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P R O C E E D I N G S

(10:05 a.m.)

CHIEF JUSTICE ROBERTS: We'll hear argument first this morning in Case 10-844, Caraco Pharmaceutical Laboratories v. Novo Nordisk.

Mr. Hurst.

ORAL ARGUMENT OF JAMES F. HURST
ON BEHALF OF THE PETITIONERS

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

Since 1984, whenever an -- a drug has multiple FDA-approved uses, there has been a statutory path for generic drugs to reach the market if there are specific uses not covered by a patent. Here, there is no dispute that Novo's patent does not claim the use of repaglinide when used alone, and that is "an approved method" of using the drug. Even though that matches the statutory language exactly, Novo is arguing that in this case, our counterclaim to correct their blocking use code is thwarted by the fact that their patent does claim a different approved use --

JUSTICE GINSBURG: Is the first -- is the first approved, the drug itself -- they're not claiming that, because that patent has expired, isn't it?

1 MR. HURST: That patent has long expired,
2 and they also had a patent using -- for the use of the
3 drug to treat diabetes through any method, and that
4 patent has long expired. The only patent that's left
5 that Novo has is specifically limited to the use of
6 repaglinide in combination with metformin to treat
7 diabetes. My client, Caraco, is attempting to get on
8 the market for admittedly noninfringing uses, which
9 occupy about 70 percent of the marketplace out there.

10 JUSTICE ALITO: Suppose I said your brief
11 does not cite a Supreme Court decision. Would that be a
12 correct statement?

13 MR. HURST: I believe that -- that -- if the
14 -- it depends on the context of the sentence, but I
15 think that would be a correct statement if I understand
16 the way you are asking the question.

17 You are asking the question in a way that
18 suggests to me, by context, you're asking whether I cite
19 any Supreme Court precedent. But the context here is a
20 little bit different, because the context here in the
21 counterclaim is a situation where drugs routinely have
22 multiple and different, distinct uses. And in that
23 context --

24 JUSTICE ALITO: Well, we have hundreds and
25 hundreds, probably thousands, of opinions, and you

1 didn't cite -- there were many of them that you didn't
2 cite. You cited quite a few, but you didn't cite all of
3 them.

4 MR. HURST: That's true. That's true. But
5 when a judge -- when a judge says to me that, you know,
6 you're going to lose this case because you did not cite
7 an applicable precedent, I'm going to hear that to mean
8 I didn't cite a specific particular case. There are
9 many ways to use the word "an" after the word "not"
10 where it clearly does not mean "any." For instance:
11 "The prosecutor failed to get a conviction because she
12 did not prove an element of the offense." "I got lost
13 on my way to the party because I failed to make a turn."
14 "My cake fell because I did not include an ingredient."
15 So, the context speaks volumes in terms of whether or
16 not "an" means "any" in any particular context.

17 JUSTICE SCALIA: But -- but the context
18 here, one would expect it to say, if it meant what you
19 say it meant a -- did not claim a use asserted by the
20 generic.

21 MR. HURST: Justice Scalia, there --

22 JUSTICE SCALIA: Not just "did not claim a
23 use." And we have to fill in, that is "the use asserted
24 by the generic." That's a strange thing to fill in.

25 MR. HURST: Well, Justice Scalia, I am not

1 quibbling with the fact that this could -- the statute
2 could have been written more elegantly. My guess is
3 that almost every statute this Court is asked to
4 construe, there are different ways that it could have
5 been written to resolve the issue in question.

6 JUSTICE SCALIA: It's not a matter of
7 elegance. It's a matter of how I would have expected it
8 to be -- to be framed if it meant what you -- what you
9 say it means. It's so easy to say "does not claim the
10 use asserted by the generic." My goodness. And that's
11 what you say it means.

12 MR. HURST: If -- and look at the context.
13 The statute does not ask the brand company to identify
14 an approved use that the patent does claim. It puts the
15 burden on the ANDA applicant to come into court, file a
16 counterclaim, and identify an approved use that the
17 patent does not claim. We've carried that burden twice
18 over. There are two approved uses that the patent does
19 not claim. Context --

20 JUSTICE ALITO: As I understand your
21 argument, you satisfy -- the ground for seeking deletion
22 or correction was satisfied even before Novo wrote the
23 new use code that you claim is overly broad. When the
24 use code said simply the use of repaglinide with
25 metformin, the ground for seeking deletion or correction

1 was satisfied, wasn't it?

2 MR. HURST: Well, I mean -- the truth is the
3 patent -- yes, the answer to that question is yes. But
4 I would have no reason to go into court to fix a use
5 code that's not blocking me.

6 JUSTICE ALITO: No, but that's another --
7 so, there are two oddities in the way you read the
8 statute. And it may be Congress just did a bad job of
9 drafting. But the first is the one we were discussing
10 before, and that's the second one, that -- your -- your
11 beef really is not that the patent does not include
12 every use. Your beef is that the source -- the use code
13 is too broad. And yet, that is not the ground that the
14 statute sets out for seeking deletion or correction.

15 MR. HURST: I believe it does, because it
16 talks about -- there's two remedies: the deletion
17 remedy and the correction remedy. As we read the
18 statute, we preserve distinct roles for the correction
19 remedy and the deletion remedy. As Novo reads this
20 statute, they all but acknowledge that they are writing
21 the word "correct" out of the statute, because there is
22 no meaningful role for the correction remedy as Novo is
23 reading this statute.

24 They call the correction remedy a -- a relic
25 of a failed bill. And, in fact, they haven't identified

1 any meaningful role for the word "correct" in the
2 statute as they read this statute.

3 Remember, what they say is there's two
4 pieces of information that qualify as patent
5 information: expiration dates and patent numbers.
6 Nothing else. The correction remedy can never reach an
7 expiration date under any circumstances.

8 I haven't heard Novo to argue otherwise.
9 What they're saying is if a patent is correctly listed
10 in the Orange Book, this counterclaim is unavailable.
11 So, what does that mean? If the brand company
12 incorrectly lists the expiration date for a properly
13 listed patent as 2150, this counterclaim is not
14 available to correct the expiration date.

15 So, that leaves only one single piece of
16 information that could possibly be addressed by the
17 correction remedy. And what does Novo say? Patent
18 numbers. They say, well, the correction remedy could be
19 available for fixing typos in a patent.

20 JUSTICE SCALIA: Yes, well, it's not much,
21 but it's something.

22 (Laughter.)

23 JUSTICE SCALIA: And -- and the way you're
24 talking, you seem to assume that all the problems in the
25 world have to be addressed by this statute. Would you

1 have no remedy by -- by suing the FCC for accepting uses
2 that -- that it should not have accepted?

3 MR. HURST: I -- whether I do have
4 alternative remedies doesn't answer the question about
5 whether I have a remedy in -- for this particular
6 counterclaim.

7 JUSTICE SCALIA: That's true, but it -- but
8 if you have alternative remedies, I am not terribly
9 shocked by the fact that you don't have a remedy under
10 this statute.

