

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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AMARIN PHARMA, INC., ET AL.,)

Respondents.)

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Washington, D.C.

Wednesday, April 29, 2026

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 12:23 p.m.

1 APPEARANCES:

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

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

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

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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 induce infringement" when dealing with statements

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

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

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

23 Reversal is needed to harmonize
24 Section viii with Section 271(b) and to
25 encourage legitimate competition that reduces

1 drug prices.

2 I welcome the Court's questions.

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

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

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

23 MR. KLEIN: The hypothetical is -- is
24 a little vague, but if -- if Hikma or a generic
25 were to send a clear message that --

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

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

8 JUSTICE THOMAS: Yeah.

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

11 JUSTICE THOMAS: Yeah.

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

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

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

25 JUSTICE THOMAS: I -- I think what I'm

1 asking you is, is the only way to actively
2 induce infringement is overstating or your own
3 statements sound as though the patented use is
4 covered by your product, as opposed to simply
5 quoting the Respondent's website or statements
6 about its product, which is patented?

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

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

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

18 JUSTICE SOTOMAYOR: It passes Twombly
19 and Iqbal?

20 MR. KLEIN: Our case, yeah.

21 JUSTICE SOTOMAYOR: Yeah, meaning --

22 MR. KLEIN: Easily.

23 JUSTICE SOTOMAYOR: -- the complaint
24 here --

25 MR. KLEIN: The complaint --

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

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

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

10 MR. KLEIN: Yes, yes.

11 JUSTICE SOTOMAYOR: -- which is you're
12 asking us to announce rules that -- that --
13 almost impossible in this area because
14 determining whether or not there's active
15 inducement is always contextual.

16 I think Grokster said that one of the
17 factors it used was that the name that the
18 infringer was using was suggestive of the
19 infringement. So that wasn't an express
20 statement of any way to infringe. It was a
21 suggestion. But, in context with other things,
22 it reached active inducement.

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

1 correct?

2 MR. KLEIN: That is correct. The
3 statements here, as the government called them,
4 were anodyne. They -- they -- they were
5 unoffensive. They were totally consistent --

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

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

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

22 JUSTICE SOTOMAYOR: All right. Thank
23 you, counsel.

24 JUSTICE JACKSON: Can I ask you a
25 similarly straightforward question? With

1 respect to Amarin's allegations concerning the
2 label, I had understood that by statute,
3 generics have to have a label that essentially
4 in all relevant circumstances mirrors the brand
5 label, except for just admitting the patented
6 indication. Is that correct?

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

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

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

20 And then the way the FDA, the -- the
21 skinny-label process works is the FDA compares
22 what Amarin says is patented in the label to
23 the proposed skinny-label, and it's a
24 ministerial role. If -- if the generic carved
25 out everything that the brand said is patented,

1 then the skinny-label can be approved. And the
2 generic can't add new disclaimers or -- or new
3 labeling.

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

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

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

20 And as a practical matter, under the
21 decision below, you can get FDA approval of
22 your skinny product label, but as soon as you
23 put that product into commerce and you say
24 anything about that product, anything, you call
25 it a generic version, even if you have

1 disclaimers, you can be sued.

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

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

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

20 CHIEF JUSTICE ROBERTS: Anything else?

21 Anything else? No?

22 Thank you, counsel.

23 Mr. Stewart.

24

25

1 ORAL ARGUMENT OF MALCOLM L. STEWART
2 FOR THE UNITED STATES, AS AMICUS CURIAE,
3 SUPPORTING THE PETITIONERS

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

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

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

19 The second thing is, when Respondents
20 explain in their brief why they sued Hikma but
21 haven't sued any of the other generic
22 manufacturers of icosapent ethyl, their
23 explanation is all of those other manufacturers
24 included in press releases express disclaimers
25 to the effect that their product is not

1 authorized for use to treat the CV indication.
2 But it's a bedrock principle of inducement law
3 that active inducement to infringe is required.
4 The question is not whether the defendant has
5 adequately warned people away from
6 infringement.

7 I welcome the Court's questions.

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

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

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

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

21 The Court in Grokster said it was with
22 reference to copyright, but it was drawing on
23 copyright -- on patent law principles.

24 The Court said one who distributes a
25 device with the object of promoting its use to

1 infringe copyright as shown by clear expression
2 or other affirmative steps taken to foster
3 infringement is liable for the resulting acts
4 of infringement by third parties. And so they
5 would have needed to point to statements or
6 actions that clearly revealed a purpose to
7 induce infringement.

