47:**12 **49:**13 **53:**4 **55:**8 **62:**17 **63:**14
cannot [7] **4:**21 **5:**5 **11:**21 **34:**6 **39:**15 **54:**3,15
can't [9] **11:**20 **12:**7,10 **34:**5 **37:**24,24 **40:**7 **48:**3 **54:**14
capable [1] **19:**6
capture [2] **40:**2,7
caraco [2] **27:**23 **28:**6
cardiovascular [17] **7:**11 **18:**5 **21:**16,16,17,22 **24:**3,14 **25:**3 **29:**5 **31:**25 **33:**6,20 **35:**23 **36:**7 **46:**13 **57:**8
carefully [1] **35:**25
carry [1] **30:**11
carve [1] **54:**15
carved [2] **12:**5 **28:**24
case [58] **4:**4 **7:**18 **8:**17,22 **13:**19 **14:**13 **17:**10 **23:**18 **24:**6 **30:**1,5,8,14 **31:**6,8,9 **32:**4,12,13 **34:**14 **36:**24 **37:**3,6,8,12 **38:**3,4,6,14,17 **39:**3,22 **42:**20,21 **47:**3 **48:**2 **49:**2 **50:**16,16,17 **51:**1,20 **52:**2,23 **53:**16,17 **54:**15 **56:**18 **57:**1 **58:**12,21 **59:**3,4,17,20 **60:**8,14 **61:**2
cases [10] **16:**18 **21:**15 **32:**9 **38:**6 **42:**1 **49:**4 **54:**21 **56:**4,5 **60:**9
catalogue [1] **64:**22
categories [1] **22:**10
category [2] **45:**20 **56:**6
cause [1] **30:**18
causing [1] **15:**21
certain [3] **6:**17 **11:**18 **21:**20
certainly [4] **17:**16,19 **23:**18 **46:**20
cetera [2] **47:**20,20
challenge [2] **5:**19 **13:**8
change [5] **10:**18,19 **11:**21 **26:**21 **59:**20
changing [1] **27:**2
charging [1] **19:**25
charles [2] **4:**7 **64:**12
chief [18] **4:**3,9 **13:**25 **14:**7 **18:**12,20 **25:**6,9,12,17 **27:**14 **29:**12 **30:**20,23 **31:**3 **63:**25 **64:**3,10
choose [2] **5:**21 **19:**14
circuit [14] **5:**15 **14:**11 **22:**10,18 **25:**19 **46:**22 **48:**23 **49:**10 **51:**7 **56:**16 **59:**4 **60:**12 **61:**7,19
circuit's [8] **15:**17 **23:**14,19 **42:**10 **43:**1,8 **58:**18 **59:**21
circumstance [2] **48:**20 **49:**23
circumstances [1] **11:**9
cite [1] **29:**19
cited [1] **60:**9
civil [1] **59:**16
claim [13] **7:**14 **8:**14 **33:**8,24,24 **37:**15 **39:**7 **40:**22 **46:**7 **48:**19 **58:**14,25 **64:**18
claiming [1] **8:**16
claims [1] **42:**11
clarify [1] **39:**1
classic [2] **34:**13 **41:**16
clear [10] **5:**1 **6:**13 **7:**1,14 **11:**22 **15:**21 **16:**4 **18:**18 **62:**17 **64:**18
clearly [2] **16:**9 **18:**15
clever [1] **36:**1
cleverly [1] **36:**20
clinical [2] **24:**24 **29:**2
closer [1] **24:**17
code [2] **28:**8,10
colleagues [1] **38:**15
collection [1] **36:**4
come [7] **36:**13 **40:**1,7 **41:**25 **44:**25 **51:**25 **59:**8
comes [5] **21:**4 **32:**13 **34:**11 **57:**1,13
coming [2] **36:**3 **42:**4
commerce [4] **12:**20,21,22 **13:**3
common [3] **41:**17 **51:**9 **58:**16
community [1] **41:**11
companies [5] **5:**10,20 **17:**20 **43:**9 **54:**7
company [4] **20:**18 **31:**21 **40:**17 **46:**20
compared [1] **55:**16
compares [1] **12:**2
compete [1] **52:**11
competition [1] **6:**1
complaining [1] **22:**13
complaint [9] **8:**25 **9:**2,7 **37:**7 **58:**13,25 **59:**12 **61:**25 **63:**3
complaint's [1] **43:**6
compliance [1] **14:**18

complicated [2] **27:**4 **30:**13
compromise [7] **31:**11 **34:**7 **43:**2 **44:**4,5,19,22
conceivably [1] **30:**14
conception [2] **50:**15 **54:**14
concern [1] **55:**3
concerned [1] **22:**11
concerning [1] **11:**6
concerns [1] **22:**6
concession [1] **49:**22
concluded [1] **25:**4
condition [3] **33:**2 **35:**1 **45:**22
conduct [3] **7:**21 **28:**1 **52:**6
conducting [1] **21:**4
confidence [1] **44:**25
conformity [1] **24:**19
congress [2] **4:**15 **12:**23
congressional [1] **26:**9
congressman [1] **42:**23
congressman's [1] **42:**25
connect [1] **24:**8
consciously [1] **41:**3
considers [1] **28:**9
consistent [6] **4:**19 **5:**8 **10:**10,25 **61:**6,22
conspiracy [1] **52:**4
constantly [1] **5:**10
constitutes [1] **51:**11
contact [1] **40:**24
contention [1] **57:**23
contents [1] **14:**16
contest [6] **40:**13,18 **48:**25 **53:**1,12,18
contested [3] **32:**12 **51:**8 **53:**13
context [4] **9:**25 **29:**21 **46:**14,17
context-dependent [1] **46:**16
contexts [1] **19:**6
contextual [1] **9:**19
continue [2] **37:**17 **38:**5
control [1] **58:**6
copyright [3] **15:**25 **16:**1,4
correct [6] **10:**5,7 **11:**11,12 **27:**13 **28:**5
correction [1] **10:**13
could [17] **7:**5,13 **8:**14 **11:**17 **17:**8,20,23,25 **18:**9 **19:**21 **20:**15 **30:**15 **52:**18 **55:**19 **56:**11 **61:**13,13
counsel [7] **11:**3 **14:**2 **25:**16 **30:**21 **45:**25 **46:**25 **64:**8
counterclaim [1] **28:**14
country [1] **32:**6
couple [1] **47:**25
course [6] **37:**16 **44:**3 **46:**15 **48:**2 **59:**15 **62:**2
court [41] **4:**10 **5:**2 **6:**12 **7:**16 **13:**24 **14:**8,14 **15:**24 **16:**2 **19:**5 **27:**23 **28:**5 **30:**1,4,7 **31:**4 **32:**13 **37:**21 **38:**2 **39:**2 **44:**24 **49:**25 **51:**6 **53:**9 **55:**16 **56:**3,23 **58:**10,20 **59:**1,2 **60:**6,10,15 **61:**1,8,8,20 **63:**2,10,15
court's [12] **6:**3 **15:**10 **16:**18 **23:**17 **31:**5 **32:**3 **33:**9 **37:**11 **50:**16 **55:**2 **58:**16 **61:**22
cover [1] **28:**9
covered [2] **8:**5 **28:**22
covers [1] **49:**22
cox [4] **5:**4 **6:**12 **12:**15 **16:**18
create [1] **23:**20
creation [1] **56:**8
crux [1] **51:**20
cure [1] **39:**20
cures [1] **44:**9
curiae [1] **14:**5
current [1] **58:**13
cv [2] **15:**4 **18:**3

D

d [1] **4:**1
damage [1] **57:**16
damages [2] **5:**23 **13:**17
dark [2] **43:**10 **44:**10
day [3] **18:**23 **30:**11 **38:**13
de [1] **19:**9
dealing [1] **4:**25
death [2] **21:**17,23
decide [2] **30:**1,4
decimate [1] **43:**2
decision [9] **5:**17 **13:**1,22 **22:**7 **23:**8,14,17 **43:**2,9
decisions [1] **42:**6
declare [2] **58:**21 **61:**2
defendant [3] **15:**7 **32:**10 **53:**13
defendants [1] **53:**17
defense [2] **20:**10 **34:**1
deferred [1] **28:**21
definitely [1] **57:**22
definition [2] **25:**16 **34:**15
degree [2] **6:**18 **54:**25
demonstrate [1] **50:**11
depend [1] **5:**5
depends [1] **27:**18
depositions [1] **59:**7
describe [3] **21:**18 **28:**8 **45:**9
described [7] **27:**2 **32:**24 **34:**20 **38:**18 **54:**4 **58:**15 **62:**11
describes [1] **54:**4
describing [2] **20:**22 **22:**3
description [3] **23:**4 **28:**22 **29:**3
descriptions [1] **5:**7
design [1] **19:**5
designed [2] **13:**10 **25:**2
determine [2] **27:**25 **28:**16
determines [1] **30:**10
determining [1] **9:**18
devastate [2] **55:**5,6
devastating [1] **13:**18
device [1] **16:**3
dialed [1] **55:**18
dictated [1] **14:**17
did [16] **6:**8,10 **23:**1 **33:**7 **40:**8 **41:**23 **45:**24 **46:**10,23 **48:**25 **49:**3 **53:**17,18 **58:**2,13 **59:**5
didn't [7] **7:**5 **12:**12 **29:**6 **30:**4 **52:**25 **57:**17 **59:**1
diet [1] **45:**14
different [6] **20:**10 **21:**2 **45:**21 **52:**2,15 **53:**22
difficult [1] **19:**3
difficulty [2] **16:**25 **17:**1
direct [4] **17:**2,2 **32:**16 **50:**3
directed [6] **40:**23 **41:**4,4,10 **42:**15 **47:**17
disaggregate [1] **49:**13
disclaim [1] **35:**19
disclaimed [1] **27:**24
disclaimer [5] **35:**6,11,16,24 **36:**20
disclaimers [4] **5:**11 **12:**8 **13:**6 **15:**2
discourage [1] **5:**10
discouragement [1] **12:**16
discover [2] **31:**23 **44:**8
discovered [3] **39:**17,24 **40:**6
discovers [1] **39:**19
discovery [6] **43:**21 **59:**6 **60:**16,17,18 **64:**17
discussed [1] **27:**23
discussion [2] **26:**8 **30:**3
disincentive [1] **23:**20
dismiss [6] **15:**13 **49:**2 **53:**11 **59:**24 **60:**11 **61:**9
dismissal [1] **64:**24
dispensed [1] **30:**11
disposition [1] **58:**22
dispute [5] **28:**19,21 **32:**10,18 **44:**18
disputed [1] **32:**15
disputes [1] **13:**11
distinct [6] **33:**1 **35:**1,2 **50:**1,22 **51:**6
distinguished [1] **7:**18
distinguishes [1] **57:**24
distinguishing [1] **7:**17
distributed [1] **41:**22
distributes [1] **16:**2
district [8] **60:**6,10,15 **61:**8,8,20 **63:**2,15
divide [1] **22:**9
do [41] **8:**15 **10:**11,18 **11:**20 **17:**8,9,23 **18:**23,24 **19:**21 **23:**2,9 **25:**16,19 **34:**6,17 **35:**5,5 **37:**5,8,18,18 **38:**4 **39:**8 **40:**4,16 **42:**1,3,5 **45:**8,23 **46:**5 **47:**1,23,23 **48:**9 **50:**3 **54:**8 **55:**12 **63:**6,8
doctor [3] **18:**6 **30:**9 **47:**22
doctors [16] **5:**6 **17:**24 **18:**1,1 **36:**5 **38:**8 **40:**17 **41:**12,23 **42:**1,17 **47:**10,13 **49:**20 **50:**11 **57:**5
doctors' [1] **42:**5
documents [1] **59:**6
does [10] **6:**11 **7:**20 **8:**17,19 **9:**7 **16:**14 **45:**3 **47:**4 **58:**25 **60:**18
doesn't [9] **12:**16 **27:**25 **35:**19 **39:**7 **40:**3 **45:**16,16,19 **63:**10
doing [3] **17:**15 **20:**22 **27:**19
dollars [3] **13:**21 **36:**15 **57:**11
done [2] **19:**17,18
don't [28] **7:**24 **10:**3 **16:**20 **17:**24 **18:**24,24 **25:**21,24 **26:**22 **27:**1 **29:**23 **33:**14 **36:**20 **37:**4 **41:**18 **42:**13,13,24 **44:**18 **49:**12,21 **56:**11,23 **60:**25 **62:**8,23,25,25
dots [1] **24:**8
down [4] **5:**20 **17:**4 **55:**18 **64:**5
dr [1] **45:**22
drawing [1] **15:**25
drug [31] **4:**18,20 **5:**10 **6:**2,6 **17:**13 **18:**8 **20:**1,12,23 **21:**3,6,11,11,21,25 **24:**1,13 **29:**4,9 **30:**10 **31:**17,24 **34:**20 **35:**9 **39:**15,17 **43:**9 **45:**10,19 **47:**10
drugs [3] **29:**20 **44:**6,8
dwarfed [1] **13:**21