11 MR. HURST: I don't have any good remedies
12 under this statute. I could not, Justice Scalia, sue
13 the FDA for accepting the use code, at least based on
14 existing law, because the FDA's position is that their
15 role with respect to patents is purely ministerial.
16 That has been upheld for about a decade now, including
17 multiple courts of appeals, the Federal Circuit, and the
18 D.C. Circuit. So, my ability to sue the FDA for
19 accepting Novo's incorrect use code is not really a true
20 alternative remedy.

21 The remedy that Congress gave me, that I --
22 that we think Congress gave us is an enormously
23 efficient remedy. We filed our counterclaim, and within
24 3-1/2 months, we got an injunction asking Novo to
25 correct its use code.

1 JUSTICE ALITO: Suppose you didn't
2 file the -- suppose the counterclaim provision wasn't
3 available, and Novo -- you filed a paragraph IV
4 certification, and Novo sues you for infringement.
5 Could you not defend the infringement action on the
6 ground that your use of the -- of the drug was not in --
7 did not infringe their patent?

8 MR. HURST: I could not.

9 JUSTICE ALITO: Why -- why is that?

10 MR. HURST: Because there's two paths that
11 are available under the FDA to get -- for a generic to
12 get approval. One is section (viii), and if I proceed
13 under section (viii), I can carve out the patented use
14 from my label. If -- and Your Honor's question assumed
15 I went through the other route, paragraph IV. I am
16 not -- FDA does not allow you to carve out any portion
17 of your label if you are proceeding under paragraph IV.
18 So, the circumstance that you just described, I would --
19 I would be infringing under paragraph IV, and the only
20 way for me to get on the market is to invalidate the
21 patent.

22 Now, think about what that means. Novo is
23 forcing us, essentially, to infringe. We don't want to
24 infringe. We are trying to carve out our label so that
25 we can proceed under section (viii). They have blocked

1 our ability to use section (viii). So, they force us
2 into paragraph IV, force us to infringe. And what
3 happens if we fail to invalidate the patent? We are
4 kept off the market until 2018 for admittedly
5 noninfringing uses of the drug. There are two
6 admittedly noninfringing uses of the drug. That's where
7 we want -- that's what we want to use to get to the
8 market.

9 JUSTICE KAGAN: Mr. Hurst, would you agree
10 that Congress did not contemplate this situation? As I
11 understand it, it wasn't until 2003 that the FDA allowed
12 companies to write their own use codes, and that's what
13 creates this problem. So, would you agree that the
14 Congress that passed this Act really couldn't have had
15 this situation in mind?

16 MR. HURST: I wouldn't agree, because look
17 at the timing. The FDA issued the regulation entitled
18 "Submission of Patent" -- "Submission of Patent
19 Information" in June of 2003. Congress enacted this
20 counterclaim using the same language in December of
21 2003. The submission of patent information regulation
22 by the FDA with respect to method-of-use patents, and
23 that's what we're talking about here, is all about
24 ensuring that the use code itself is accurate and
25 correct and matches up with the patent.

1 So, I think this is something that Congress
2 clearly had in mind, because they -- you have to assume
3 that they knew about the regulation enacted by the
4 agency that was administering this statute, issued just
5 months before they enacted the counterclaim using the
6 same -- the same --

7 JUSTICE GINSBURG: But what about the fact
8 that the FDA, and not the patent holders, were drafting
9 the use codes at the time this legislation passed?

10 MR. HURST: Justice Ginsburg, that is
11 incorrect; your timing is incorrect. Prior to June of
12 2003, the FDA was authoring the use codes based on
13 information from the brand companies; but after June of
14 2003, the brand companies were authoring the use codes,
15 and the statute was enacted after June of 2003.

16 JUSTICE KAGAN: So, you're suggesting the --

17 JUSTICE KENNEDY: When the FDA was writing
18 the codes, was -- was it writing about the scope of the
19 patent or was it writing about labeling?

20 MR. HURST: It was writing about the scope
21 of the patent. The use codes have always been about the
22 scope of the method-of-use patent; it has never been
23 about anything other than the scope of the method-of-use
24 patents. The only --

25 JUSTICE KENNEDY: I mean, we can ask the

1 Government, but why did it think that it lacked the
2 expertise, because it didn't want to opine under the
3 patent laws?

4 MR. HURST: I think the short answer is yes;
5 the FDA has always done their very best to not get
6 anywhere near the patents. They don't do patents,
7 essentially. And so, they decided -- and there was a --
8 there was a notice and rule -- I mean -- I'm sorry -- a
9 notice-and-comment rulemaking about this, and eventually
10 decided to make -- to have the brands submit the use
11 codes.

12 JUSTICE KENNEDY: Would it suffice in the
13 description just to give a cross-reference to the
14 patent, to say the use of this drug is described in
15 patent claim number 43?

16 MR. HURST: It -- it would not be
17 sufficient, because the way -- the whole purpose of the
18 use code is to administer section (viii). So, what the
19 FDA does is they take the use code, and they match it up
20 with the label, and then the generic gets to carve out
21 whatever the brand company says is patented via the use
22 code.

23 JUSTICE SOTOMAYOR: Counsel --

24 MR. HURST: But if I could get back to a
25 question, Justice Scalia, that you asked about the --

1 whether correcting typos in patent numbers is a real
2 role for the correction remedy. I would submit it is
3 not. And for all practical purposes, Novo is asking you
4 to eliminate the correction remedy from this statute,
5 and here's why. Think about what they're saying.

6 Novo is saying that the brand company
7 decides to put the patent in the Orange Book, but
8 somebody transposes two numbers. There's a -- there's a
9 mistake that's made. What does that mean in concrete
10 terms? Well, if you transpose the two numbers, the odds
11 are astronomically high that the brand company is citing
12 a patent that they don't own and that certainly doesn't
13 relate to the drug in question. It might relate to tire
14 treads; who knows?

15 But you do not -- Congress did not enact a
16 Federal cause of action to address typos in patents.
17 The brand company has every incentive in the world --
18 and the generic company has no incentive to file a
19 lawsuit to fix that. But the brand company has every
20 incentive in the world to ensure that they don't make
21 such mistakes, because there is a statutory benefit to
22 properly listing patents.

23 JUSTICE SOTOMAYOR: Counsel --

24 JUSTICE SCALIA: Well, it's -- it's -- the
25 issue is not whether Congress enacted it only for that.

1 The issue is whether Congress enacted it for that in
2 addition to a lot of other stuff.

3 MR. HURST: But --

4 JUSTICE SCALIA: I mean, it's a very small
5 detail, you know -- "correct." You're saying this one
6 word, "correct," in this immense bill with all sorts of
7 causes of actions and other provisions here and there --
8 that one word has this -- this minimal meaning.