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

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

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

20 MR. STEWART: I mean, the preliminary
21 point I would make is the perceived difficulty
22 or the actual difficulty of going after the
23 direct infringer or getting the direct
24 infringement to start -- to -- to stop is not a
25 justification for watering down inducement

1 principles.

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

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

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

18 The other thing they could do, I
19 understand they don't want to sue the doctors,
20 but they could attempt informational campaigns
21 to doctors and tell the doctors our product is
22 the only one that is authorized to be used for
23 the CV indication. It would be infringement of
24 patent to administer icosapent ethyl for the
25 purpose of reducing cardiovascular risk.

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

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

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

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

22 MR. STEWART: I -- I mean, it is
23 supposed to be a -- a difficult standard for
24 the pleader to satisfy, but I think that's for
25 design. That is, the Court has said in various

1 contexts that when a product is capable of both
2 infringing and non-infringing use -- uses, it's
3 important that a patent on one method of use
4 not become a de facto monopoly on the product
5 as a whole.

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

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

18 MR. STEWART: It's very substantial in
19 part because the generic is charging a lot --
20 typically, a lot less for the drug than the
21 brand name manufacturer is. And so, if the
22 generic has to pay lost profits to the -- the
23 brand name, the profits that the brand name
24 would have earned on a particular volume of
25 sales would -- would be much more than the

1 generic has actually earned.

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

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

19 But, in fact, that's a normal thing to
20 say. It really refers to two different things.
21 One of them is, under the abbreviated new drug
22 application process, the generic comes on the
23 market not by conducting independent studies of
24 safety and efficacy but by showing that it is
25 equivalent to a drug that's already been found

1 safe and efficacious.

2 And so, when Hikma says we're the
3 generic version of Vascepa, they just mean
4 Vascepa is what's called the reference listed
5 drug. It is the drug as to which we
6 established equivalence in order to get
7 approval.

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

15 And everybody agrees, if Hikma's drug
16 is used to reduce the risk of cardiovascular
17 death or events through the performance of
18 those steps, infringement will occur. The
19 reason that's so is that Hikma's drug is ethyl
20 icosapent. It's the same stuff. And it's the
21 same stuff for infringement purposes, but it's
22 also the same stuff for describing the product.

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

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

11 And so the Federal Circuit, I think,
12 thought it was being limited by saying the
13 label by itself is not enough to get past
14 12(b)(6), but the flavor of its opinion was
15 this is almost enough, and if you have some
16 pretty ethereal stuff at the -- in addition,
17 that will be enough to get you over the hump.
18 And we think it shouldn't have attached any
19 weight to the label. Hikma just did what it
20 was supposed to do.

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

24 JUSTICE KAVANAUGH: I understand that,
25 but the interest -- the implications of the

1 decision in the marketplace at large, I
2 understood -- do you want to speak to that or
3 not speak to that?

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

15 JUSTICE ALITO: What if --

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

18 JUSTICE ALITO: What if Hikma -- Hikma
19 had -- had not just said its drug is generic
20 Vascepa but went on to say that Vascepa is
21 approved to treat cardiovascular risks?

22 MR. STEWART: I think, if it had said
23 those two things in the -- in the same breath,
24 that you would have a pretty strong case of
25 active inducement, that it would not take much

1 work to connect the dots that this is something
2 Vascepa has been approved for and ours is the
3 same stuff.

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

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

16 But a second thing that it took off of
17 Amarin's label was, in the clinical studies
18 section of Amarin's label, Amarin summarized
19 the results of what they call the REDUCE-IT
20 study, which was designed to test the efficacy
21 of the product for reducing cardiovascular
22 risks, and the study concluded that Vascepa was
23 efficacious for this purpose. And --

24 CHIEF JUSTICE ROBERTS: I -- I see
25 your red light is on.

1 MR. STEWART: Okay.

2 CHIEF JUSTICE ROBERTS: Justice
3 Thomas?

4 JUSTICE THOMAS: No.

5 CHIEF JUSTICE ROBERTS: Justice Alito?
6 Justice Sotomayor?

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

14 MR. STEWART: I don't --

15 JUSTICE SOTOMAYOR: -- for Petitioner
16 to win?

17 MR. STEWART: I -- I don't think you
18 need special rules. I -- you are interpreting
19 Section 271(b), which is not specific to
20 Hatch-Waxman. It's just the general inducement
21 provision. And we think application of the
22 general rules is sufficient.