E

e [2] **4:**1,1
each [2] **30:**8 **52:**18
early [1] **47:**3
earned [2] **20:**4,6
easily [1] **8:**24
easy [1] **18:**24
economic [1] **13:**12
economically [3] **31:**20 **39:**

18 **44:**12
effect [3] **15:**3 **54:**18 **59:**10
effectively [1] **57:**7
effects [2] **23:**13 **60:**20
efficacious [2] **21:**7 **25:**5
efficacy [4] **21:**5 **25:**2 **29:**4,8
either [2] **26:**23 **27:**7
elect [1] **60:**11
element [5] **32:**18 **49:**18 **50:**12,25 **51:**8
elements [4] **50:**1,2,23 **51:**7
else [3] **12:**9 **13:**25 **14:**1
embodies [1] **27:**5
emerges [1] **16:**17
emphasize [1] **47:**2
en [1] **57:**6
encourage [9] **6:**1 **7:**20 **8:**13 **16:**13 **18:**18 **26:**11 **32:**20 **44:**6 **48:**18
encouraged [3] **12:**22 **19:**16 **27:**10
encouraging [2] **13:**23 **17:**12
end [1] **27:**4
engaged [1] **6:**17
enough [14] **19:**19 **22:**20,22,24 **25:**19 **26:**5 **28:**24 **43:**6,13,20,20 **46:**4,7 **48:**19
ensure [1] **4:**16
enter [3] **23:**15 **58:**19 **61:**4
entering [1] **23:**21
entertain [1] **63:**2
entirely [4] **4:**19 **5:**8 **10:**25 **52:**5
equivalence [1] **21:**12
equivalent [2] **20:**24 **21:**6
erred [1] **14:**14
error [1] **10:**13
especially [2] **40:**19 **59:**2
essentially [1] **11:**8
established [2] **21:**12 **42:**10
et [2] **47:**20,20
ethereal [1] **22:**23
ethyl [6] **14:**25 **18:**4 **21:**19,25 **24:**12 **32:**22
even [16] **11:**16 **13:**5 **32:**25 **35:**12,14,15,15 **39:**2,3,7,13 **51:**22 **53:**23,24 **54:**14 **59:**18
event [1] **59:**1
events [3] **21:**16,23 **29:**5
every [1] **10:**23
everybody [2] **21:**21 **52:**17
everything [3] **10:**15 **12:**5 **43:**24
evidence [17] **14:**19 **41:**10,19,25 **42:**7 **48:**14 **56:**6,19,21,24 **59:**9,22 **60:**24 **64:**17,19,19,23
exacerbated [1] **57:**19
exactly [6] **12:**20 **23:**13 **25:**18 **33:**19 **49:**7 **60:**19
example [3] **33:**21 **45:**1,11
examples [1] **44:**11
except [2] **11:**10 **38:**14
exchange [1] **31:**14
exchanged [1] **59:**7
excise [1] **28:**25
excluded [1] **11:**18
existing [3] **31:**23 **39:**17 **44:**6
expand [1] **26:**21
expectation [1] **19:**18
expertise [1] **27:**24
explain [4] **14:**23 **22:**5 **30:**12 **54:**3
explained [3] **28:**5 **52:**19 **53:**4
explanation [3] **10:**24 **15:**1 **54:**1
explanations [1] **10:**22
explicit [1] **5:**12
expose [1] **43:**10
express [4] **9:**23 **10:**16 **15:**2 **37:**23
expression [1] **16:**5
expressly [1] **41:**4
extend [1] **36:**25
extensive [1] **59:**5
extent [3] **17:**18 **37:**25 **58:**6
extraordinary [1] **63:**19

F

face [1] **5:**8
fact [5] **20:**25 **38:**9,12 **40:**24 **51:**17
fact-bound [2] **37:**3 **38:**16
facto [1] **19:**9
factors [1] **9:**21
facts [3] **30:**5 **37:**13 **38:**3
factually [2] **55:**7 **57:**2
failure [1] **6:**13
fair [4] **20:**16 **40:**21 **42:**13,14
faith [1] **42:**24
fall [1] **7:**25
false [1] **34:**23
famous [1] **35:**21
far [5] **31:**6 **41:**7,22 **47:**12 **58:**16
faster [1] **54:**24
favor [1] **40:**21
favorite [1] **7:**19
fda [12] **11:**23,25 **12:**2 **13:**1 **27:**19,24 **28:**9,13,21 **31:**12,12 **34:**24
fda's [1] **23:**12
feasible [1] **19:**11
fed [1] **15:**17
federal [24] **5:**14 **14:**11,17 **22:**9,18 **23:**13,19 **25:**19 **42:**9,23 **43:**1,8 **46:**22 **48:**23 **49:**10 **51:**7 **56:**16 **58:**18 **59:**4,16,21 **60:**12 **61:**6,18
fees [1] **5:**22
fewer [2] **35:**8,18
fighting [1] **39:**22
figure [1] **18:**9
file [1] **61:**13
filed [2] **5:**17 **42:**23
fill [1] **17:**13
finally [1] **26:**7
finish [1] **51:**3
first [10] **14:**10 **18:**23 **30:**4 **35:**12 **41:**7 **43:**19,24 **48:**1 **53:**7 **57:**6
five [1] **39:**23
flagged [1] **51:**16
flavor [1] **22:**21
focus [3] **47:**6 **48:**10 **49:**5
focused [2] **49:**15,19
follow [1] **55:**12
following [1] **25:**18
for [97] **4:**12,18 **5:**16 **6:**6,19 **9:**8 **10:**19 **11:**10 **12:**17 **13:**11,11,17,20 **14:**5 **15:**4 **16:**6,13,22 **17:**4 **18:**2,4,8 **19:**3,5,12,13,14,25 **20:**13 **22:**2,3 **24:**9 **25:**3,5,22 **27:**9 **28:**3,7 **29:**4,9,20 **30:**3 **31:**12,13,16,21 **32:**8,24 **33:**1,13,24,24 **34:**8,9,12,21,22 **35:**8,18 **36:**16 **39:**7,16,22 **40:**5,15 **42:**10,11 **44:**8,14 **45:**9,11 **46:**7 **47:**8,10,20,21 **48:**5,8,12 **51:**18 **53:**3,8 **54:**1,5,10 **56:**3,14,14 **57:**6,6,15 **58:**14 **59:**2,17 **61:**5,13 **64:**18
foreclose [1] **4:**17
foresee [1] **62:**12
form [2] **41:**16 **58:**19
former [1] **42:**25
foster [1] **16:**6
found [4] **21:**7 **48:**23 **51:**7 **58:**11
four [1] **38:**14
frankly [1] **33:**15
friend [1] **33:**22
friends [3] **55:**4 **60:**14 **63:**20
from [10] **15:**8 **16:**17,18 **17:**22 **29:**6 **42:**14 **47:**14 **57:**16,25 **58:**11
full [2] **31:**10 **62:**24
fully [1] **17:**13
fundamental [2] **36:**3 **44:**3
fundamentally [3] **54:**20 **56:**7,9
further [8] **29:**13 **35:**6 **61:**5,21 **64:**1,4,5,7
future [1] **30:**14

G

g [1] **4:**1
gains [1] **40:**2
game-changing [1] **40:**6
gate [1] **43:**21
gave [3] **25:**17 **33:**21 **41:**11
general [2] **26:**3,4
generally [3] **27:**6 **39:**13 **56:**23
generic [57] **4:**18,20 **5:**9,20 **6:**6 **7:**1 **8:**11 **12:**4,7 **13:**5,9,14,16 **14:**18,24 **16:**22 **17:**17 **18:**14 **19:**21,24 **20:**2,6,9,12,14,17,23,24 **21:**4,9 **22:**14 **23:**4,5,15,21 **24:**1 **28:**15,24 **31:**18 **32:**22 **35:**7 **36:**14,14,15 **40:**10 **43:**4,9 **45:**12,16 **46:**4,6,21,24 **47:**19 **54:**7 **57:**10,25
generics [14] **11:**8 **16:**13 **23:**17 **29:**20 **33:**7 **42:**4 **43:**7 **45:**2,6 **55:**5,6,10,14 **58:**1
generics' [1] **28:**3
get [11] **13:**1 **14:**12 **21:**12 **22:**20,24 **39:**15 **40:**25 **41:**22 **43:**20,21 **44:**13
gets [1] **13:**16
getting [4] **17:**2 **47:**21 **52:**23 **57:**4
given [2] **30:**15 **59:**19
giving [1] **14:**14
glad [1] **42:**22
go [8] **23:**23 **31:**6 **36:**10 **48:**14 **51:**3 **55:**22 **58:**11 **61:**19
going [22] **10:**13 **17:**1 **32:**10 **38:**2 **39:**8,9,11 **42:**8,9,16 **43:**14,22,23 **44:**25 **46:**21 **51:**16 **52:**17 **54:**20,23 **55:**5 **61:**25 **63:**11
good [5] **22:**16 **43:**6,13,19,20
gorsuch [22] **29:**13 **35:**3 **50:**24 **51:**2,22,25 **52:**8,11,14 **53:**20 **54:**9,12 **61:**3,12 **62:**1,6,10,14,21 **63:**9,15,24
got [5] **13:**20 **31:**10 **53:**20 **54:**9,12
government [2] **10:**8 **47:**7
grant [1] **37:**12
granted [2] **59:**24 **61:**10
grants [1] **60:**10
great [2] **6:**19 **7:**4

greater [2] **37:**5 **54:**25
green [1] **44:**10
grokster [9] **5:**3 **6:**12 **7:**16 **9:**20 **12:**14,19 **15:**24 **41:**16 **46:**14
ground [1] **51:**9
grounded [1] **40:**23
gsk [1] **13:**19
guess [4] **27:**17 **42:**18 **47:**1 **48:**9