9 MR. HURST: You have --

10 JUSTICE SCALIA: It's conceivable.

11 MR. HURST: You have to give it some
12 meaning. You have to give it some practical meaning.
13 And right now -- and it's only -- the counterclaim has
14 only two remedies. So, Novo is arguing that the first
15 of the two remedies is practically nonexistent.

16 JUSTICE SOTOMAYOR: Counsel --

17 MR. HURST: There is no role -- I'm sorry.

18 JUSTICE SOTOMAYOR: I'm sorry. Finish
19 answering.

20 MR. HURST: There is -- there is no role
21 whatsoever. It is surplusage by any definition to -- to
22 say that "correct" -- "correct" is surplusage by any
23 meaningful definition. If you even put a dose of
24 realism to this, "correct" has no role under Novo's
25 reading, while we preserve distinct roles for both the

1 correction and the deletion remedy.

2 JUSTICE SOTOMAYOR: I'll wait for your
3 rebuttal.

4 MR. HURST: Thank you. I'm sorry, Justice.
5 Sotomayor.

6 CHIEF JUSTICE ROBERTS: Thank you, counsel.
7 Mr. Horwich.

8 ORAL ARGUMENT OF BENJAMIN J. HORWICH

9 ON BEHALF OF THE UNITED STATES,

10 AS AMICUS CURIAE, SUPPORTING THE PETITIONERS

11 MR. HORWICH: Mr. Chief Justice, and may it
12 please the Court:

13 I'd like to pick up with Justice Kennedy's
14 question about FDA and writing use codes. The first
15 thing I'd point out is that before 2003, although FDA
16 wrote the actual text that went in the Orange Book, it
17 was relying on information submitted on a sort of
18 free-form declaration by the -- by the brand. So, the
19 brand was still kind of -- excuse me -- calling the
20 shots in that -- in that respect.

21 But the -- but the more important point is
22 that FDA doesn't have the resources or expertise or --
23 and to engage in the substantive patent evaluations
24 that, that would be required under a theory where you
25 would go sue the FDA if you had a problem with this.

1 But more to the point --

2 JUSTICE GINSBURG: Mr. Horwich, do we -- do
3 we know what FDA's position is in this case? Is the
4 position you're presenting the position of the FDA?

5 MR. HORWICH: We -- yes. We represent the
6 United States here; and so, we -- we speak -- we speak
7 for FDA and the other agencies of the government who are
8 very concerned here about the competition law effects of
9 this. I mean, that's -- that's in some ways the bigger
10 story here.

11 JUSTICE KAGAN: Well, Mr. Horwich, what does
12 that mean exactly, that you represent? I mean, this
13 might be a case where we would give the agency
14 deference, except the agency's name doesn't appear on
15 the brief. So, should we give you any deference?

16 MR. HORWICH: Well, the -- the names on the
17 briefs I think should not be a guide to the deference
18 question. But we're not really claiming deference in
19 the sense -- because what we're construing here, or what
20 the Court is construing here, is the counterclaim
21 provision, which is a Federal cause of action. And so,
22 the Adams Fruit decision of this Court would say that
23 agencies don't get deference in defining the terms of a
24 Federal cause of action.

25 And we do think that -- we do think that

1 it's important to recognize that Congress and the agency
2 were engaged in a dialogue in 2003. And although I
3 wouldn't label that deference, I would -- I would
4 probably characterize it more accurately as Congress
5 building upon what FDA had done in constructing its
6 patent information regulation and Congress saying we
7 need a means to -- to protect the integrity of the
8 system FDA has set up.

9 JUSTICE KENNEDY: Just one more question on
10 how this works. Why does the FDA rely on use codes in
11 the Orange Book to make the carve-outs if it doesn't do
12 anything to ensure the accuracy of the code?

13 MR. HORWICH: Well, the statute -- well, let
14 me start with the basic that the statute envisions that
15 there will be carve-outs. That's the whole principle
16 behind section (viii).

17 JUSTICE KENNEDY: Yes.

18 MR. HORWICH: And so, FDA says, well, we
19 need to know when a generic has made a valid carve-out.
20 And FDA says -- and FDA goes through this in the 2003
21 rulemaking -- if you read through the preamble, there's
22 more detail. But the short of it is FDA has three
23 choices.

24 It could rely on the generics to say that
25 they've carved out, but that doesn't really work because

1 the generics could say something and then get on the
2 market when they hadn't properly carved out, and that
3 kind of defeats the whole point of Hatch-Waxman's
4 principle of getting patent issues resolved before
5 regulatory approval.

6 FDA could, as the second alternative, try to
7 evaluate patents itself. But nowhere else in the
8 statute is FDA given any role in the substantive
9 evaluation of patents, and with good reason. This Court
10 has said in its Markman decision that claim construction
11 of patents is a question of law. The actors in our
12 system that decide what patents mean are courts and
13 ultimately this Court; it's not FDA.

14 JUSTICE ALITO: If a patent holder --

15 MR. HORWICH: So, the third choice --

16 JUSTICE ALITO: If a patent holder writes a
17 use code that is ridiculously, totally, unreasonably
18 broad, is there anything that FDA can do about that?

19 MR. HORWICH: Well, I think the problem,
20 Justice Alito, is that from FDA's point of view, it's a
21 very slippery slope, because as soon as FDA starts
22 undertaking criticism of a use code, its effective --
23 the only basis for criticizing it is looking at the
24 patent. Now, this may be a very easy case, but the
25 Court shouldn't be fooled that all cases are going to be

1 easy. And if FDA here were to go in and said, well,
2 this doesn't look like it's the same as the claim of the
3 patent, in the next case, where it's a more difficult
4 question, where there may be some very good faith
5 dispute between the parties about the very meaning of
6 the patent, FDA is going to have to make a decision one
7 way or the other --

8 JUSTICE ALITO: Well, what about after --

9 MR. HORWICH: -- and it's going to get sued.

10 JUSTICE ALITO: What about after there has
11 been litigation and a court has decided that a use code
12 that was written in a particular case was totally
13 unreasonable? Does that -- does that mean that the
14 writing of that was in violation of some provision of
15 the -- of the Food and Drug Act or FDA regulations and
16 that there would be some sanction against the company
17 that did that?

18 MR. HORWICH: Well, I think the -- I think
19 the only posture in which a court would actually look at
20 a use code and evaluate it is under the counterclaim.
21 There's -- the court would not be looking at a use code
22 under traditional paragraph IV litigation --

23 CHIEF JUSTICE ROBERTS: What about --

24 MR. HORWICH: -- and so, the author of the
25 majority opinion below was kind of mistaken in that

1 regard.

2 CHIEF JUSTICE ROBERTS: What about an APA
3 action against the FDA for relying on the use code?
4 Couldn't that be challenged as arbitrary and capricious?

5 MR. HORWICH: Well, it seems to me that --
6 that that challenge would fail because FDA has made a
7 reasonable construction of the statute, that its role is
8 ministerial. It does not engage in substantive
9 evaluation of patents because the statute doesn't
10 envision that. So, FDA would win that suit.