23 JUSTICE SOTOMAYOR: Is enough? Okay.

24 MR. STEWART: Yes.

25 JUSTICE SOTOMAYOR: And then, finally,

1 there's a whole lot of discussion about
2 congressional policy, both in your brief and in
3 Petitioners' brief, that they wanted to
4 encourage this, and we should rule that what
5 active infringement means in patent law is very
6 narrow because of that.

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

9 MR. STEWART: Right.

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

15 MR. STEWART: I don't --

16 JUSTICE SOTOMAYOR: -- to avoid either
17 result?

18 MR. STEWART: I -- I basically agree.
19 I don't think it's a main -- matter of changing
20 the rules. We have described the Hatch-Waxman
21 scheme at some length because it's pretty
22 complicated. But, in the end, Hatch-Waxman
23 embodies the same basic principles as the
24 Patent Act generally; namely, if you sell
25 something that can be used either in an

1 infringing or a non-infringing way, then you
2 still won't be held liable for others'
3 infringement unless you've actively encouraged
4 them to infringe.

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

7 CHIEF JUSTICE ROBERTS: Justice Kagan?

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

13 So what's the answer to that question?

14 MR. STEWART: I mean, I think the --
15 the Court discussed this in Caraco. The FDA
16 has disclaimed patent expertise, and so it
17 doesn't purport to read patents and determine
18 what conduct would infringe them.

19 But Respondents suggest that the
20 result is we take the generic's word for what
21 is and isn't infringing. And I think that's
22 not correct. As the Court explained in Caraco,
23 the brand-name manufacturer will provide for
24 the Orange Book what's called a use code, which
25 will describe what it believes its patents

1 cover. And the FDA considers itself bound by
2 the use code.

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

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

18 And what I was saying before about the
19 clinical studies, although Amarin's label had a
20 description of the REDUCE-IT study that was
21 about efficacy of the drug for treating
22 cardiovascular -- or preventing cardiovascular
23 events, Hikma omitted that from its own label.
24 So it didn't just omit the indication. It
25 omitted another part of the label that referred

1 to the efficacy of the drug for that purpose
2 because the purpose was still patented.

3 JUSTICE KAGAN: Thank you.

4 CHIEF JUSTICE ROBERTS: Justice
5 Gorsuch?

6 Justice Kavanaugh?

7 Justice Barrett?

8 Justice Jackson?

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

17 MR. STEWART: I -- I mean, I think the
18 Court can decide the case without referring to
19 them. The -- we had two basic reasons for
20 including some discussion. The -- the first
21 was we didn't want the Court to decide the case
22 based on a misimpression of the facts or the
23 way the world works. And I think portions of
24 the court of appeals opinion are written as
25 though, in -- in each case, the doctor who's

1 writing the prescription determines which
2 version of the drug will be dispensed and that
3 will carry the day.

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

11 JUSTICE JACKSON: I see.

12 CHIEF JUSTICE ROBERTS: Thank you,
13 counsel.

14 MR. STEWART: Thank you.

15 CHIEF JUSTICE ROBERTS: Mr. Huston.

16 ORAL ARGUMENT OF MICHAEL R. HUSTON

17 ON BEHALF OF THE RESPONDENTS

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

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

25 Hikma got the full benefit of the

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

8 That limitation on generic marketing
9 of their products is absolutely vital. It is
10 the only thing that makes it economically
11 rational for a branded company like Amarin to
12 spend the \$300 million that Amarin spent in the
13 REDUCE-IT trial to discover that an existing
14 drug, Vascepa, actually had life-changing
15 implications to treat cardiovascular risk. And
16 that rule of induced infringement liability is
17 not unique to pharmaceuticals.

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

23 The standard for induced infringement
24 liability is settled. In most cases, the key
25 dispute is going to be whether the defendant

1 had the requisite intent to infringe. But
2 Hikma has not contested its intent as this case
3 comes to the Court because the case is at the
4 pleading stage.

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

11 It is plausible. There are seven
12 other generic manufacturers of icosapent ethyl
13 on the market, but Hikma alone was the one who
14 described its product as AB rated for
15 "hypertriglyceridemia," even though that
16 product is not approved for that distinct
17 medical condition.

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

24 I welcome the Court's questions.

25 JUSTICE THOMAS: Was there anything

1 inaccurate about that statement?

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

13 And I heard Mr. Stewart say that would
14 state a claim for induce -- a strong claim for
15 induced agreement. I agree with that. So
16 truth is not a defense to liability in an
17 induced infringement situation.