H

had [21] **6:**17 **10:**13 **11:**7 **15:**15,19,20 **24:**1,1,4,11 **28:**20 **29:**2 **30:**2 **31:**24 **32:**11 **40:**15 **51:**8 **53:**11 **55:**1 **58:**7 **60:**21
happen [4] **20:**16 **44:**12 **50:**5 **61:**18
happened [4] **13:**19 **44:**11 **54:**24 **60:**5
happening [1] **17:**22
harbor [2] **18:**21 **56:**8
hard [2] **10:**12 **53:**8
harder [1] **39:**10
harm [1] **57:**20
harmonize [1] **5:**24
has [28] **10:**24,24 **15:**7 **19:**5 **20:**2,6 **24:**9 **27:**24 **28:**23 **32:**12,15 **36:**13 **41:**25 **42:**12 **44:**11 **47:**5 **49:**25 **50:**2,3,4 **51:**6 **55:**24 **56:**2,10,23 **59:**6,9 **60:**8
hatch-waxman [13] **4:**16 **13:**10 **14:**16 **26:**2 **27:**3,5 **31:**8,11 **42:**20 **43:**3 **44:**1,2 **56:**14
have [71] **6:**4 **7:**3 **8:**16 **10:**16 **11:**8,8,17,18 **12:**12 **13:**5 **15:**12,12,14,19 **16:**8,14 **17:**9,17 **18:**22,22 **19:**16 **20:**4,10 **22:**22,25 **24:**6,12 **26:**14 **27:**2 **28:**21 **30:**16 **36:**18 **37:**4 **39:**8,11 **40:**6,21 **41:**18,20 **42:**1 **43:**7,14,22 **44:**24 **45:**6,8 **47:**10,14 **48:**10,13,18 **49:**14,14,16 **50:**5 **52:**4 **53:**10,17 **54:**16,18,25 **55:**4 **59:**7,7,8,8,8 **61:**21 **62:**7,18 **63:**7
haven't [3] **14:**24 **45:**3 **60:**21
having [5] **16:**15 **36:**11,12,16 **40:**1
he [1] **61:**20
head [1] **5:**13
health [3] **17:**10,11,19
hear [1] **4:**3
heard [1] **33:**23
heart [2] **43:**3 **56:**17
held [6] **27:**9 **43:**23 **46:**22,22 **54:**20 **56:**11
here [27] **9:**1 **10:**8 **12:**21,22 **20:**11 **28:**19 **29:**24 **32:**18 **34:**19 **38:**14 **42:**22,22 **43:**9 **46:**20 **47:**7 **48:**11 **50:**13 **51:**10 **53:**9 **54:**13 **55:**13,14 **58:**3,4,11,25 **59:**18
hey [2] **52:**17 **53:**3
high [1] **18:**25
highlight [1] **47:**5
hikma [66] **4:**4 **6:**8,25 **7:**7 **11:**17,20,21 **14:**23 **20:**21 **21:**8 **23:**1,25,25 **24:**18 **29:**5 **31:**10,14 **32:**12,15,19,23 **33:**3,7,17 **34:**7,11,21 **36:**13 **38:**8 **39:**6,25 **40:**7 **41:**7,10,11,17,20 **45:**3,23 **46:**9,17,23 **48:**25 **49:**6,14 **51:**7,12 **53:**11,18 **55:**1,12 **56:**10,11,14 **57:**9,15,18,24 **58:**2,4,5,20 **59:**5 **62:**4 **63:**6 **64:**20
hikma's [22] **19:**12 **21:**21,25 **23:**4 **32:**17 **34:**19,23 **35:**7,17,19 **36:**2,4,6 **40:**22 **42:**15 **48:**3 **49:**2 **54:**3,17 **59:**10 **60:**19,25
his [1] **42:**25
hit [2] **13:**17,20
honor [20] **6:**8 **10:**21 **33:**13 **34:**6 **35:**10,16 **36:**12 **37:**9 **40:**19 **41:**15 **45:**1 **46:**6 **48:**22 **49:**8,24 **53:**7 **59:**13,25 **61:**17 **64:**14
honor's [1] **49:**5
hope [4] **58:**23 **62:**23,23,23
how [8] **12:**18 **27:**18 **30:**17 **44:**8 **50:**24 **51:**16 **55:**11 **62:**11
hump [1] **22:**24
hundreds [1] **13:**20
huston [52] **30:**23 **31:**1,3 **33:**12 **34:**5 **35:**10 **36:**11,22 **37:**8 **38:**22,25 **40:**14,18 **41:**13 **43:**16 **44:**16,23 **46:**5 **47:**25 **48:**21 **49:**11,24 **50:**14,20,22,25 **51:**4,23 **52:**7,10,13 **53:**6,21 **54:**10,13 **55:**15,25 **56:**22 **59:**13,25 **60:**2,7 **61:**11,15 **62:**3,7,15,22 **63:**5,13,17 **64:**9
hypertriglyceridemia [11] **31:**14 **32:**25 **34:**10,22,25 **36:**16 **45:**15,20 **54:**6,11 **57:**11
hypothetical [1] **6:**24

I

icosapent [6] **14:**25 **18:**4 **21:**19 **22:**1 **24:**12 **32:**22
i'd [1] **14:**9
idea [1] **55:**3
identify [1] **15:**20
if [69] **5:**21 **6:**16,17,25,25 **7:**7,7,14,14,24 **8:**10,11 **11:**16,19 **12:**4,4 **13:**5,16 **20:**2,12 **21:**21 **22:**22 **23:**18,22,25 **24:**4,11 **26:**18,19 **27:**6 **28:**11,19,20 **34:**3,11,23 **35:**3,15,15,15 **36:**23 **38:**2,16,17,20 **39:**2,14,14,14,14 **43:**5,13,17,19 **44:**13 **47:**18 **48:**8,11,11,11,15 **49:**18 **53:**11,24,24 **55:**19,24 **58:**10,11
i'll [1] **51:**5
i'm [25] **8:**1,2,9 **9:**5,5 **10:**2 **17:**17 **38:**14,17,23 **42:**22 **46:**19 **49:**6 **51:**2,4,21,22 **55:**20 **59:**17 **60:**4 **61:**21 **62:**4,19 **63:**18,22
imagine [1] **33:**17
impact [4] **16:**12 **36:**24 **38:**18,20
implications [7] **22:**7 **23:**7 **31:**5,25 **39:**9,12 **43:**15
important [5] **19:**8 **34:**17 **37:**19,19 **59:**2
impossible [1] **9:**17
inaccurate [3] **33:**11,14,16
included [2] **11:**18 **15:**2
including [3] **30:**3 **33:**20 **36:**7
independent [2] **21:**5 **52:**5
indicated [2] **35:**8 **45:**13
indication [6] **6:**7 **11:**11 **15:**4 **18:**3 **24:**21 **29:**7
indications [1] **35:**9
indicative [1] **48:**17
induce [13] **4:**21 **7:**6,24 **8:**3 **15:**21 **16:**10 **36:**18 **48:**12 **49:**15,20 **50:**11 **64:**21,23
induced [17] **4:**25 **7:**22 **32:**1,8 **33:**24 **34:**1,14,15 **37:**22 **38:**7 **39:**10 **41:**16 **42:**11 **45:**7 **46:**15 **50:**1 **54:**22
inducement [17] **5:**5 **6:**21 **9:**19 **10:**1,17 **14:**20 **15:**5,6 **17:**4 **20:**13 **24:**7 **26:**3 **47:**24 **49:**18,20 **50:**9 **64:**18
inducer [1] **50:**4
induces [1] **4:**14
inducing [5] **6:**22 **12:**10 **47:**9,22 **54:**19
industry [4] **13:**9 **31:**7 **37:**1 **43:**5
inference [2] **42:**13,14
inferences [1] **40:**20
information [1] **11:**19
informational [1] **17:**25
infringe [11] **9:**24 **14:**20 **15:**6,22 **16:**4 **19:**19 **27:**11 **28:**1 **30:**18 **32:**11 **59:**10
infringement [49] **4:**22,25 **5:**2,11 **6:**14 **7:**15,23,25 **8:**3 **9:**23 **12:**11,17 **15:**9 **16:**6,7,10 **17:**3 **18:**3,16,19 **21:**24 **22:**2 **26:**12 **27:**10 **32:**1,8,16,20 **33:**25 **34:**2,14,16 **37:**22 **38:**7 **39:**10 **41:**17 **42:**11 **45:**8 **46:**15 **47:**22 **48:**12 **50:**1,3 **53:**5 **54:**19,22 **58:**7 **64:**22,23
infringer [2] **9:**22 **17:**2
infringes [2] **7:**21 **36:**8
infringing [17] **4:**13,15,17 **5:**6 **8:**13 **19:**7,15 **20:**15 **26:**18,19,19 **27:**8 **28:**4 **36:**19 **50:**4 **54:**6,24
ingredient [1] **24:**13
initial [1] **42:**19
innovations [1] **32:**6
instead [1] **54:**7
instructions [1] **5:**7
insurer [1] **17:**11
insurers [1] **17:**19
intended [1] **64:**20
intent [30] **18:**18 **32:**11,12 **36:**18 **39:**6 **47:**8 **48:**9,12,18,25 **49:**4,15,16,20,22 **50:**5,11,12,25 **51:**8 **52:**21 **53:**3,12,14,16,18,19 **54:**17 **59:**10 **60:**19
intention [1] **47:**18
intentional [3] **14:**20 **39:**5,5
intentionally [1] **41:**21
intents [1] **52:**19
interest [1] **23:**7
interpretation [1] **32:**3
interpreting [1] **26:**1
interrupt [1] **51:**3
intimation [2] **20:**20,21
into [10] **5:**7 **6:**21,22 **13:**3 **22:**10 **43:**21 **46:**17 **50:**12 **52:**18 **57:**8
intuition [1] **53:**24
invest [1] **44:**7
investment [2] **39:**19 **47:**21
investor [1] **41:**1
investors [10] **40:**15,23 **41:**4,5 **42:**16 **47:**17 **48:**6,18 **53:**4 **54:**3
iqbal [6] **8:**18,21 **9:**4,9 **10:**4 **38:**3
irrational [1] **39:**18
isn't [4] **28:**4 **51:**1 **52:**23,24

issue [1] **37:**5
issued [1] **40:**15
its [38] **5:**12,16 **6:**9 **7:**10 **8:**7 **11:**24 **13:**14,15,21 **16:**3 **17:**11 **20:**22 **22:**21 **24:**1,18 **28:**9,22 **29:**6 **31:**12,15 **32:**12,24 **34:**8,12,20,21 **39:**17 **40:**9 **53:**13,18 **54:**4,4 **57:**9,13,16 **60:**18 **64:**20,22
it's [51] **7:**14 **11:**12,15,15,16 **12:**4,23,23 **13:**12,12,17 **15:**5 **18:**24,25 **19:**8,11,23 **20:**8,11,11 **22:**1,1,3 **26:**2 **27:**1,3 **30:**13 **31:**8 **34:**17 **35:**25 **37:**11,18 **39:**4,9 **42:**13,22 **43:**19 **44:**2,12 **48:**7,13 **53:**8,8,21 **54:**4 **55:**7,9 **57:**3,8,22,24
itself [5] **14:**12 **22:**20 **28:**9 **40:**9,17