11 On the other hand, if in -- going back to my
12 answer to Justice Kennedy, if we're talking about kind
13 of the second scenario where FDA does engage in
14 substantive patent review, yes, FDA could get sued. But
15 the problem with that is that FDA is going to get sued
16 in an APA suit; the real parties in interest are going
17 to be the generic and the brand. FDA is not going to be
18 owed any deference because it's going to turn on a
19 matter of claim construction, which is a question of
20 law.

21 JUSTICE KENNEDY: So -- so, how do -- how do
22 you describe what the FDA does as your third --

23 MR. HORWICH: So, what FDA does do is it
24 accepts the submission from the brand describing its --
25 describing its use code. And FDA says in its 2003

1 rulemaking we're trying to do the best we can through
2 the administrative process to get good information in
3 the first instance.

4 JUSTICE KAGAN: And it's your understanding
5 that you require companies to state the scope of the
6 patent in the use code, or might you think it's
7 perfectly permissible for a company to write its use
8 code in terms of indications?

9 MR. HORWICH: It's certainly possible in a
10 particular case that the indications will be
11 appropriate. This is -- what we are asking for in the
12 use code is something that's good enough to do the job
13 that the use code is intended for, which is to inform
14 FDA --

15 JUSTICE SOTOMAYOR: Except that --

16 MR. HORWICH: -- what needs to be carved
17 out.

18 JUSTICE SOTOMAYOR: Except, counsel --

19 JUSTICE KAGAN: So, that -- I'm sorry.

20 JUSTICE SOTOMAYOR: I'm sorry.

21 JUSTICE KAGAN: Go ahead.

22 CHIEF JUSTICE ROBERTS: Justice Sotomayor.

23 JUSTICE SOTOMAYOR: Except the FDA tells
24 parties not to rely on the orange code.

25 MR. HORWICH: Well, it tells parties --

1 JUSTICE SOTOMAYOR: It tells them that what
2 controls is the patent.

3 MR. HORWICH: Well, that is true that FDA
4 said that parties should, of course, look at the patent.
5 But what FDA said in the 2003 rulemaking is that it
6 would rely on the use code.

7 Let me also point out --

8 JUSTICE SOTOMAYOR: Could I ask -- could I
9 ask you --

10 MR. HORWICH: I'm sorry.

11 JUSTICE SOTOMAYOR: -- just on a practical
12 basis -- I understand that the Petitioner has filed an
13 amended label in 2010. I presume that that amended
14 label copies the current label with the exception of
15 substituting the manufacturer.

16 MR. HORWICH: The -- the labeling -- I can't
17 speak to what the labeling in the application is right
18 now, because it's confidential.

19 JUSTICE SOTOMAYOR: But let's assume that's
20 what --

21 MR. HORWICH: But if we assume for the sake
22 of argument that it's the same, yes.

23 JUSTICE SOTOMAYOR: Now, it claims that when
24 the paragraph IV -- the paragraph IV action is started
25 and it's sued for infringement, that it's automatically

1 going to lose --

2 MR. HORWICH: Well, that's right. And, in
3 fact --

4 JUSTICE SOTOMAYOR: -- because --

5 MR. HORWICH: In fact, Caraco has stipulated
6 to that. That's at joint appendix 177 --

7 JUSTICE SOTOMAYOR: All right. Could you
8 explain to me --

9 MR. HORWICH: Because it includes the
10 metformin use.

11 JUSTICE SOTOMAYOR: Could you explain to me
12 why? Is merely the use of a label that's identical
13 infringement or is it an infringement of the underlying
14 patent?

15 MR. HORWICH: It would be inducement of
16 infringement to sell a product with labeling that
17 suggests that the product be used for a patented method
18 of use.

19 JUSTICE SOTOMAYOR: Okay. So, tell us how a
20 court gets out of the quandary of there being a claim
21 that is stipulated to -- I've infringed -- and then how
22 does it deal with the counterclaim? Now, the district
23 court just ignored --

24 MR. HORWICH: Well, the --

25 JUSTICE SOTOMAYOR: -- the act of

1 infringement below and went straight to the
2 counterclaim. But I'm not quite sure how you get out of
3 the quandary that this creates for the courts and the
4 parties.

5 MR. HORWICH: The counterclaim is designed
6 precisely to get out of the quandary, because what it
7 says is the paragraph IV litigation here, the choice
8 between infringement and noninfringement, is a false
9 choice, because if the counterclaim prevails and the use
10 code changes, the paragraph IV litigation is going to go
11 away because Caraco is going to want to go proceed
12 through section (viii). It's going to be able to carve
13 out --

14 JUSTICE SOTOMAYOR: All right. How about --

15 MR. HORWICH: -- and get approval that way
16 without a judgment in the paragraph IV litigation.

17 JUSTICE SOTOMAYOR: Let's assume that Caraco
18 puts in a label like the one it wants to use under claim
19 4. Will the FDA just kick it out?

20 MR. HORWICH: Yes. It's not --

21 JUSTICE SOTOMAYOR: It will not even --

22 MR. HORWICH: It's not permissible.

23 JUSTICE SOTOMAYOR: It will not even ask for
24 a response from Novo?

25 MR. HORWICH: FDA will not permit -- does

1 not permit -- will not approve the application where a
2 -- where there's carve-out labeling combined with a
3 section -- with a paragraph IV.

4 JUSTICE SOTOMAYOR: But is that before --
5 without an infringement action by Novo?

6 MR. HORWICH: I'm not -- I'm not sure of the
7 timing. Of course, it's possible that -- I mean, the
8 paragraph IV litigation is somewhat in the control of
9 the parties; so, it's not as if FDA sends out the
10 notices that could trigger the litigation. But there --

11 JUSTICE SOTOMAYOR: Well, if you tell me
12 that the FDA --

13 MR. HORWICH: There might not be a -- there
14 might be --

15 JUSTICE SOTOMAYOR: If you tell me the FDA
16 doesn't want to get involved in construing the patent,
17 why is it kicking out the claim for -- claim until Novo
18 does a suit on whether or not the generic is infringing
19 or not and let that issue be decided below?

20 MR. HORWICH: From FDA's point of view, it's
21 not a sufficient application if there's carve-out
22 labeling presented with a paragraph IV certification.
23 And I'd also say this, to take a step back: The fact
24 that there might be conceivably alternative remedies
25 under some other construction of the operation of the

1 statute shouldn't make you think the counterclaim isn't
2 available here. After all, the situation that Novo
3 agrees --

4 CHIEF JUSTICE ROBERTS: Finish your
5 statement.

6 MR. HORWICH: Thank you.

7 -- the situation Novo agrees is covered by
8 the counterclaim, where the patent doesn't belong in the
9 Orange Book at all, is one that can be remedied at some
10 -- at some expense and delay through paragraph IV
11 litigation by proving noninfringement if the patent's
12 irrelevant.