18 JUSTICE THOMAS: So what if they
19 simply quote you?

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

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

7 I -- I also do think it's important to
8 say, though, that the -- the key statement on
9 which we rely here, the statement on Hikma's
10 website where it described what its drug is
11 for, was not accurate. Hikma said its product
12 was for treating hypertriglyceridemia. That's
13 misleading, if not false, because Hikma's
14 product was approved by FDA only to treat
15 severe hypertriglyceridemia, and that's a
16 distinct medical condition that presents
17 distinct medical risks.

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

25 MR. HUSTON: Sure, Your Honor. So two

1 points about that disclaimer which is at JA
2 195. First, as you can see even on the
3 blown-up version in the Joint Appendix, it
4 really appears in quite tiny print, but even
5 if the -- even if somebody read it, even if
6 they saw the disclaimer, just as Your Honor
7 read, all it says is Hikma's product is
8 approved for fewer than all uses of Vascepa.

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

14 So there's nothing -- the disclaimer
15 is I think at best carefully worded, it's sort
16 of written by a clever lawyer to try to
17 minimize Hikma's liability while still sending
18 the fundamental message that is coming across
19 by all the collection of Hikma's statements
20 that says doctors can and should prescribe
21 Hikma's product anytime they would prescribe
22 Vascepa, including to treat cardiovascular
23 risk, in a way that infringes Amarin's patents.

24 So I --

25 JUSTICE BARRETT: Oh, go ahead.

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

12 JUSTICE BARRETT: Mr. Huston, I just
13 wondered, if you -- you started in your opening
14 talking about the impact of this case that
15 would be more broad, that it would extend
16 beyond just the pharmaceutical industry.

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

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

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

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

14 I -- I -- I can't -- I just can't
15 understate the extent to which that would be a
16 transformation of the scope of patent law. So,
17 if the Court is going to simply apply *Twombly*
18 and *Iqbal* to the facts of this case, and I -- I
19 do think that's the right approach to the case,
20 then I continue to think that the key question
21 in the case is in -- in -- as in most cases of
22 induced infringement, what was the message that
23 the doctors who read these Hikma statements
24 took away? And that's typically a fact
25 question.

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

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

12 MR. HUSTON: Yeah. No, I -- I'm
13 totally --

14 JUSTICE BARRETT: Okay.

15 MR. HUSTON: Let me -- I appreciate
16 the opportunity to clarify.

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

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

11 And I think that's what we are really
12 fighting for in this case, is the opportunity
13 to say: We spent five years, we spent \$300
14 million, and we discovered something that is
15 literally saving people's lives. Hikma wants
16 to come and, having spent no money basically at
17 all, try to capture all of those gains. The
18 patent law doesn't allow them to do that. They
19 are allowed to sell their product for the
20 unpatented use, but when we have discovered
21 this game-changing "new use," Hikma can't come
22 in and try to capture those -- those -- those
23 sales. That's what it did with its repeated
24 statements by calling itself generic Vascepa
25 over and over again by mis --

1 JUSTICE KAGAN: Would -- would --

2 JUSTICE KAVANAUGH: What --

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

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

12 I think Hikma's claim that these were
13 directed at investors is really just grounded
14 in the fact that there's a "Contact us" section
15 of the press release that allows you to get in
16 touch with the investor relations team, in
17 addition to other kinds of, you know, phone
18 numbers provided. So they're not consciously
19 directed at investors, not expressly directed
20 at investors.

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

24 JUSTICE KAGAN: I mean, is there any
25 evidence at all Hikma directed these to the --

1 to the medical community, that Hikma gave these
2 press releases to doctors?

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

15 And evidence has come in in other
16 cases where doctors have testified that they do
17 pay attention to press releases and that they
18 do pay attention to the announcements of when
19 generics are coming online. And those kinds of
20 announcements do affect doctors' prescription
21 decisions.

22 So that's all evidence that, you know,
23 we're going to put on -- you know, that --
24 those -- we're going to use the Federal
25 Circuit's established standards for pleading

1 induced -- or for proving induced infringement
2 claims. It only has to be plausible at this
3 stage. And I don't think it's a fair inference
4 -- I don't think you can say the only fair
5 inference from Hikma's statements is that they
6 were directed solely at investors and were not
7 going to reach doctors.

8 JUSTICE KAVANAUGH: But I guess, to
9 your initial statement when you started out
10 saying this is not a Hatch-Waxman case at all,
11 I think you said that, and to why this case is
12 here, because I'm glad it's here, the federal
13 -- Congressman Waxman filed an amicus brief.
14 And I don't want to put too much faith in a
15 former Congressman's brief about his own
16 statute, but it says, "the Federal Circuit's
17 decision threatens to decimate the compromise
18 at the heart of the Hatch-Waxman Act, which in
19 turn threatens to undermine the generic
20 pharmaceutical industry, if this kind of
21 complaint is good enough." And it points out,
22 you know, "generics have saved 3.4 trillion
23 over the past ten years, but the Federal
24 Circuit's decision here leaves generic drug
25 companies in the dark about what might expose

1 them to liability."