J

ja [1] **35:**11
jackson [19] **11:**4,15 **12:**9 **19:**20 **20:**7 **29:**16,17 **30:**19 **45:**25 **46:**2,25 **48:**1,7 **49:**9,12 **50:**7,18,21 **52:**22
job [2] **26:**18 **60:**18
joint [1] **35:**13
judge [4] **59:**23 **60:**10,15 **63:**2
judgment [5] **51:**19 **58:**19 **60:**3,11 **61:**4
judicial [1] **28:**15
just [44] **6:**5 **11:**10 **18:**22 **21:**9 **23:**1 **24:**1 **26:**2 **28:**23 **29:**6,17 **33:**4,13 **35:**16 **36:**11,22 **37:**1,6,24 **38:**17 **39:**18 **40:**23 **43:**12 **44:**19 **46:**1,3,4,10 **47:**13 **48:**3 **50:**22 **51:**4,5 **52:**23 **53:**21 **55:**7,13 **58:**5,9 **60:**5 **62:**8,10,25 **63:**12 **64:**18
justification [1] **17:**4

K

kagan [11] **23:**23 **27:**14,15 **29:**11 **40:**11,13 **41:**9 **47:**15 **55:**15,25 **56:**20
kavanaugh [17] **22:**5 **23:**6 **29:**14 **40:**12 **42:**18 **43:**16 **44:**15,18 **59:**23 **60:**1,4 **62:**13,18 **63:**4,11,14,22
keep [1] **57:**1
key [7] **32:**9 **34:**18 **38:**5,12 **46:**11,12 **57:**23
kind [13] **8:**10 **24:**19 **28:**18 **30:**14 **32:**7 **33:**21 **37:**5,6 **39:**15,19 **43:**5 **48:**10 **53:**24
kinds [3] **41:**2 **42:**4 **49:**7
klein [23] **4:**6,7,9 **6:**8,24 **7:**7,10,13 **8:**9,19,22,24 **9:**2,5,12 **10:**7,21 **11:**12,21 **12:**13 **64:**11,12,14
know [29] **10:**11 **18:**22 **29:**23 **37:**4,14,16 **38:**13,19 **41:**2 **42:**7,8 **43:**7,13 **44:**20 **45:**6 **49:**12,21 **52:**3 **55:**3,8,11 **56:**11,12 **57:**19 **58:**23 **59:**19 **60:**22 **61:**20 **63:**19
knowledge [1] **19:**17
knows [1] **52:**17

L

l [1] **14:**4
label [44] **11:**7,8,10,20,22 **12:**3,3,6,12 **13:**2 **14:**12,15,17 **22:**12,14,15,20 **23:**1 **24:**18,19,21,24,25 **25:**18 **27:**16,20 **28:**24 **29:**2,6,8 **31:**13 **55:**18,22,24 **56:**15,17,25 **57:**1,13,14,14,18,22 **58:**5
language [3] **7:**3,3 **12:**8
large [1] **23:**8
largely [1] **14:**17
last [2] **44:**17,24
later [2] **4:**15 **57:**2
laughter [1] **51:**24
launch [1] **13:**11
launched [2] **6:**9 **46:**17
launches [3] **5:**18 **13:**14 **57:**9
law [9] **6:**11 **14:**17 **15:**5 **16:**1 **26:**12 **38:**1 **40:**3 **41:**17 **62:**9
lawful [2] **4:**14 **53:**3
lawfully [1] **55:**11
laws [3] **17:**17 **29:**18 **30:**17
lawsuit [2] **13:**7 **29:**22
lawsuits [1] **5:**17
lawyer [1] **36:**1
least [2] **18:**9 **47:**15
leave [1] **61:**14
leaves [1] **43:**9
left [1] **51:**15
legal [3] **5:**22 **37:**14 **48:**10
legislative [1] **56:**9
legislatures [1] **17:**21
legitimate [1] **6:**1
length [1] **27:**3
less [1] **19:**25
let [4] **38:**25 **51:**25 **62:**16,16
levels [1] **45:**14
liability [10] **19:**14,21 **32:**1,9 **34:**1 **36:**2 **43:**11 **45:**8 **46:**8 **47:**24
liable [5] **16:**6 **20:**13 **27:**9 **46:**22 **56:**12
lies [1] **47:**24
life [1] **10:**12
life-changing [1] **31:**24
lifesaving [1] **39:**19
light [2] **25:**7 **30:**16
like [14] **7:**19 **10:**15,15 **14:**9 **27:**17 **31:**21 **34:**14 **37:**23 **39:**15 **52:**14,23 **55:**13 **56:**8 **57:**12
limitation [1] **31:**18
limited [2] **22:**19 **45:**9
line [4] **20:**17 **24:**17 **27:**13 **28:**18
lines [1] **49:**4
listed [2] **21:**10 **35:**9
listener [1] **51:**16
literal [1] **34:**15
literally [1] **39:**25
litigation-related [1] **64:**21
little [3] **6:**25 **36:**19 **52:**2
lives [2] **35:**22 **39:**25
long [1] **63:**8
look [3] **28:**13 **45:**5 **48:**15
looking [4] **27:**16 **47:**8 **48:**8,12
lost [2] **13:**17 **20:**2
lot [3] **19:**25,25 **26:**8
low [1] **18:**25
lower [1] **13:**15

M

made [7] **6:**13 **36:**17 **46:**23 **53:**11 **54:**16 **55:**1 **58:**2
magic [1] **8:**10
main [1] **27:**1
make [10] **10:**12,14 **16:**25 **39:**9,18 **41:**22 **53:**23 **58:**3 **62:**10 **63:**1
makes [1] **31:**20
making [1] **44:**19
malcolm [1] **14:**4
mandate [2] **59:**5 **60:**13
manufacturer [4] **20:**1 **28:**6 **46:**24 **47:**9
manufacturers [6] **14:**25 **15:**1 **23:**15 **32:**22 **45:**12 **57:**25
manufacturers' [1] **14:**18
many [2] **45:**1 **61:**10
market [17] **19:**12 **21:**4 **22:**7 **23:**21 **32:**23 **33:**5 **34:**8 **36:**13 **46:**11,12,12 **47:**20 **55:**5,6,10,11 **57:**8
marketed [1] **40:**17
marketing [4] **31:**18 **34:**12 **47:**14,16
marketplace [2] **23:**8,16
market-wide [1] **43:**15
masse [1] **57:**6
massive [2] **5:**23 **44:**7
material [1] **59:**20
materials [2] **47:**14,16
matter [4] **12:**25 **27:**1 **29:**23 **30:**15
matters [1] **33:**15
may [3] **4:**10 **14:**8 **31:**4
maybe [7] **29:**22 **43:**17,17 **52:**5 **55:**16,21 **57:**18
me [9] **37:**2 **38:**25 **47:**1 **51:**25 **53:**8 **55:**19 **56:**7 **62:**16,16
mean [20] **16:**16,20,21,24 **17:**16 **18:**21 **19:**2 **20:**8,19 **21:**9 **22:**8 **23:**11 **27:**22 **29:**25 **41:**9 **43:**20 **49:**13,25 **51:**5 **53:**22
meaning [1] **8:**23
means [3] **5:**21 **26:**12 **56:**18
measures [1] **17:**21
mechanism [1] **28:**14
medical [6] **33:**2,19 **35:**1,2 **41:**11 **45:**21
mention [1] **47:**19
mentioned [1] **39:**14
mere [1] **19:**17
merely [3] **6:**20 **37:**13 **46:**6
message [7] **5:**1 **7:**1,14 **13:**9 **36:**3 **38:**7 **47:**13
messages [2] **18:**17 **41:**7
method [3] **18:**10 **19:**9 **21:**17
methods [1] **21:**15
michael [1] **31:**1
might [6] **5:**6 **43:**10,17 **49:**14,14 **58:**10
million [2] **31:**22 **39:**24
millions [3] **5:**22 **13:**20 **59:**6
mind [1] **57:**1
minimize [1] **36:**2
ministerial [1] **12:**4
mirrors [1] **11:**9
misimpression [1] **30:**5
misleading [1] **34:**23
missed [1] **58:**5
misunderstood [1] **9:**6
mitigate [1] **57:**16
moment [4] **33:**4 **46:**11 **57:**3 **58:**10
money [1] **40:**1
monopoly [1] **19:**9
more [13] **5:**3 **6:**7,22 **20:**5,20 **30:**13 **33:**7 **36:**25 **39:**12 **46:**23 **47:**13 **49:**16 **55:**20
most [9] **16:**18 **22:**11 **24:**20 **32:**9 **34:**13 **35:**21 **38:**6 **49:**3 **58:**16
mostly [1] **62:**22

motion [8] **15:**12 **49:**2 **53:**11 **59:**24 **60:**10 **61:**9,13 **63:**2
motion-to-dismiss [2] **47:**4 **53:**2
move [1] **62:**2
much [13] **13:**15,15 **20:**5 **24:**7 **27:**18 **39:**9,9 **42:**24 **46:**23,23 **49:**5 **59:**14 **60:**23
must [1] **5:**10
my [7] **33:**22 **38:**15 **51:**23 **55:**4,15 **60:**14 **63:**20
myself [1] **53:**10

N

n [1] **4:**1
name [6] **9:**21 **20:**3,4 **28:**11 **33:**4,5
named [1] **44:**2
namely [1] **27:**6
name's [1] **22:**14
narrow [2] **26:**13,21
necessarily [3] **5:**2 **7:**15,21
need [9] **8:**15 **10:**3,15,17,19 **25:**16,20,25 **44:**5
needed [3] **5:**24 **16:**8 **55:**12
net [1] **17:**10
new [12] **12:**7,8 **21:**3 **25:**16 **37:**22 **38:**21 **39:**16 **40:**6 **44:**8 **59:**9,22 **64:**16
newly [1] **39:**16
next [1] **4:**4
no [24] **9:**7 **10:**6,21 **14:**1 **16:**20 **20:**9 **23:**23 **25:**11 **28:**19 **38:**22 **40:**1 **46:**24 **48:**7 **50:**14 **55:**24 **56:**2 **60:**13 **62:**6 **64:**2,2,6,16,19,19
nobody [1] **55:**5
none [1] **45:**23
non-infringement [1] **11:**1
non-infringing [5] **4:**13,18 **5:**9 **19:**7 **27:**8
non-problematic [1] **52:**21
nor [1] **32:**15
normal [1] **21:**1
normally [2] **59:**15 **63:**10
not [79] **4:**17 **6:**11,14 **7:**2,20,22 **8:**9 **9:**8,18 **10:**12 **14:**12 **15:**3,7,16 **17:**3,18 **19:**9,19 **21:**4 **22:**20 **23:**10 **24:**1,7 **25:**19 **26:**1,17,19,20 **27:**16 **28:**5 **31:**7,8,15 **32:**2,12 **33:**1,7 **34:**1,21,23 **37:**11,21 **38:**14 **40:**16 **41:**3,4 **42:**16,20 **44:**25 **46:**5,8,20 **47:**21 **48:**25 **49:**3,15 **51:**8,18,22 **52:**11,17 **53:**18 **55:**1,7,9,24,24 **56:**1,4,17 **57:**22,24 **58:**2,4,13,19 **59:**5 **63:**7,11
nothing [3] **6:**7 **35:**24 **40:**16
november [1] **6:**10
now [5] **10:**11 **11:**14 **17:**7 **56:**10 **61:**10
numbers [1] **41:**3