13 CHIEF JUSTICE ROBERTS: Thank you, counsel.
14 Mr. Perry.

15 ORAL ARGUMENT OF MARK A. PERRY

16 ON BEHALF OF THE RESPONDENTS

17 MR. PERRY: Mr. Chief Justice, and may it
18 please the Court:

19 I think the last half-hour has made clear
20 that what really is at issue here is a challenge to
21 FDA's administration of the Orange Book. That is an APA
22 challenge, not this counterclaim.

23 Justice Kennedy, you asked if when FDA was
24 writing the -- the use codes, did it describe the scope
25 of the patent? And Mr. Hurst said yes. That's false.

1 The answer is no. For example, if I could point to the
2 joint appendix at page 522, these are some FDA-authored
3 use codes. Everything before U-530 is an FDA-authored
4 use code. U-275 --

5 CHIEF JUSTICE ROBERTS: Oh, I'm sorry. What
6 page were you again?

7 MR. PERRY: Page 522, Your Honor.

8 CHIEF JUSTICE ROBERTS: Thanks.

9 MR. PERRY: U-275, "Method of use of the
10 drug substance." U-278, "Method of use of the
11 indication of the drug product." U-279, "Method of use
12 of the approved product." These were the ones that the
13 FDA wrote when it was responsible for writing use codes
14 to put the world on notice.

15 So, U-278, method of use of an indication of
16 the drug product -- the patent relates to secondary
17 hyperparathyroidism, but you will never know that from
18 the use codes, and -- and that's when FDA was writing
19 it.

20 In 2003, FDA decided to turn it over to the
21 industry. And it said in this rulemaking -- you've
22 heard a little bit about the rulemaking but not what FDA
23 actually said. It said to this: "We believe" -- and
24 I'm quoting by the way from page 19a of the reply brief.
25 This is 68 Federal Register page 36,682. "We believe an

1 approach that requires the NDA applicant or holder or
2 patent owner to identify the approved methods of use
3 protected by the patent is most consistent with the
4 general balance adopted in" the Hatch-Waxman Act. And
5 then the generic industry, during this very rulemaking,
6 made all of the arguments that Mr. Hurst has made today,
7 said we should have more of a challenge, we should have
8 litigation and so forth. And the FDA said no, that's
9 not right, because that would let the generics pick it.

10 And we said -- they said we shouldn't do
11 that. And this is important. This is on page 24a of
12 the reply brief. The FDA said very clearly, "There
13 would be repeated litigation over individual patent
14 listing decisions." That's a bad idea, the FDA said,
15 because there is no assurance that ANDAs would be
16 approved sooner or generic drugs would enter the market
17 any more rapidly.

18 CHIEF JUSTICE ROBERTS: But the alternative
19 is that the FDA is going to have to hire an awful lot of
20 patent lawyers to review the -- the use codes and their
21 correspondence to the actual patents.

22 MR. PERRY: There are several alternatives,
23 Your Honor. First, the FDA could de-link the
24 indications from use codes. Right now the regulations
25 say that you can base your use code on the indication.

1 Our use code is identical to our indication, applies
2 with every regulation.

3 You didn't hear Mr. Horwich say that FDA
4 thinks our use code is wrong. FDA has accepted our use
5 code. Caraco filed an administrative challenge to the
6 use code arguing that it was arbitrary and capricious.
7 FDA rejected the administrative challenge. And they
8 didn't go to the D.C. Circuit to say that was arbitrary
9 or capricious under the APA. I mean, that's the way
10 agency action gets challenged in the ordinary course as
11 this Court has seen many times. Not here.

12 CHIEF JUSTICE ROBERTS: Well, that's the way
13 agency action gets challenged when it's substantive
14 action. The FDA's position -- the United States'
15 position is that this is purely ministerial act.

16 MR. PERRY: Your Honor, they have chosen to
17 make it a ministerial act, which is not a negative, by
18 the way. It is the Federal Drug -- Food and Drug
19 Administration. What they do is administer this
20 program. And they have in other areas, such as patent
21 term extensions, entered into memorandums of
22 understanding with PTO where there are patent issues so
23 that there is interagency cooperation to deal with
24 patent issues. They could do that here, but they've
25 chosen not to and, in the exercise of their enforcement

1 discretion, said we are going to accept the NDA
2 applicant's submission.

3 And, more importantly, FDA has made the
4 policy decision to tie the section (viii) determination
5 to the use code. They don't have to do that. That's
6 not in the statute. They could change that by
7 rulemaking. And, third, on the indication, for example,
8 Novo's use code always follows the indication. The
9 change in this case was because FDA changed the
10 indication.

11 JUSTICE SOTOMAYOR: What odds would you
12 put --

13 MR. PERRY: I'm sorry?

14 JUSTICE SOTOMAYOR: What odds would you put
15 as a betting lawyer on them winning a challenge to the
16 FDA policy decisions of what it's capable of doing and
17 not doing?

18 MR. PERRY: Your Honor, there have been
19 about a dozen APA challenges to various aspects of this
20 administration in the D.C. Circuit over the past 10
21 years. The generics have won several of them including
22 most importantly the Purepac case, which we cite in our
23 brief, which is a direct challenge to FDA's refusal of a
24 section (viii) carve-out because of the use code. And
25 the generic won that argument. It said it was arbitrary

1 and capricious for the agency to do what it did. So --
2 look, every APA battle is an uphill battle. They're the
3 plaintiff. They have burden -- the burden of proof. It
4 is an available remedy. You couple that, Your Honors,
5 with the --

6 JUSTICE GINSBURG: What you -- what you
7 described sounded very much like this case. So, if the
8 -- what was the D.C. Circuit case? If -- if the D.C.
9 Circuit said it's arbitrary and capricious not to -- to
10 just accept the -- the brand's use code --

11 MR. PERRY: In Purepac, Your Honor, the
12 brand changed its position but the FDA did not change
13 its position accordingly, and that was the arbitrariness
14 there. Here, the -- the brand changed its position, and
15 the FDA went along. So, I -- I don't think they would
16 win that case, to be clear, in our particular facts.
17 That's because Novo has done nothing wrong. I mean,
18 you've heard about -- a lot about over breadth,
19 misleading, blah, blah, blah. There is nothing wrong
20 with Novo's use code if the agency agrees with that.

21 JUSTICE BREYER: Can I bring you back for a
22 minute, please, to the statute? And if you -- it's in
23 page 3 of the blue brief. And in just reading it, I
24 might be missing something which you will point out to
25 me, I'm sure. But if you get the statute at the bottom

1 of the page, it says, as I -- if you've got it there,
2 right?

3 MR. PERRY: Yes, Your Honor.

4 JUSTICE BREYER: Okay. It says, "If the
5 [NDA] holder" -- now that's -- that's Novo -- "holder of
6 the approval" -- "the approval holder for the drug,
7 a" -- I'm skipping words -- "a use of which is claimed
8 by the patent" -- and that's what you are doing. And
9 what is that use? Well, I look at page 12, and the use
10 is "a method for improving glyceemic control in adults
11 with type 2 diabetes mellitus."