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

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

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

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

25 The dark green briefs are replete with

1 examples of situations where that has happened.
2 It can only happen, it's only economically
3 rational to occur, if they can get patent
4 protection for that subsequent use.

5 JUSTICE KAVANAUGH: And --

6 MR. HUSTON: And then I think the last
7 --

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

13 MR. HUSTON: Well, I think the -- the
14 -- the last reason why the Court can have
15 confidence that that is not going to come to
16 pass, Your Honor, is the example of the many
17 other generics who sell the very same product
18 that Hikma does. And we haven't sued any of
19 them.

20 And you can look at what they say on
21 their press release to know that generics have
22 a ready road map to avoid induced infringement
23 liability. All they have to do is accurately
24 describe the limited purpose for which their
25 drug is approved.

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

15 JUSTICE JACKSON: But, counsel --

16 JUSTICE ALITO: Just saying --

17 JUSTICE JACKSON: -- can I --

18 JUSTICE ALITO: -- just -- just saying
19 generic Vascepa would be enough?

20 MR. HUSTON: I do not think, Your
21 Honor, that merely saying, one time, generic
22 Vascepa is enough to state a claim for
23 liability. And that's not our allegation. Our
24 allegation is that Hikma said it over and over
25 and over again and that they did it at just the

1 key moment where there was a market -- a
2 market -- key market association between
3 Vascepa and treating cardiovascular risk.

4 That was the context. Grokster says,
5 of course, that induced infringement is a
6 context-dependent analysis. That was the
7 context into which Hikma launched these
8 statements over and over and over again.

9 But I take the point, I'm certainly
10 not here to say that a company that one time
11 says generic Vascepa is going to be held
12 liable. As the Federal Circuit held, Hikma did
13 much, much more. It made statements that no
14 other generic manufacturer --

15 JUSTICE JACKSON: But, counsel, I
16 guess it -- it seems to me you -- you do
17 emphasize that we're talking about plausibility
18 and this is early in the case and we're at the
19 motion to dismiss stage. But that does
20 highlight what has to be plausible, what is the
21 focus of this.

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

1 patented purpose.

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

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

15 MR. HUSTON: A couple points about
16 that, Justice Jackson. I think the first is
17 that, of course, at this stage of the case,
18 your own -- you can't just take Hikma's
19 assertion that, oh, we put out that press
20 release for the purpose of talking to our --

21 JUSTICE JACKSON: No, but it's your
22 burden if we are supposed to be looking for
23 intent. And I guess that's why I think we do
24 have to kind of focus on what the legal
25 standard is here. If -- if -- if we are

1 looking for intent to induce infringement, then
2 I would think it's your burden to actually have
3 statements and evidence that go to that.

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

10 MR. HUSTON: I understand the
11 question, Your Honor, but I -- I -- I want to
12 stress the Federal Circuit found that it was
13 undisputed -- that's their word -- that in --
14 Hikma did not contest the requisite intent.
15 That's at Pet. App. 15a.

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

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

24 MR. HUSTON: Yes --

25 JUSTICE JACKSON: I don't know that we

1 can disaggregate. I mean, they've they -- they
2 might have -- Hikma might have said we're not
3 really focused on our intent to induce
4 something or our intent to have people buy more
5 of this product.

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

12 MR. HUSTON: So, Your Honor, I mean,
13 the Court has always talked about those as
14 distinct elements of induced infringement.
15 There are three elements. There has to be --
16 direct infringement, somebody has to do the
17 infringing. And then the inducer has to both
18 have the intent that that happen and take
19 active steps.

20 JUSTICE JACKSON: I understand, but
21 the United States today said the active
22 inducement -- active steps prong of this is
23 statements and acts that are -- that
24 demonstrate an intent to induce the doctors.
25 So they brought intent into the very element

1 we're talking about here.

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

6 JUSTICE JACKSON: So they're wrong
7 about that?

8 MR. HUSTON: They're wrong --

9 JUSTICE JACKSON: All right.

10 MR. HUSTON: There are just distinct
11 elements --

12 JUSTICE GORSUCH: Well, how --

13 MR. HUSTON: -- and the intent element
14 isn't part of this case at this stage.

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

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

1 statements.

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

9 Justice? I'm sorry.

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

12 (Laughter.)