O

o [1] **4:**1
object [1] **16:**3
observations [1] **14:**10
observed [1] **38:**13
obtain [1] **28:**15
obvious [2] **10:**22 **24:**20
obviously [2] **58:**23 **60:**22
occur [2] **21:**24 **44:**13
occurred [2] **55:**1 **59:**6
occurs [1] **16:**12
off [5] **22:**17 **24:**20,23 **56:**7,24
offensive [2] **36:**17 **57:**9
oh [3] **9:**5 **36:**10 **48:**4
okay [9] **25:**8 **26:**5 **38:**24 **53:**20,25 **60:**1 **61:**9 **63:**23 **64:**8
omit [1] **29:**7
omitted [2] **29:**5,7
on [58] **4:**8 **5:**5,7,12 **6:**10 **7:**19 **10:**13 **11:**19 **12:**11,19 **15:**25 **16:**1,14,20 **18:**10,22 **19:**8,9 **20:**4 **21:**4 **22:**10,13 **23:**14,17 **24:**2 **25:**7 **27:**18 **30:**5 **31:**2,18 **32:**23 **34:**11,19,19 **35:**6,12 **36:**13 **42:**8 **44:**4 **45:**5 **47:**8 **48:**10 **49:**15,19 **51:**19 **53:**1,1 **55:**18 **57:**23 **59:**3 **60:**9,14 **63:**10,12,12,20,23 **64:**13
once [1] **13:**14
one [20] **4:**16,23 **9:**20 **16:**2,17 **18:**2,10 **19:**8 **21:**2 **22:**11 **24:**17 **32:**23 **45:**11 **46:**6,21 **51:**15 **52:**12 **56:**18,21 **58:**9
online [2] **42:**4 **64:**22
only [15] **6:**6 **8:**2 **18:**2 **31:**20 **32:**17 **34:**8,9,24 **39:**4 **42:**12,14 **44:**12,12 **51:**10,14
opening [1] **36:**23
opens [1] **60:**15
opinion [5] **22:**21 **30:**7 **58:**18 **59:**21 **61:**23
opportunity [11] **39:**1,22 **43:**22 **57:**15 **58:**5 **59:**14,18 **60:**21,24 **63:**6,7
oppose [1] **63:**19
opposed [2] **8:**5 **10:**16
opposition [1] **37:**10
or [35] **6:**19,21,25 **8:**3,6 **9:**18 **11:**17,18 **12:**8,8,9 **15:**20 **16:**5,9 **17:**1,2 **18:**17,25 **19:**18 **20:**23 **21:**17,23 **23:**9 **25:**17 **26:**21 **27:**8 **29:**4,19 **30:**6 **42:**11 **43:**17 **47:**9 **49:**16 **56:**12 **64:**22
oral [3] **4:**7 **14:**4 **31:**1
orange [1] **28:**7
order [1] **21:**12
original [1] **11:**20
other [31] **6:**19 **9:**25 **11:**19 **14:**24 **15:**1 **16:**5 **17:**7,23 **18:**7 **20:**9 **23:**15 **32:**22 **33:**7 **38:**13 **41:**2,6,25 **44:**4 **45:**2,12 **46:**24 **49:**3 **53:**22,23 **54:**7,21 **55:**9,14 **57:**25 **60:**14 **63:**20
others [1] **15:**21
others' [1] **27:**9
other's [1] **52:**18
our [30] **4:**23 **8:**19,22 **9:**9 **10:**19 **15:**18 **18:**1 **24:**13 **26:**17,21 **33:**18 **36:**16 **37:**10 **40:**21 **41:**18 **46:**8,8 **48:**5 **49:**15,16 **51:**20 **53:**12 **54:**24 **56:**17 **57:**19 **58:**15 **59:**18 **60:**9 **61:**24,24
ours [1] **24:**9
out [16] **12:**5,18 **18:**9 **28:**24 **42:**19 **43:**6,20 **47:**15 **48:**4 **51:**13 **52:**20,21 **53:**2 **54:**15 **57:**13 **60:**22
over [12] **22:**24 **40:**10,10 **43:**7 **46:**9,9,10,18,18,18 **58:**21 **61:**2
overstating [1] **8:**3
own [5] **8:**4 **28:**22 **29:**6 **42:**25 **48:**3

P

p [1] **4:**1
p.m [1] **4:**2
page [1] **60:**9
papers [2] **55:**16,17
part [5] **19:**24 **23:**16 **29:**7 **47:**8 **51:**1
particular [3] **20:**4 **37:**7 **49:**23
parties [4] **16:**8 **19:**14 **28:**17 **51:**10
party [1] **29:**23
pass [3] **8:**17 **9:**8 **45:**1
passed [1] **4:**15
passes [1] **8:**20
passive [1] **5:**16
past [3] **14:**13 **22:**20 **43:**8
patent [23] **4:**11 **5:**17 **11:**24 **13:**10 **16:**1 **18:**4,10 **19:**8 **21:**18 **26:**12,18,19,20 **27:**6,19,24 **28:**22 **32:**4 **38:**1 **39:**10,12 **40:**3 **44:**13
patented [16] **7:**4 **8:**4,8 **11:**11 **12:**2,6 **16:**14,23 **28:**12,20,25 **29:**10 **31:**16 **32:**6 **34:**13 **47:**11
patents [5] **21:**14 **27:**25 **28:**9 **32:**17 **36:**8
patent-specific [1] **22:**16
path [1] **55:**13
pathway [2] **5:**20,21
patients [3] **21:**20 **45:**15 **57:**7
patients' [1] **35:**22
pay [3] **20:**2 **42:**2,3
paying [1] **5:**22
people [8] **6:**21,22 **15:**8 **19:**12,18 **20:**13 **47:**9 **49:**16
people's [1] **39:**25
perceived [1] **16:**25
performance [1] **21:**23
permitted [1] **31:**11
permitting [1] **29:**19
person [1] **18:**15
pertained [1] **11:**24
pet [1] **49:**1
petitioner [1] **25:**22
petitioners [3] **4:**8 **14:**6 **64:**13
petitioners' [2] **25:**15 **26:**10
pharma [1] **4:**5
pharmaceutical [4] **31:**7 **37:**1 **39:**13 **43:**5
pharmaceuticals [2] **4:**5 **32:**2
pharmacies [1] **17:**13
phone [1] **41:**2
piece [3] **35:**4 **56:**18,21
plaintiff [1] **52:**20
plausibility [4] **9:**8 **37:**3 **39:**4 **47:**2
plausible [6] **30:**17 **32:**19,21 **33:**8 **42:**12 **47:**5
plausibly [4] **7:**13 **8:**14 **52:**21 **53:**4
plead [1] **39:**10
pleaded [2] **30:**15 **37:**13
pleader [1] **19:**4
pleading [9] **5:**19 **13:**8 **32:**14 **39:**3,4 **40:**20 **41:**19 **42:**10 **56:**4
please [3] **4:**10 **14:**8 **31:**4
point [18] **9:**11 **12:**18 **14:**10 **16:**9,25 **23:**23 **27:**16 **34:**7 **43:**25 **44:**1,20 **46:**19 **48:**17 **52:**2,25 **53:**23 **55:**21 **64:**16
pointed [1] **47:**15
points [5] **35:**11 **41:**6 **43:**6,17 **47:**25

policies [1] **17:**12
policy [2] **26:**9,15
portions [1] **30:**7
position [2] **18:**7 **19:**12
possible [2] **41:**23 **52:**19
posture [1] **60:**8
practical [1] **12:**25
practice [3] **37:**12 **58:**16 **63:**18
practices [1] **18:**11
prejudice [2] **64:**25,25
prelaunch [1] **64:**20
preliminary [1] **16:**24
premise [1] **37:**20
prepare [1] **56:**14
prepared [1] **24:**18
prescribe [2] **36:**5,6
prescribing [3] **18:**8,11 **57:**5
prescription [2] **30:**9 **42:**5
presents [1] **35:**1
press [14] **6:**10 **15:**2 **20:**23 **40:**14,25 **41:**12,21 **42:**2 **45:**6,13 **48:**4 **54:**1 **57:**5 **64:**21
pretty [8] **18:**21,24,25 **19:**22 **22:**23 **24:**6 **27:**4 **37:**2
prevent [2] **6:**14 **17:**21
preventing [1] **29:**5
prices [1] **6:**2
principle [1] **15:**5
principles [4] **16:**1,17 **17:**5 **27:**5
print [1] **35:**14
private [1] **28:**17
probably [4] **24:**16 **35:**4 **57:**19 **61:**18
problem [1] **16:**15
problematic [1] **24:**16
problems [2] **16:**21 **26:**14
procedure [1] **59:**16
proceed [2] **59:**3 **61:**24
proceeding [1] **61:**24
proceedings [3] **61:**5,22,23
process [2] **12:**1 **21:**3
product [48] **4:**12 **5:**7,18 **6:**9,19,22 **8:**5,7 **13:**2,3,4,11,14 **15:**3 **18:**1 **19:**6,10,13,15 **20:**7,11 **22:**4 **23:**4 **25:**3 **31:**12,16 **32:**17,24 **33:**1,18 **34:**8,12,21,24 **35:**7,17,20 **36:**6,16 **40:**5 **45:**2 **49:**17,21 **54:**5,24 **55:**10,11 **64:**22
products [4] **4:**20 **12:**24 **31:**19 **44:**7
profits [6] **13:**15,16,17,21 **20:**2,3
promise [1] **31:**15
promote [1] **31:**15
promotes [2] **5:**2 **7:**15
promoting [1] **16:**3
promotion [1] **37:**23
prong [1] **50:**9
proposed [1] **12:**3
proposition [2] **55:**23 **56:**1
protecting [1] **44:**5
protection [3] **39:**16 **44:**14 **56:**13
protects [1] **32:**5
prove [3] **43:**23 **49:**7 **54:**21
provide [1] **28:**7
provided [1] **41:**3
proving [1] **42:**11
provision [1] **26:**3
public [1] **4:**19
puffery [1] **53:**3
pull [1] **36:**21
purport [1] **27:**25
purpose [14] **15:**21 **16:**10 **18:**5,8,15 **25:**5 **29:**9,9 **34:**13 **45:**9 **47:**11,21,22 **48:**5
purposes [2] **22:**2 **33:**19
put [7] **12:**11 **13:**3 **42:**8,24 **48:**4 **51:**13 **53:**10

Q

question [20] **9:**7 **10:**2 **11:**5 **15:**7 **25:**15 **27:**21 **28:**23 **38:**5,10,12,12,16 **43:**13 **48:**22 **49:**5 **51:**14,18,23 **52:**16,24
questions [4] **6:**3 **15:**10 **33:**9 **37:**21
quite [1] **35:**14
quote [2] **7:**5 **34:**4
quoted [2] **6:**20 **7:**7
quotes [1] **34:**11
quoting [1] **8:**6