12 So, that's the use that you're -- that's the
13 use that's claimed by the patent. If you bring "a
14 patent infringement action against the [ANDA] applicant"
15 -- that's them -- "the [ANDA] applicant may assert a
16 counterclaim" -- which they want to do -- "seeking an
17 order requiring the holder to correct...the patent
18 information on the ground that the patent does not
19 claim...an approved method of using the drug."

20 So, I look at that with those words -- I've
21 skipped words. I look at those words, and I say that's
22 what they're saying. They're saying the use that --
23 that your patent does not cover a portion of the set of
24 things described by your use. And, therefore, they
25 would like to correct the description so that the

1 description no longer covers something that you do not
2 have -- a use that you do not have a patent on.

3 Now, that would seem to me to fit within
4 those literal words. And, of course, the purpose is
5 what we've been arguing about. But just looking at the
6 literal words, why doesn't it fit?

7 MR. PERRY: Justice Breyer, your question
8 conflated, as Caraco often does, the use and the
9 indication. You quoted the indication, that is, a
10 method of -- of improving glycemic control. The use is
11 repaglinide combined with metformin. They are disclosed
12 in different parts of the label. The indication is
13 under indications, and the use is under dosage and
14 administration. That's the way FDA has always
15 administered this, and that's the distinction between
16 indication and method of use, which is why the
17 regulations and the form are written in the alternative.

18 JUSTICE BREYER: In other words, you're
19 saying that the -- this -- a method for improving
20 glycemic control in adults with type II diabetes
21 mellitus is not patent information.

22 MR. PERRY: Your Honor, that is the
23 indication that's --

24 JUSTICE BREYER: I know, but are you saying
25 it is patent information?

1 MR. PERRY: It is not patent information
2 submitted under (b) or (c) of section 505, which is the
3 statutory language. It is information submitted under
4 314.53(p) and (e) of the regulation, which is a different
5 question.

6 JUSTICE KAGAN: Was not the regulation
7 issued under this statutory section?

8 MR. PERRY: No, Your Honor. The regulation
9 was issued under section 701, the general rulemaking
10 authority. They cite section 505, but there was a
11 subsequent rulemaking when Pharma, the trade association
12 for the -- for the branded industry, challenged FDA's
13 authority to require all of this information. And in
14 2007 rulemaking that my friends on this side never cite,
15 FDA came back and explained that our -- that the patent
16 submission reg is based on section 701 to facilitate the
17 section (viii) and ANDA process, not -- not an
18 interpretation of section 505. And there are lots and
19 lots of interpretations of the statute. Drug --

20 JUSTICE SCALIA: Can you give us of the cite
21 of that, please?

22 MR. PERRY: I'm sorry. The 2007 rulemaking
23 is --

24 JUSTICE SCALIA: You don't have to do it
25 now. Just -- just file it with the Court. I don't want

1 to eat your time up.

2 MR. PERRY: You Honor, it's cited in our
3 brief, and my colleague will hand up to you momentarily.

4 JUSTICE SCALIA: Oh, it's cited in your
5 principal brief?

6 MR. PERRY: In the red brief, Your Honor.

7 JUSTICE SCALIA: Yes. Don't waste your
8 time. Go ahead.

9 MR. PERRY: Justice Breyer --

10 JUSTICE SCALIA: I don't really care.

11 (Laughter.)

12 MR. PERRY: To further answer your
13 question -- I do.

14 (Laughter.)

15 CHIEF JUSTICE ROBERTS: Maybe your colleague
16 can find it --

17 MR. PERRY: Yes.

18 CHIEF JUSTICE ROBERTS: -- before your time
19 is finished.

20 MR. PERRY: Justice Breyer, there is another
21 point on the structure of the statute. If you look at
22 the -- at the chart in the back of our red brief where
23 we tried to lay out the various provisions of the actual
24 statute, the counterclaim that the Court read and that
25 we're focused on talks about "a" use. In the preamble,

1 it says, "If the patentholder claims a use" --

2 JUSTICE BREYER: You know, I know that
3 argument.

4 MR. PERRY: Right. So --

5 JUSTICE BREYER: You don't need that
6 argument.

7 MR. PERRY: Well, "a" use --

8 JUSTICE BREYER: If you're right that patent
9 information in this particular provision does not have
10 anything to do with, or at least does not cover, the
11 words about diabetes I just read, well, then I guess
12 this section would have nothing to do with it because
13 those are the words they want corrected, aren't they?

14 MR. PERRY: That's correct, Your Honor, but
15 there's a second --

16 JUSTICE KAGAN: Mr. Perry, so, in your view,
17 patent information is just the patent number and the
18 expiration date, and that's all?

19 MR. PERRY: The patent information submitted
20 under (b) and (c) of section 505, correct, Your Honor.

21 JUSTICE KAGAN: Is that just the patent
22 number and the expiration date?

23 MR. PERRY: That's right. And we know that
24 because the Congress at the same time debated a -- an
25 alternative bill that was sponsored by the Democrats

1 that had lots and lots of additional patent information.

2 JUSTICE KAGAN: Well, why would anybody have
3 created this counterclaim to fix the patent number and
4 the expiration date when that can be done by way of a
5 defense to a patent claim?

6 MR. PERRY: Your Honor, it's important to
7 remember the counterclaim is only a delisting provision.
8 It was -- it is a very narrow provision. The FTC report
9 that's cited in the briefs identified eight cases in the
10 first 18 years of Hatch-Waxman that raised this problem
11 of improper listing, mostly due to successive 30-month
12 stays. That was fixed in the counterclaim, and the
13 30-month stays were fixed, and there has never been a
14 case since -- since 2003, there has never been --

15 JUSTICE GINSBURG: What was fixed? I missed
16 what you said. What was fixed in the counterclaim?

17 MR. PERRY: The counterclaim addressed the
18 problem of improper listing that was addressed in the
19 FTC report. The purpose of the counterclaim, according
20 to its sponsors, according to the conference report, the
21 listing of improper patents -- that problem has gone
22 away. There is no such problem anymore. It has never
23 come up again. The counterclaim was entirely successful
24 in solving the problem that Congress set out to address.
25 It had nothing to do with use codes.

1 JUSTICE SCALIA: What do you mean by the
2 problem of improper listing?

3 MR. PERRY: Your Honor, what the FTC report
4 explained was that certain branded companies near the
5 expiration of the listed patent would come in and file a
6 second patent in the Orange Book, even though it was not
7 properly listed, it didn't fit within section 505(b) in
8 the listing requirements, solely for the purpose of
9 getting a second 30-month stay, essentially to box out
10 the generic companies; and that that was an
11 anticompetitive action. They recommended the
12 counterclaim to fix that.

13 And at the same time, the FTC said if
14 Congress were to enact such a counterclaim, it is
15 unclear how frequently it ever would be used. So, this
16 was always intended to be a very narrow -- it's not a
17 fix-all remedy.