13 JUSTICE GORSUCH: Let me come at it
14 this way. I understand your -- your -- your
15 point about this case being a little different,
16 but, you know, Twombly and Iqbal talking about
17 whether you have an antitrust conspiracy versus
18 maybe entirely rational independent conduct,
19 right?

20 MR. HUSTON: Yes.

21 JUSTICE GORSUCH: The Baby Bells,
22 right?

23 MR. HUSTON: Yes.

24 JUSTICE GORSUCH: Not to compete in
25 one another's territory.

1 MR. HUSTON: Yes.

2 JUSTICE GORSUCH: It seems like a
3 whole different world.

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

10 And I -- I think what Justice Jackson
11 is getting at is, why isn't this case just like
12 that? Why isn't that the question? I
13 understand your point that, well, they didn't
14 contest it, but it is your burden on -- on a
15 motion to dismiss stage to -- to rule out that
16 lawful intent, hey, this is puffery for
17 investors, and this can be plausibly explained
18 by -- by that rather than infringement.

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

1 defendant in Twombly contested its intent.

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

7 JUSTICE GORSUCH: Okay. I got you.

8 MR. HUSTON: So I just think it's a
9 different -- but, I mean, the other -- the
10 other point I would make is, though -- even
11 that kind of intuition, even a -- if you -- if
12 you think, okay, there's a -- there's an
13 alternative explanation for the press releases,
14 which is what -- that they were aimed at
15 investors, that cannot explain Hikma's website,
16 where it's described its -- it describes its
17 product as a treatment for
18 hypertriglyceridemia, the infringing use,
19 instead of, as all the other generic companies
20 do, as a treatment --

21 JUSTICE GORSUCH: Got you.

22 MR. HUSTON: -- for severe
23 hypertriglyceridemia use.

24 JUSTICE GORSUCH: I got you.

25 MR. HUSTON: So here again, I think

1 you're -- you can't -- even that conception of
2 the case cannot carve out all of the
3 allegations we have made, all of which add up
4 together to support Hikma's unlawful intent and
5 their active steps that have the effect of
6 inducing infringement. And that is
7 fundamentally what we're going to be held to
8 the burden to prove, as in all other cases of
9 induced infringement.

10 We're going to show that the
11 infringing sales of our product happened faster
12 and to a greater degree than would have
13 occurred had Hikma not made these statements.
14 And so, again, I -- I understand the Court's
15 concern about the idea that, you know, and I
16 think my friends have attempted to say this is
17 going to devastate the generics market. Nobody
18 wants to devastate the generics market. But
19 it's just factually not true.

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

1 other generics aren't here.

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

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

12 MR. HUSTON: Sure. So, Justice Kagan,
13 I would not accept Mr. Stewart's proposition
14 that that has no relevance, and I think the --
15 I think the reason for that is that this Court
16 is not accustomed in pleading cases and in
17 Section 271(b) cases to saying there's a
18 category of evidence that's sort of
19 fundamentally off the table. That to me sounds
20 like the creation of a safe harbor, and I think
21 that's a legislative task fundamentally.

22 Now, to be sure, Hikma has -- you
23 know, I -- I don't think Hikma could be held
24 liable -- or, you know, I -- I -- I -- I think
25 that there is a protection in the statute in

1 Hatch-Waxman for -- for Hikma to prepare a
2 skinny label.

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

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

9 MR. HUSTON: Sure. Because, again, I
10 don't think that the Court has generally said
11 there's sort of evidence that's off the table.
12 But the way I think about the label in this
13 case, because keep in mind the label comes
14 factually later in time.

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

25 Then it comes out with its label. And

1 the way I think about the label is the label
2 was an opportunity for Hikma to try to -- to
3 sort of mitigate the damage from its unlawful
4 statements and it didn't take it. And in that
5 sense, I think the Hikma -- the Hikma label
6 maybe -- you know, probably, arguably,
7 exacerbated our harm, but that's the way I
8 think about the label.

9 It's -- it is definitely not the --
10 the key contention that we rely on because,
11 again, it's not the thing that distinguishes
12 Hikma from all the other generic manufacturers.

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

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

1 a claim for relief.

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

9 And I think that disposition, again,
10 I -- you know, obviously, we -- we hope that
11 you will agree that the -- the -- the -- the
12 complaint here does state a claim, but in the
13 event the Court didn't, it would be especially
14 important for the Court to allow the case to
15 proceed back on remand because, since the
16 Federal Circuit remanded the case and since
17 Hikma did not stay the mandate, extensive
18 discovery has occurred. Millions of documents
19 have been exchanged, 12 depositions have --
20 have come -- have been taken, and that has
21 revealed substantial new evidence of Hikma's
22 intent to infringe and the effect.