R

r [2] **4:**1 **31:**1
rang [2] **36:**11 **58:**7
range [1] **28:**12
rate [1] **52:**16
rated [1] **32:**24
rather [1] **53:**5
rational [3] **31:**21 **44:**13 **52:**5
reach [2] **37:**5 **42:**16
reached [2] **10:**1 **38:**20
read [5] **5:**6 **27:**25 **35:**15,17 **38:**8
ready [1] **45:**7
ready's [1] **45:**22
real [1] **30:**12
really [18] **18:**6,21 **20:**10,16 **21:**1 **28:**19 **31:**7,8 **35:**14 **39:**21 **40:**15,23 **48:**16 **49:**15,22 **55:**17 **57:**3,7
reason [8] **13:**12,13 **21:**25 **22:**16 **44:**2,24 **55:**8 **56:**3
reasonableness [1] **27:**18
reasons [3] **12:**17 **26:**15 **30:**2
rebuttal [3] **63:**23 **64:**10,12
recently [2] **5:**4 **16:**18
reconcile [1] **50:**15
record [1] **7:**19
red [1] **25:**7
reduce [2] **21:**22 **45:**14
reduce-it [3] **25:**1 **29:**3 **31:**23
reduces [2] **6:**1 **24:**13
reducing [3] **18:**5 **21:**15 **25:**3
refer [1] **21:**15
reference [4] **8:**11 **15:**25 **21:**10 **35:**9
references [1] **28:**25
referred [1] **29:**8
referring [1] **30:**1
refers [2] **21:**1,18
refusing [1] **12:**11
regard [1] **7:**10
regular [2] **12:**19,21
regulating [1] **17:**18
reimbursement [1] **17:**12
relations [1] **41:**1
release [5] **6:**10 **40:**25 **45:**6,13 **48:**5
releases [8] **15:**2 **20:**23 **40:**14 **41:**12,21 **42:**2 **54:**1 **64:**21
relevance [4] **29:**18 **55:**21,24 **56:**2
relevant [2] **11:**9 **29:**22
reliance [1] **55:**18
relied [1] **22:**10
relief [2] **39:**8 **58:**14
rely [2] **34:**19 **57:**23
remand [5] **58:**18 **59:**3 **61:**5,19 **63:**12
remanded [1] **59:**4
repeated [2] **36:**12 **40:**9
repeatedly [2] **33:**3 **36:**13
replete [1] **44:**10
requested [1] **61:**24
requests [2] **58:**20 **63:**19
require [2] **6:**12 **12:**16
required [4] **15:**6 **18:**14 **31:**15 **37:**23
requirement [1] **11:**13
requirements [1] **14:**19
requires [2] **5:**1 **49:**20
requiring [1] **29:**19
requisite [2] **32:**11 **48:**25
resolution [1] **51:**19
resolve [1] **13:**10
resources [1] **44:**7
respect [1] **11:**6
respondent [5] **6:**17 **15:**11,19 **16:**15,23
respondents [4] **14:**22 **17:**8 **28:**2 **31:**2
respondents' [1] **20:**21
respondent's [1] **8:**6
response [1] **43:**18
result [2] **26:**24 **28:**3
resulting [1] **16:**7
results [1] **25:**1
returns [1] **60:**14
reveal [2] **18:**15,18
revealed [2] **16:**10 **59:**9
reveals [1] **60:**18
reversal [1] **5:**24
reverse [2] **13:**24 **61:**5
reverses [1] **60:**13
review [2] **27:**19 **28:**15
revolutionary [1] **45:**18
right [21] **11:**2,16 **12:**12 **26:**16 **38:**4 **49:**10 **50:**21 **52:**6,9 **53:**15 **55:**20 **59:**24 **60:**7 **61:**14,16 **62:**6,8,14,24 **63:**4,15
risk [12] **18:**5 **19:**20 **20:**17 **21:**16,22 **31:**25 **33:**6,20 **35:**23 **36:**8 **46:**13 **57:**8
risks [4] **24:**3,14 **25:**4 **35:**2
roadmap [1] **45:**7
roberts [14] **4:**3 **13:**25 **18:**12,20 **25:**6,9,12 **27:**14 **29:**12 **30:**20,23 **63:**25 **64:**3,10
role [2] **12:**4 **16:**11
routinely [1] **5:**18
rule [8] **10:**14 **22:**14 **26:**11 **32:**1 **38:**21 **52:**20,21 **53:**2
rules [9] **8:**16 **9:**16 **24:**19 **25:**20,25 **26:**4,21 **27:**2 **59:**16
ruling [1] **31:**6
running [1] **19:**13

S

s [1] **4:**1
safe [4] **6:**5 **18:**21 **21:**7 **56:**8
safety [1] **21:**5
said [28] **6:**18 **7:**20 **9:**20 **10:**17 **12:**5 **14:**11 **15:**24 **16:**2 **19:**5 **24:**1,4,11 **25:**19 **30:**17 **33:**17 **34:**21 **36:**14 **37:**16 **41:**16 **42:**21 **46:**9 **49:**14 **50:**8 **53:**11 **56:**17,23 **61:**10 **63:**16
sales [7] **20:**5 **36:**15,19 **40:**8 **45:**17 **54:**24 **57:**11
same [12] **22:**1,2,3,15 **24:**5,10 **25:**14 **27:**5 **33:**19 **45:**2 **53:**12 **60:**8

sameness [1] **11:**13
satisfy [1] **19:**4
saved [1] **43:**7
saving [2] **35:**22 **39:**25
saw [1] **35:**16
say [31] **6:**5,8,10 **10:**12,15 **13:**3 **18:**8,23 **21:**1 **24:**2,17 **33:**13,23 **34:**18 **37:**19 **39:**23 **42:**14 **43:**12,19 **45:**5,18,19 **46:**20 **48:**16 **49:**3 **51:**5 **53:**6 **55:**4 **59:**17 **61:**9,20
saying [13] **8:**9 **22:**19 **25:**17 **28:**11 **29:**1 **35:**6 **42:**20 **46:**1,4,6 **56:**5 **59:**11 **62:**4
says [12] **12:**2,15 **21:**8 **35:**17 **36:**5 **39:**2 **43:**1 **44:**21 **45:**12 **46:**14,21 **47:**7
scheme [2] **12:**14 **27:**3
scope [1] **38:**1
second [6] **4:**18 **14:**22 **21:**14 **23:**3 **24:**23 **44:**1
section [13] **4:**11,16,21 **5:**20,25,25 **7:**25 **12:**23 **24:**25 **26:**1 **32:**4 **40:**24 **56:**5
sections [1] **11:**23
see [7] **25:**6 **30:**19 **35:**12 **37:**5,8 **41:**24 **48:**16
seems [4] **10:**14 **37:**2 **47:**1 **52:**14
self-adulation [1] **6:**18
sell [4] **27:**7 **31:**12 **40:**4 **45:**2
seller [1] **4:**14
selling [4] **4:**12,17,20 **55:**10
seminar [1] **18:**22
send [2] **7:**1 **61:**7
sending [1] **36:**2
sends [1] **13:**8
sense [4] **41:**14 **51:**12 **55:**15 **57:**18
separately [1] **17:**10
series [1] **21:**20
serious [2] **39:**8 **43:**14
seriously [1] **44:**20
set [1] **26:**15
settled [2] **32:**9 **37:**14
seven [2] **32:**21 **55:**9
severe [6] **31:**13 **34:**9,25 **45:**15 **54:**10 **57:**7
sg [1] **47:**7
sh [1] **6:**7
should [9] **11:**17 **26:**11,20 **33:**18 **35:**20 **36:**5 **56:**20 **61:**23 **63:**7
shouldn't [3] **22:**25 **62:**7,18
show [2] **30:**16 **54:**23
showing [1] **21:**6
shown [2] **16:**4 **24:**12
shows [1] **7:**19
shuts [1] **5:**19
side [3] **44:**4 **60:**14 **63:**20
significant [1] **19:**22
similar [2] **7:**17 **20:**8
similarly [2] **11:**5 **17:**20
simple [1] **10:**2
simply [6] **6:**5 **7:**5 **8:**6 **34:**4 **38:**2 **61:**1
since [4] **41:**17 **59:**3,4,20
single [2] **10:**23 **18:**7
sitting [1] **53:**8
situated [1] **17:**20
situation [5] **7:**17 **12:**20 **34:**2 **58:**17 **60:**23
situations [1] **44:**11
size [1] **47:**19
skinny [13] **12:**3,6 **13:**2 **14:**16 **22:**11 **24:**19 **27:**16,20 **31:**13 **55:**18,22 **56:**15,17
skinny-label [6] **4:**20 **5:**18 **12:**1,24 **31:**9 **49:**3
slight [1] **61:**17
so [45] **4:**19 **9:**23 **10:**13 **11:**15,16 **13:**16 **16:**8 **19:**11 **20:**2,9,12 **21:**8,25 **22:**18 **27:**21,24 **28:**11 **29:**6 **32:**17 **33:**25 **34:**3 **35:**10,24 **36:**9 **37:**5 **38:**1 **41:**3,13 **42:**7 **43:**16 **45:**11,22 **47:**18 **49:**24 **50:**12,18 **53:**21 **54:**13 **55:**2,19,25 **57:**3 **59:**11 **60:**3,7
solely [2] **38:**20 **42:**16
some [12] **10:**14 **11:**19 **17:**9,14 **19:**18 **22:**22 **27:**3 **30:**3,14 **38:**20 **43:**14 **47:**16
somebody [3] **30:**18 **35:**15 **50:**3
somehow [3] **10:**15 **64:**16,20
someone [1] **44:**21
something [7] **11:**22 **15:**22 **20:**22 **24:**8 **27:**7 **39:**24 **49:**16
sony [1] **7:**18
soon [2] **13:**2 **23:**12
sorry [5] **9:**5,5 **51:**2,21 **62:**19
sort [9] **10:**14 **36:**1,19 **56:**6,24 **57:**16 **58:**21 **60:**25 **63:**19
sotomayor [18] **8:**15,20,23,25 **9:**3,10,13,16 **10:**11 **11:**2 **25:**13,14,22 **26:**5,7,17,23 **27:**12
sotomayor's [1] **37:**21
sound [1] **8:**4
sounds [1] **56:**7
space [2] **39:**12,13
speak [2] **23:**9,10
special [3] **8:**16 **25:**20,25
specific [1] **26:**2
specifics [1] **64:**16
spend [2] **31:**22 **58:**9
spent [4] **31:**22 **39:**23,23 **40:**1
spread [1] **41:**7
stage [10] **32:**14 **39:**3 **40:**20 **41:**19 **42:**12 **47:**4 **48:**2 **51:**1 **53:**2,19
standard [14] **5:**3 **6:**15 **8:**10 **9:**8 **19:**3 **26:**15 **32:**8 **37:**4,14,22 **39:**4 **47:**12 **48:**11 **50:**16
standards [2] **10:**19 **42:**10
start [2] **17:**3 **64:**15
started [2] **36:**23 **42:**19
starting [1] **43:**21
state [10] **7:**14 **8:**14 **17:**20 **29:**18 **33:**8,24 **39:**7 **46:**7 **58:**13,25
stated [1] **48:**19
statement [8] **9:**24 **10:**24 **33:**11,16,17 **34:**18,19 **42:**19
statements [31] **4:**19 **5:**1 **7:**19 **8:**4,7,12 **10:**8,16,23 **15:**20 **16:**9 **33:**6 **36:**4,17 **38:**8 **39:**6 **40:**9 **42:**15 **46:**18,23 **48:**14,15,17 **50:**10 **51:**13,17 **55:**1 **57:**10,17 **58:**2 **60:**20
states [9] **4:**24 **14:**5 **16:**12 **17:**15,16,18 **37:**15 **50:**8 **53:**9
states' [1] **22:**6
statute [7] **5:**12 **11:**7,14 **12:**15 **32:**5 **43:**1 **56:**13
statutory [2] **5:**15 **12:**14
stay [2] **59:**5 **60:**13
steps [10] **6:**14 **16:**5 **21:**20,24 **32:**19 **50:**6,9 **51:**11,12 **54:**18
stewart [30] **14:**3,4,7 **15:**14,18 **16:**16,24 **17:**7,16 **18:**17 **19:**2,23 **20:**19 **22:**8 **23:**11 **24:**4,15 **25:**8,21,24 **26:**6,16,22,25 **27:**15,22 **29:**25 **30:**22 **33:**22,23
stewart's [2] **55:**23 **56:**1
still [5] **16:**23 **27:**9 **29:**10 **31:**16 **36:**2
stop [1] **17:**3
straightforward [1] **11:**5
stress [1] **48:**23
strong [2] **24:**6 **33:**24
stronger [1] **59:**18
studies [4] **21:**5 **24:**12,24 **29:**2
study [4] **11:**18 **25:**2,4 **29:**3
stuff [5] **22:**1,2,3,23 **24:**10
subsequent [1] **44:**14
substantial [6] **4:**13 **19:**24 **23:**20 **32:**16 **59:**9 **60:**17
substantially [1] **20:**8
substitution [2] **17:**17 **29:**20
successfully [2] **60:**3,12
such [1] **64:**19
sue [1] **17:**24
sued [5] **13:**6 **14:**23,24 **17:**9 **45:**3
suffice [1] **58:**13
sufficient [3] **14:**12 **26:**4 **36:**21
suggest [1] **28:**2
suggestion [1] **9:**25
suggestive [1] **9:**22
suit [2] **27:**17 **28:**16
suitable [1] **51:**18
suited [1] **4:**12
summarized [1] **24:**25
summary [1] **51:**19
supplied [1] **11:**23
support [1] **54:**17
supported [1] **60:**25
supporting [1] **14:**6
supports [2] **62:**9 **64:**17
supposed [6] **19:**3,11 **22:**15 **23:**2 **48:**8 **61:**21
supreme [2] **53:**9 **61:**22
sure [11] **17:**18 **35:**10 **38:**14 **49:**6 **51:**22 **55:**25 **56:**10,22 **62:**11 **63:**1,22
surest [1] **55:**8
survive [3] **5:**19 **13:**7 **15:**12
swapped [1] **5:**15
synonymous [1] **33:**5