18 JUSTICE KAGAN: And so, your argument, Mr.
19 Perry, is not just that the word "correct" does no work.
20 Your argument is that the entire provision no long does
21 any work?

22 MR. PERRY: No, Your Honor. My -- my
23 argument is very simple. A delisting question -- it's
24 an on/off switch. Either the patent is properly listed
25 in the Orange Book or it's not. The counterclaim gives

1 the generic a one-shot knock-out remedy. If it's not
2 properly delisted, it goes away, and a bunch of things
3 follow from that. There's no 30-month stay. There's no
4 paragraph IV litigation. There's no impediment to FDA
5 approving the ANDA, because if the patent isn't listed
6 in the Orange Book, then a whole separate set of ANDA
7 approval requirements kick in. A use code is nothing
8 like that.

9 CHIEF JUSTICE ROBERTS: But I'm still not
10 following it. It's not listed simply because the number
11 is wrong?

12 MR. PERRY: Your Honor, the usual case is
13 it's not listed because it doesn't fit. The most famous
14 example, the Buspar case, they claimed a metabolite
15 rather than the drug substance, and that wasn't a proper
16 listing for that reason.

17 The correction language, which does come out
18 of the other bill, the alternative bill, and we do think
19 is an artifact, is the language we've used, is there to
20 give flexibility to courts. If you have a situation of
21 an improperly listed patent, then a court has more
22 flexibility than simply delisting.

23 CHIEF JUSTICE ROBERTS: The brand
24 manufacturer has an overwhelming incentive to list the
25 correct patent, doesn't it?

1 MR. PERRY: Yes, Your Honor, and --

2 CHIEF JUSTICE ROBERTS: So, why would we
3 give a procedure to an adversary to fix the number when
4 the brand manufacturer is going to fix it as soon as
5 it's alerted to the problem?

6 MR. PERRY: Because, Your Honor, if the
7 generic raises a counterclaim, if it's delisted, the
8 generic gets no more 180-day marketing exclusivity stay
9 at the end of the ANDA process. If it's corrected to a
10 different patent number, the generic would still have
11 its 180-day exclusivity. So, there's every incentive
12 for the generic to bring the counterclaim for a
13 correction if that's the appropriate remedy.

14 And, again, it just gives more flexibility
15 to the courts. That is something that very much would
16 benefit the generic, and it would be an available use of
17 the word "correct." It may be an unusual one, but it's
18 certainly available.

19 JUSTICE GINSBURG: I can't imagine that that
20 would really come to -- I mean, if it's a transposition
21 of numbers, that there would be -- have to be a
22 proceeding to get it changed. I mean, the minute that
23 was noticed, I assume that the brand manufacturer would
24 change it.

25 MR. PERRY: Your Honor, the transposition is

1 not the problem. The more frequent -- the way we think
2 it would come up is these branded companies have large
3 portfolios of patents. They list many patents in the
4 Orange Book. You know, Novo has five or six right now.
5 Other companies have many more, dozens and dozens. They
6 write these use codes, and they associate with -- them
7 with the patents. And in the Orange Book -- by the way,
8 this -- it's called "the Orange Book" because it's
9 orange. And it's thick. It's got a lot of information
10 in it. It has to list every single approved drug with
11 the use code. I mean, it's just pages and pages of
12 numbers, is what's in here.

13 It's not a transposition of numbers but,
14 rather, the -- listing one patent and improperly
15 associating it with a drug. That could be corrected
16 through this counterclaim. But, again, that's worlds
17 away from this use code challenge, which is really what
18 Caraco wants to bring, something that wasn't on
19 Congress's radar screen because FDA wrote the use codes
20 at that point.

21 JUSTICE SOTOMAYOR: Counsel, let's -- let's
22 assume -- because I now take from your earlier
23 conversation with Justice Breyer that you're saying the
24 use code here is absolutely right, because the only use
25 that we claimed was the combination use of the drug,

1 your drug, with the metformin -- that the only thing
2 that's wrong here is the indication that the FDA has
3 required. So, that's not even wrong because you had no
4 choice about that; is that correct?

5 MR. PERRY: That -- the indication is
6 correct.

7 JUSTICE SOTOMAYOR: Tell me -- what this
8 means practically, I believe, is that until your patent
9 expires, no generic can come in with a use that's
10 different than yours because they're going to be boxed
11 out by this indication, this overbroad indication. Do
12 you actually think that that's what Congress intended?
13 I thought, with claim IV and section (viii), that what
14 Congress intended was to ensure that drugs got onto the
15 market as quickly as possible.

16 MR. PERRY: Your Honor, that argument was
17 made to FDA by the generic industry in the 1994
18 rulemaking, the first time this issue came up, and they
19 said you should not allow use codes to be based on
20 indications; you should instead require a description of
21 the patented method of use. You heard Mr. Hurst say
22 that again this morning. Here's what FDA said in
23 response. It's page -- 59 Federal Register page 50,346,
24 quote: "For a use patent, FDA includes in the Orange
25 Book a code identifying the indication covered by the

1 patent." We decline to expand the Orange Book to
2 include patent descriptions. And then it went on to
3 explain that persons interested in patent descriptions
4 should consult the Official Gazette for Patents.

5 JUSTICE BREYER: Yes, but what it also says
6 is this -- and that's what I want to go back to this
7 literal statutory argument. We took the words --
8 because this is what you can correct. What you can
9 correct, the statute says, is you can correct "patent
10 information submitted by the holder under subsection (b)
11 or (c)." So, we look at (b), and what (b) says is (b)
12 tells us that you're supposed to submit, in respect to
13 where you claim the use of a drug, the patent number and
14 the expiration date. So, so far, that seems to support
15 you.

16 But then we look at the regulations which
17 the FDA promulgated, I take it promulgated in respect to
18 (b) and (c), particularly the sentence I read or maybe
19 some similar sentence. And it tells you that you have
20 to provide the description of the patented method of use
21 as required for publication. So, now I go back and look
22 to what you did provide. And what you did provide was
23 you provided -- you said that what we do, we have a
24 method for improving glycemic control in adults with
25 type 2 diabetes mellitus.

1 That seems to fit directly under (3) of the
2 FDA's requirement, and that FDA requirement was an
3 expansion of (b). And, therefore, it sounds to me as if
4 when they say "correct," "correct the patent
5 information," it includes the sentence that you put
6 there that they'd like to see corrected. Now, what's
7 wrong with that?

8 MR. PERRY: Justice Breyer, first, the
9 regulation is not an interpretation of 505(b). It's an
10 implementation of 701.

11 Second and more substantively, however, the
12 form -- you quoted accurately from Box 4.2b of the form.
13 There is also Box 4.2a of the form, which includes the
14 description of the method of use tied to the label,
15 which is required by subsection (P) of the regulation
16 that you were just quoting to me. And that part of the
17 form -- Novo very carefully describes claim 4 of the
18 patent and ties it to the dosage and administration and
19 clinical pharmacology sections of the patent and calls
20 out by reference combination trials. The only
21 combination trial in the label is the
22 metformin-repaglinide combination.