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

25 MR. HUSTON: Absolutely, Your Honor.

1 We would -- we very much want the opportunity
2 to amend. That would normally be the course
3 under the Federal Rules of Civil Procedure, and
4 all I'm trying to say is I think the case for
5 our opportunity to amend is even stronger here
6 given that there -- you know, there's been a
7 material change in the case since the Federal
8 Circuit's opinion. We've uncovered all of this
9 new evidence.

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

12 MR. HUSTON: Yes, Your Honor.

13 JUSTICE KAVANAUGH: Okay.

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

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

19 MR. HUSTON: That's right. And so,
20 again, the case has the same posture as all the
21 cases cited on, I think, page 51 of our brief.
22 A district court judge grants a motion to
23 dismiss. We elect to appeal that judgment. We
24 successfully appeal it. The Federal Circuit
25 reverses. There is no stay of the mandate by

1 my friends on the other side. The case returns
2 to district court. Judge Andrews opens
3 discovery.

4 And we take substantial discovery, and
5 discovery does its job. It reveals that
6 exactly what we allege about Hikma's intent and
7 the effects of their statements is true. And
8 we haven't yet had an opportunity to bring that
9 out, but, you know, obviously, in -- in this
10 situation, we very much want that opportunity
11 to bring that evidence. And what I don't think
12 is supported is Hikma's sort of very unusual
13 ask that this Court would simply declare case
14 over and --

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

23 MR. HUSTON: Well --

24 JUSTICE GORSUCH: -- and -- and
25 you could -- you could then file a motion for

1 leave to amend. Is -- is that about right?

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

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

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

18 JUSTICE GORSUCH: Yeah, no, right.

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

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

25 JUSTICE KAVANAUGH: You agreed with

1 Justice Gorsuch, right?

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

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

7 JUSTICE BARRETT: I thought you agreed
8 with Justice Gorsuch.

9 MR. HUSTON: I think I mostly agree,
10 and I hope I -- I hope I don't -- I hope I
11 agree in full. But I -- I think the right way
12 to think -- I don't -- I don't -- I just want
13 to make sure that there would be an
14 opportunity -- the district court judge would
15 entertain a motion to amend the complaint.

16 JUSTICE KAVANAUGH: Right.

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

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

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

25 MR. HUSTON: That is your --

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

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

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

11 JUSTICE GORSUCH: Thank you.

12 CHIEF JUSTICE ROBERTS: Anything
13 further?

14 JUSTICE THOMAS: No. No.

15 CHIEF JUSTICE ROBERTS: Anything
16 further?

17 Is there anything further down there?

18 No?

19 Anything further?

20 Okay. Thank you, counsel.

21 MR. HUSTON: Thank you.

22 CHIEF JUSTICE ROBERTS: Rebuttal,
23 Mr. Klein.

24

25

1 REBUTTAL ARGUMENT OF CHARLES B. KLEIN

2 ON BEHALF OF THE PETITIONERS

3 MR. KLEIN: Thank you, Your Honor.

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

13 The dismissal below also was with
14 prejudice. And it was with prejudice because
15 Amarin conceded to that judgment. And so if --
16 if the Court were to remand, it -- the only
17 thing left -- if the Court were to reverse and
18 remand, the only thing left would be a Rule 60
19 motion. And Amarin could file that if -- if --
20 if they wish.

21 I do want to address this argument
22 that the conduct element turns on how a
23 physician would understand vague and equivocal
24 statements. That -- that is not the standard
25 when there's an obvious alternative

1 explanation. Twombly and Iqbal make it very
2 clear, if there's an obvious alternative
3 explanation, a complaint doesn't survive the
4 pleadings stage just because maybe some
5 physician out there might possibly read an
6 instruction to infringe into an equivocal or
7 vague statement like generic version of
8 Vascepa.

9 And there are obvious alternative
10 explanations for all the accused statements in
11 this case. The -- the press releases that are
12 accused were all archived as of the launch.
13 They concern litigation victories. And -- and
14 -- and the only indication mentioned is
15 Vascepa's non-infringing indication. At the
16 time of launch -- and this is not record -- the
17 November 2020 press release, so this is when
18 the product is first available, makes it clear
19 the product is only accused -- the -- the
20 product is only approved for the non-infringing
21 indication and not approved for any other
22 indication. And it has all the labeling
23 information in the press release itself. That
24 -- there's no way that induces infringement.