T

table [2] **56:**7,24
take [14] **6:**13 **10:**13 **17:**21 **22:**17 **24:**7 **28:**3 **44:**6,20 **46:**19 **48:**3 **50:**5 **57:**17 **60:**17 **61:**6
taken [4] **16:**5 **40:**21 **47:**14 **59:**8
taking [1] **20:**14
talk [2] **45:**16,17
talked [2] **49:**25 **51:**6
talking [10] **12:**21 **36:**24 **38:**19 **47:**2 **48:**5 **50:**13 **51:**11 **52:**3 **58:**10 **60:**5
task [1] **56:**9
team [1] **41:**1
tell [5] **18:**1 **23:**13 **47:**12 **55:**19 **62:**4
telling [1] **63:**7
term [1] **5:**15

terms [1] **47:**23
terrible [1] **13:**9
territory [2] **52:**12,18
test [2] **18:**13 **25:**2
testified [1] **42:**1
teva [2] **13:**20,20
textbook [1] **34:**15
than [10] **6:**23 **13:**15 **20:**1,6, 20 **30:**13 **35:**8,18 **53:**5 **54:** 25
thank [13] **4:**9 **11:**2 **14:**2,7 **25:**7 **27:**13 **29:**11 **30:**20,22 **63:**24 **64:**8,9,14
that's [53] **7:**22 **9:**11 **11:**13 **12:**13,14,22 **13:**23 **18:**20 **19:**4 **20:**8,25 **21:**7,25 **26:**17 **27:**12 **28:**5 **32:**18 **34:**13,14, 22,25 **35:**3 **37:**9 **38:**4,9,11 **39:**8,11,21 **40:**8 **42:**7 **43:**14, 24 **45:**21 **46:**8 **48:**9,24 **49:**1 **51:**17,18,19 **56:**6,9,16,24 **57:**21 **58:**3,4 **60:**7 **61:**16 **62:** 3 **63:**5,6
their [16] **5:**8 **7:**3 **14:**23,25 **15:**3 **19:**12 **20:**14 **31:**19 **40:** 4 **45:**6,10 **48:**24 **49:**22 **54:** 18 **55:**11 **60:**20
them [16] **7:**6 **10:**8 **17:**9 **21:**2 **26:**21,21 **27:**11 **28:**1 **30:**2 **40:**3 **41:**22 **43:**10 **45:**4,23 **48:**16 **51:**6
then [19] **8:**14 **11:**25 **12:**6 **23:** 3 **26:**7 **27:**8 **28:**23 **38:**5 **43:** 14 **44:**16 **48:**12,18 **49:**21 **50:**4 **51:**14 **57:**13 **61:**7,13, 19
theory [1] **18:**9
therapeutic [1] **45:**20
there [27] **8:**9 **10:**22 **17:**7 **18:** 10 **20:**19,20 **28:**13,19,20 **32:** 15,21 **33:**10,12,14 **35:**5 **41:** 9 **46:**11 **50:**2,2 **52:**16 **56:**13 **59:**19 **60:**13 **63:**1 **64:**5,5,19
therefore [1] **7:**22
there's [16] **9:**18 **12:**15 **20:**9 **22:**16 **26:**8 **35:**24 **40:**24 **44:** 19 **50:**14 **53:**25,25 **55:**9 **56:** 5,24 **59:**19 **61:**21
these [18] **17:**17 **21:**15 **30:**16 **38:**8 **39:**5 **40:**14,22 **41:**7,10, 11,14,21,24 **46:**17 **47:**16 **51:** 12 **55:**1 **58:**2
they [46] **7:**3,4 **10:**9,9,9,10 **11:**25 **14:**23 **15:**14 **16:**8 **17:** 9,9,10,23,24,25 **19:**16 **20:** 11 **21:**9,17 **25:**1 **26:**10 **29:** 23 **34:**3,5,6 **35:**16 **36:**6 **40:** 4,15 **42:**1,2,15 **44:**13 **45:**5,8, 22 **46:**10 **49:**13,14 **50:**12 **52:**25 **54:**2 **55:**13 **58:**1,7
they'll [1] **63:**22
they're [13] **12:**15 **20:**12 **26:** 18,18,19,20 **41:**3 **50:**18,20, 22 **52:**17 **58:**3,4
they've [1] **49:**13
thing [10] **14:**22 **17:**23 **21:**1, 14 **23:**3 **24:**17,20,23 **31:**20 **57:**24
things [13] **9:**25 **10:**3 **12:**11 **17:**8 **21:**2 **22:**12,13,17 **24:**5 **41:**24 **45:**23 **49:**7 **53:**7
think [92] **7:**4 **8:**1 **9:**20 **14:**13 **15:**14 **16:**17 **19:**4,22 **20:**15 **22:**8,18,25 **23:**12,18 **24:**4, 15 **25:**25 **26:**3 **27:**1,22 **28:**4 **29:**21,25 **30:**6 **33:**15,21 **34:** 5,17 **35:**4,25 **36:**11,20 **37:** 11,17,18,18,20 **38:**4,5 **39:**8, 11,21 **40:**22 **41:**6,13 **42:**13, 14,21 **43:**12 **44:**16,23 **46:**5 **47:**16 **48:**1,9,13 **51:**8,14 **52:** 22 **53:**6,21,25 **54:**13 **55:**4 **56:**2,3,8,11,12,23,25 **57:**14, 18,21 **58:**3,9,15,22 **59:**17 **60:**9,25 **61:**15,16,16,17 **62:** 4,8,22,24,25 **63:**17,20
thinks [1] **11:**17
third [3] **16:**7 **19:**14 **29:**23
this [87] **5:**3,19 **6:**18,19 **8:**17, 17 **9:**17 **13:**19 **14:**13 **16:**18, 21 **17:**10,21 **20:**17 **22:**22 **23:**17,18 **24:**8 **25:**5 **26:**11 **27:**17,23 **28:**12 **29:**21 **31:**5, 6,7 **32:**3,3,6,12 **36:**24 **37:**2, 6,7,11 **38:**3,14 **39:**3,16,22 **40:**6,16 **41:**14 **42:**12,20,21 **43:**5,13 **44:**21 **45:**18 **47:**3,6, 9,10 **48:**2,19 **49:**2,17,19,21, 23 **50:**9,16 **51:**1,1 **52:**1,2,23 **53:**3,4,19 **55:**4,10,10,16 **56:** 3,25 **57:**4 **58:**11,19 **59:**22 **60:**23 **61:**1 **63:**9 **64:**15,16
thomas [19] **6:**4,16 **7:**2,9,12 **8:**1 **9:**15 **10:**6 **15:**11,16 **16:** 11,20 **17:**6,14 **25:**10,11 **33:** 10 **34:**3 **64:**2
those [22] **11:**19 **12:**17 **14:** 19 **15:**1 **21:**24 **24:**5 **29:**21 **33:**6 **36:**17 **40:**2,7,8,8 **42:**4, 9 **44:**8 **48:**15,16 **49:**25 **51:** 17 **58:**1 **61:**23
though [7] **8:**4 **30:**8 **32:**25 **34:**18 **39:**2,3 **53:**23
thought [5] **9:**6 **11:**24 **22:**19 **51:**9 **62:**20
threatens [2] **43:**2,4
three [3] **22:**10 **43:**17 **50:**2
threshold [2] **18:**25 **19:**1
through [2] **17:**11 **21:**23
time [4] **46:**6,21 **57:**2,6
tiny [2] **35:**14 **36:**19
today [2] **32:**18 **50:**8
together [1] **54:**17
too [3] **17:**15 **23:**12 **42:**24
took [5] **24:**20,23 **32:**19 **38:**9 **41:**20
totally [2] **10:**10 **38:**23
touch [1] **41:**1
transformation [1] **38:**1
treat [9] **14:**18 **15:**4 **24:**3 **31:** 25 **34:**12,24 **35:**20 **36:**7 **57:** 7
treating [5] **29:**4 **33:**6 **34:**22 **35:**23 **46:**13
treatment [4] **31:**13 **34:**9 **54:** 5,8
trenching [1] **12:**19
trial [2] **31:**23 **49:**6
tried [1] **17:**9
triglyceride [1] **45:**14
trillion [1] **43:**7
true [6] **12:**13,14 **33:**17 **55:**7, 9 **60:**20
truth [1] **33:**25
try [7] **17:**8 **36:**1 **40:**2,7 **57:** 15 **58:**6 **62:**16
trying [3] **59:**17 **62:**4 **63:**18
turn [1] **43:**4
turns [1] **5:**12
tweak [1] **61:**17
twiqbal [1] **37:**7
two [10] **14:**9 **21:**1 **24:**5 **28:** 17 **30:**2 **35:**10 **41:**6 **43:**17 **52:**19 **53:**7
twombly [8] **8:**18,20 **9:**4,9 **10:**4 **38:**2 **53:**13,15
twombly/iqbal [2] **52:**3 **58:** 12
type [1] **7:**17
types [1] **21:**20
typical [2] **37:**12 **63:**18
typically [3] **19:**25 **38:**9 **51:** 18