25 I do want to talk about the web page

1 because I don't think my friend accurately
2 characterized the web page. The web page
3 refers to an AB rating for
4 hypertriglyceridemia, which is a lot of jargon,
5 but the jargon is conceded and explained in the
6 complaint and in the decision below. And it
7 means therapeutically equivalent only as
8 labeled to reduce high triglycerides. That's
9 what it means. The label is linked to the web
10 page. So there is no plausible way to read
11 that web page as somehow encouraging doctors to
12 go off-label and -- and use the product for a
13 patented method that has been carved out. That
14 is not plausible. The obvious alternative
15 explanation is the plain reading of -- of the
16 -- of the web page.

17 I see I'm out of time.

18 CHIEF JUSTICE ROBERTS: Thank you,
19 counsel.

20 The case is submitted.

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

23

24

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12 [1] 58:19 12(b)(6) [2] 14:10 22:14 12:23 [1] 4:2 15a [1] 48:15 195 [1] 35:2	addressed [1] 7:15 addressing [1] 64:4 adequate [1] 9:1 adequately [1] 15:5 adjunct [1] 45:3 adjust [1] 18:5 administer [1] 17:24 admitting [1] 11:5 adopt [1] 37:11 adopts [1] 8:9 adult [1] 45:4 advanced [1] 4:24 advertising [1] 41:5 affect [1] 41:20 affirmative [2] 6:12 16:2 affirmatively [1] 19:11 affirmed [1] 23:12 afoul [1] 19:9 ago [1] 60:22 agree [6] 26:18 33:15 38:1 58:11 62:9, 11 agreed [4] 61:25 62:2,2,7 agreeing [1] 5:13 agreement [1] 33:15 agrees [1] 21:15 ahead [3] 23:17 35:25 50:16 aimed [1] 53:14 alito [8] 23:15,18 24:4 25:5 33:11 38:3 45:16,18 allegation [2] 45:23,24 allegations [6] 11:1 38:20 41:8,10 54:3 57:24 allege [2] 43:14 60:6 alleged [2] 15:9 17:5 allow [2] 39:18 58:14 allowed [2] 33:23 39:19 allows [1] 40:15 almost [3] 6:19 9:13 22:15 alone [3] 25:11 32:13,18 already [2] 20:25 57:19 alternative [5] 10:17 53:13 64:25 65:2, 9 although [3] 14:7 24:9 28:19 amarin [18] 4:5 5:8,13 7:7 11:11,18,19, 22 14:9 17:14 22:5 24:18 29:14 31:11,12 39:5 64:15,19 amarin's [10] 11:1 24:14,17,18 28:19 31:6 32:6,18 34:1 35:23 amazing [1] 56:16 amend [5] 58:24 59:2,5 61:1 62:15 amended [1] 61:12 amicus [2] 14:2 42:13 amount [1] 20:11 analysis [2] 23:12 46:6 andrews [2] 59:11 60:2 announce [2] 8:15 9:12 announcements [2] 41:18,20		anodyne [2] 10:4,18 another [1] 28:25 another's [1] 51:25 answer [2] 27:13 41:3 antitrust [1] 51:17 antonym [1] 5:15 anytime [1] 35:21 app [1] 48:15 appeal [2] 59:23,24 appealed [1] 59:15 appeals [2] 14:11 29:24 appears [1] 35:4 appendix [1] 35:3 application [2] 20:22 25:21 applied [1] 5:2 apply [1] 37:17 applying [1] 36:22 appreciate [1] 38:15 approach [2] 4:23 37:19 appropriately [1] 14:8 approval [2] 12:21 21:7 approved [12] 6:5 12:1 23:21 24:2 31:3 32:16 34:14,23 35:8 44:25 65:20, 21 approves [1] 27:12 archived [2] 64:9 65:12 area [1] 9:13 aren't [3] 11:14 17:9 55:1 arguably [1] 57:6 argue [1] 63:1 argued [1] 36:25 argues [1] 5:8 arguing [1] 9:25 argument [7] 4:4,7 9:7 14:1 30:16 64:1,21 arguments [1] 52:23 articulated [1] 18:8 asks [1] 37:2 assertion [1] 47:19 association [1] 46:2 assume [1] 23:9 attached [1] 22:18 attempt [2] 17:20 48:20 attempted [2] 41:11 54:16 attention [3] 41:17,18 56:17 authorized [2] 15:1 17:22 available [1] 65:18 avoid [2] 26:16 44:22 award [2] 5:22 13:12 away [4] 15:5 37:24 47:4 58:3
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