U

uncovered [1] **59:**21
under [12] **4:**11,21,23 **5:**16 **7:** 25 **9:**4,8 **10:**4 **12:**25 **21:**2 **37:**13 **59:**16
undermine [1] **43:**4
understand [9] **17:**24 **23:**6 **48:**21 **50:**7 **51:**17 **52:**1,25 **55:**2 **60:**4
understanding [1] **47:**23
understate [1] **37:**25
understood [3] **11:**7 **18:**12 **23:**9
undisputed [2] **39:**6 **48:**24
unique [1] **32:**2
united [5] **4:**24 **14:**5 **22:**6 **50:** 8 **53:**9
unlawful [5] **53:**12,18,19 **54:** 17 **57:**16
unless [4] **4:**14 **19:**15 **22:**16 **27:**10
unlike [1] **49:**3
unoffensive [1] **10:**10
unpatented [5] **6:**23 **16:**22 **19:**13 **34:**9 **40:**5
unusual [1] **61:**1
up [3] **10:**14 **54:**16 **64:**17
upsetting [1] **44:**21
urge [1] **17:**20
urging [1] **13:**23
us [2] **9:**14 **40:**24
use [38] **4:**15,17,18 **5:**9 **6:**23 **7:**11 **8:**4,14 **15:**4 **16:**3,13, 14 **18:**10 **19:**7,9,13,15 **21:** 18 **22:**15 **26:**14 **28:**8,10,25 **31:**16 **33:**8,18,18 **34:**9 **35:** 21,22 **39:**17 **40:**5,6 **42:**9 **44:** 14 **49:**21 **54:**6,11
used [8] **9:**21 **16:**22 **18:**2 **21:** 22 **27:**7 **33:**3 **35:**20 **44:**8
uses [6] **4:**13 **7:**4 **16:**23 **19:**8 **28:**12 **35:**18
using [7] **6:**22 **7:**2,3 **9:**22 **20:** 14 **32:**17 **47:**10

V

vacate [1] **58:**17
vague [1] **6:**25
various [2] **19:**6 **21:**19
vascepa [26] **20:**24 **21:**9,10 **24:**2,2,9 **25:**4 **31:**24 **33:**4, 20 **35:**18,21 **36:**7,14,14,15 **40:**10 **45:**16,17 **46:**4,7,13, 21 **47:**19 **57:**4,10
version [7] **13:**5 **20:**23 **21:**9 **23:**5 **30:**10 **35:**7,13
versus [2] **4:**5 **52:**4
very [12] **10:**2 **14:**9 **19:**23 **26:** 12 **37:**19 **45:**2 **49:**5 **50:**12 **53:**8 **59:**14 **60:**23 **61:**1
view [3] **10:**23 **23:**12 **55:**21
viii [5] **4:**16,21 **5:**20,25 **12:**23
vital [1] **31:**19
volume [2] **20:**5 **45:**17

W

waiting [1] **23:**17
want [21] **10:**18 **11:**22 **12:**18

17:24 **23:**9 **30:**4 **33:**13 **37:**18 **41:**23 **42:**24 **48:**22 **51:**5,23 **53:**12 **58:**9 **59:**14 **60:**23 **62:**10,25 **63:**5 **64:**15
wanted [5] **15:**23 **26:**10 **30:**12 **38:**15 **41:**8
wants [2] **39:**25 **55:**6
warned [2] **12:**19 **15:**8
was [64] **6:**6,6 **9:**21,22,22,24 **13:**10 **14:**12 **15:**24,25 **17:**12 **18:**14 **20:**22 **22:**11,19,21 **23:**2 **24:**21,24 **25:**2,4 **28:**19,20 **29:**1,3,10 **30:**4,15 **31:**11,15 **32:**15,23 **33:**5,10,13,14,15 **34:**21,22,24 **35:**5,7 **37:**20 **38:**7 **40:**16 **44:**3,5,19 **46:**11,14,16 **48:**23 **51:**9 **52:**16,19 **53:**15,16,17 **55:**12 **57:**15 **58:**1,5 **64:**24,25
wasn't [1] **9:**23
watering [1] **17:**4
waxman [1] **42:**23
way [20] **7:**6 **8:**2 **9:**24 **11:**25 **20:**15 **27:**8 **30:**6,15 **36:**8 **37:**6,9 **40:**16 **50:**14 **52:**1 **53:**13 **56:**25 **57:**14,21 **62:**11,24
ways [2] **19:**15 **21:**19
we [82] **8:**16 **10:**12,12,16,19 **13:**23,23 **14:**13 **20:**10,11 **22:**8,11,25 **23:**18 **25:**16,19 **26:**3,11,14,20 **27:**2 **28:**3 **30:**2,2,4,12,17 **34:**19 **36:**14 **37:**4,9,9,10,17,17,17,17 **38:**20 **39:**21,23,23,24 **40:**5 **41:**18,20 **43:**19,20,24 **45:**3 **47:**23 **48:**4,8,9,11,15,16,16 **49:**12 **53:**10,12 **54:**16 **57:**23 **58:**15,23,23 **59:**14,14 **60:**2,11,12,17,19,21,23 **61:**3,4,4,19 **62:**7 **63:**5,7,12
website [6] **6:**11 **8:**6 **34:**20 **35:**5,6 **54:**3
weigh [2] **63:**10,12
weight [2] **14:**14 **23:**1
welcome [3] **6:**3 **15:**10 **33:**9
well [12] **7:**2 **20:**10 **24:**16 **35:**3 **44:**23 **45:**25 **50:**24 **52:**25 **56:**20 **59:**23 **61:**3,11
we'll [1] **4:**3
went [1] **24:**2
were [14] **7:**1 **10:**9,9,10 **22:**11,13 **23:**19 **40:**14,22 **42:**15,16 **47:**17 **54:**2 **58:**1
we're [21] **10:**12 **12:**21 **21:**8 **40:**19 **41:**19 **42:**8,9 **43:**22,23 **47:**2,3,8 **49:**14,19 **50:**13 **51:**10,15 **54:**20,23 **63:**8,11
we've [2] **21:**11 **59:**21
what [67] **6:**14,16,17 **8:**1 **10:**16 **12:**2 **13:**22 **15:**11 **16:**11,11,14 **17:**18 **18:**8,14 **19:**21 **21:**18 **22:**9 **23:**1,13,22,25 **24:**11 **25:**1,18 **26:**11 **28:**1,3,8,20,22 **29:**1,18,18 **30:**17 **34:**3,20 **35:**5 **37:**9 **38:**7,17 **39:**21 **40:**8,12 **43:**10 **45:**5 **47:**5,5,8,13,22 **48:**10 **49:**19 **51:**11 **52:**5,22 **53:**10 **54:**2,20 **55:**21 **60:**5,19,24 **61:**18,23 **62:**3 **63:**5,6
whatever [2] **18:**23 **32:**7
what's [4] **21:**10 **27:**21 **28:**7 **38:**18
when [18] **4:**25 **6:**9 **7:**17 **14:**22 **19:**6 **21:**8 **24:**18 **26:**14 **27:**19 **31:**11 **33:**4 **36:**12 **40:**5 **42:**3,19 **43:**19 **44:**21 **61:**7
where [12] **34:**20 **39:**6 **40:**20 **42:**1 **43:**22 **44:**11 **46:**11 **49:**4,6 **53:**16 **54:**4 **58:**10
whether [10] **5:**6 **9:**18 **15:**7 **32:**10,18 **33:**15 **37:**13 **47:**24 **52:**4 **63:**10
which [21] **8:**7 **9:**13 **21:**11 **25:**2 **26:**1 **28:**8,14 **30:**10 **34:**19 **35:**11,22 **37:**25 **41:**15 **43:**3,12 **45:**10 **46:**17 **51:**16 **54:**2,16 **58:**20
while [1] **36:**2
who [6] **16:**2 **19:**14 **32:**23 **38:**8 **45:**2 **55:**11
whole [4] **19:**10 **26:**8 **34:**7 **52:**15
who's [1] **30:**9
why [19] **7:**5 **13:**23 **14:**23 **20:**8 **26:**20 **29:**23 **38:**14 **42:**21 **44:**24 **48:**9,18 **52:**23,24 **55:**19,24 **56:**16,20 **58:**3,4
wide [2] **28:**12 **41:**8
widely [1] **41:**23
will [16] **4:**17 **5:**18 **13:**7,15 **19:**17,18 **21:**24 **22:**24 **28:**6,8 **30:**10,11 **31:**6 **32:**4 **49:**6 **58:**24
willingness [1] **23:**14
win [4] **8:**17 **10:**4,20 **25:**23
with [42] **4:**19,25 **5:**8,11,14,25 **7:**10 **9:**25 **10:**25 **11:**5 **13:**19 **14:**9,19 **15:**24 **16:**3,21 **21:**20 **22:**11 **24:**19 **31:**12 **33:**5,25 **35:**5 **37:**22 **40:**8,16 **41:**1 **44:**10 **45:**15 **47:**23 **50:**16 **51:**15 **57:**7,13 **61:**17,22 **62:**13,16,21 **64:**16,24,25
without [2] **19:**13 **30:**1
wondered [1] **36:**23
won't [3] **5:**21 **27:**9 **28:**13
word [2] **28:**3 **48:**24
worded [2] **35:**25 **36:**20
words [4] **8:**10 **10:**18 **20:**9 **37:**22
work [2] **18:**23 **24:**8
works [2] **12:**1 **30:**6
world [6] **15:**16,17,18 **30:**6,13 **52:**15
worst [1] **5:**22
would [70] **8:**13,13 **14:**20 **15:**11,14,19 **16:**8,25 **18:**3 **19:**22,22 **20:**4,5,5,15,16 **22:**9 **23:**14,20 **24:**6,7,15,17 **28:**1,12,21,23 **29:**21,21 **30:**18 **33:**23 **36:**6,25,25 **37:**25 **39:**17 **40:**11,11,13,18 **46:**4 **47:**13 **48:**13 **49:**5 **53:**6,10,23 **54:**25 **55:**22,22 **56:**1 **58:**11,17,18,20 **59:**1,14,15 **61:**1,4,6,7,9,18,19,19,20 **63:**1,2,12
wouldn't [6] **6:**4,20 **7:**6 **55:**13 **61:**3,4
writing [1] **30:**9
written [2] **30:**8 **36:**1
wrong [4] **14:**21 **20:**22 **50:**18,20

Y

yeah [14] **7:**9,12 **8:**22,23 **9:**15 **17:**6 **38:**22 **44:**15 **60:**8 **62:**1,1,2,6 **63:**9
years [3] **39:**23 **43:**8 **61:**10
yes [13] **9:**12,12 **20:**19 **23:**11 **26:**6 **33:**12 **41:**14 **48:**16 **49:**11 **52:**7,10,13 **59:**25
yet [1] **60:**21
you'd [4] **30:**16 **59:**12 **62:**2,11
your [54] **6:**8 **7:**2,19 **8:**3,5 **10:**21 **13:**2 **15:**16 **18:**22 **23:**23 **25:**7,16 **26:**9 **27:**15 **33:**13 **34:**6 **35:**3,10,16 **36:**12,23 **37:**9 **38:**19 **40:**19 **41:**15 **42:**19 **45:**1 **46:**5 **47:**12 **48:**3,3,7,13,22 **49:**4,8,24 **52:**1,1,1,25 **53:**1,7 **55:**16,17,18,21 **59:**12,13,25 **61:**16 **63:**13,17 **64:**14
you're [4] **8:**16 **9:**13 **53:**15 **54:**14
you've [3] **10:**3 **27:**10 **55:**17

Z

zero [1] **64:**23
zydus [1] **45:**22