23 And in FDA speak, that is a sufficiently --
24 because these forms -- by the way, you've got them in
25 here. They're these little tiny boxes. You can't put

1 very much information in there. That is described in
2 there. It is not that every piece of information
3 required by the regulation -- the regulation has 19
4 lettered questions, of which several have subparts; so,
5 it's 26 separate pieces of information. They're not all
6 provided in one box, box 4.2b. There's actually a whole
7 form. It's four pages long. We filled it all out.

8 And there's an important point, Justice
9 Breyer. This is a summary judgment case. We put in a
10 declaration from an FDA expert -- it's in the record
11 before the Court -- explaining how every single box ties
12 to every single thing in the regulation. That's
13 absolutely undisputed on this record. There is no
14 contrary evidence as to Novo doing anything wrong.

15 So, whether Congress -- you know -- to go
16 back to this counterclaim, we know Congress didn't
17 intend it to reach this form, because this form didn't
18 exist when Congress was debating the counterclaim.

19 JUSTICE BREYER: The Government -- now, the
20 Government, which is representing all the government
21 agencies, whether the FDA signs it or not, tells us that
22 that language, that (b) and (c) language, about patent
23 information as interpreted by the regs does cover this
24 stuff.

25 MR. PERRY: Your Honor --

1 JUSTICE BREYER: And this is about the most
2 technical statute I ever read --

3 MR. PERRY: Your Honor --

4 JUSTICE BREYER: -- and -- and when I'm
5 talking about patent information among (b) and (c), we
6 have the Government telling us that that covers this.
7 And why don't I just stop right there and say thank
8 goodness I'm out of this case -- and I'm not out of it.

9 (Laughter.)

10 MR. PERRY: I -- I think I can do no better
11 than refer the Court again to the 2007 rulemaking,
12 Justice Scalia, 72 Federal Register page 21,268, which
13 the United States does not address and which Caraco does
14 not address, in which FDA addressed your point,
15 Justice Breyer, and explained that this information,
16 while useful -- and we have never challenged FDA's
17 authority to require the information, but it is not an
18 interpretation of that language, "patent information."
19 And this Court sees agency --

20 JUSTICE SCALIA: And even if it were, as I
21 believe the Government acknowledged, this is not a
22 situation in which we owe deference to the FDA. The
23 issue is whether a lawsuit can be brought or not.

24 MR. PERRY: Correct.

25 JUSTICE SCALIA: And we -- we don't decide

1 whether we have authority to decide cases on the basis
2 of what the agency thinks.

3 MR. PERRY: It is certainly --

4 JUSTICE SOTOMAYOR: What is the parade of
5 horrors that you imagine if we were to read the
6 counterclaim provision in the way your adversary is
7 promoting and the Government is promoting? What --
8 what, presumably, in the normal case and the one that
9 the regulations appear to expect is that the use code,
10 the indication code, everything is going to match the
11 patent. So, in that situation, the counterclaim would
12 have no work to do.

13 So, what's the parade of horrors?

14 MR. PERRY: Your Honor, first, the
15 counterclaim has no work to do for use codes. There's a
16 complete disconnect there. So --

17 JUSTICE SOTOMAYOR: I -- I'm asking you to
18 accept that we were to -- as an assumption only,
19 don't -- it's not intended to be a -- a ruling -- to
20 assume that we read the counterclaim in the way your
21 adversaries want us to.

22 MR. PERRY: Yes.

23 JUSTICE SOTOMAYOR: What's the parade of
24 horrors?

25 MR. PERRY: Your Honor, it is going to add

1 complexity, expense, and so forth. The reason -- the
2 problems with all civil litigation, all new causes of
3 action -- and this was raised during the congressional
4 debates. When they proposed a freestanding cause of
5 action for generics to sue over a whole bunch of things,
6 Congress was up in arms, said no, we're not going to do
7 that because we don't want to let private parties into
8 the FDA process.

9 This Court is familiar with that and the
10 parade of horrors from the Buckman case.

11 JUSTICE KAGAN: But, Mr. Perry, there are
12 also horrors on the other side, of course. I mean,
13 here's -- there's -- there's the statute, and it has
14 three provisions, and two of them are vague, and one of
15 them works against you. One is "an approved method." I
16 think, you know, you both go back and forth about it; it
17 depends on context. One is "patent information," which,
18 you know, maybe you're right, and maybe Mr. Hurst is
19 right. It's not really quite clear what it means to be
20 under subsection (b) or (c). The third is "correct."
21 You basically read "correct" out of the statute. So, at
22 best, this is an unclear statute from your point of
23 view.

24 And then there's the question of what it
25 allows you to do. The statute read your way essentially

1 allows you to unilaterally expand your patent in areas
2 in which it's quite clear that your patent ought not to
3 go -- does not go -- but allows you to do that. So, why
4 should we read the statute so that it effects a purpose
5 that's entirely antagonistic to the purpose that
6 Congress had in passing this statute, given that the
7 statute is at best from your perspective ambiguous?

8 MR. PERRY: Justice Kagan, this statute was
9 a political compromise. There is no debate on the
10 historical record about that.

11 And the compromise, as Mr. Hurst indicated
12 earlier, was that the statute would deal with some
13 things -- the counterclaim would deal with some things,
14 delisting -- and almost everything else would be turned
15 over to the FDA. And FDA had this extensive rulemaking
16 that, as Mr. Hurst said, Congress was aware of.

17 And during that rulemaking, Congress did
18 several things. First, it confirmed that the -- the
19 industry would use the use codes. Second, that use
20 codes could be based on the indication. So, there's no
21 extension of the patent monopoly. It is simply
22 following FDA's instructions as to indication-based use
23 codes --

24 JUSTICE GINSBURG: Mr. Perry, may I ask you,
25 on that core question: We have a patent on a drug

1 alone. It expires, and then the patent holder gets a
2 label patent that's on a method of use, and we have a
3 generic that wants to sell the drug alone which is no
4 longer patented. Doesn't want to sell it in combination
5 with anything else. Wants to sell the drug alone.

6 Can it do so without infringing the
7 method-of-use patent?

8 MR. PERRY: No. Your Honor, we will -- they
9 will be sued for infringement if they ever go to market,
10 because the generic substitution laws present in 49
11 States require or allow pharmacists to substitute the
12 products whether or not the combination is on the label.
13 So, there will always be an infringement suit, which
14 gets back to Justice Kagan's question: Why would
15 Congress have contemplated this? They didn't
16 contemplate this. They contemplated delisting, where
17 you take it out of the infringement suit altogether.

18 This issue -- indications, use codes,
19 section (viii) -- that is all within the agency. And if
20 there's a litigation problem with it or challenge to it,
21 that is what the APA is for. And, again, there have
22 been dozens of APA cases where the generics largely have
23 challenged FDA's determinations in that respect.

24 It is not what the counterclaim is for.
25 This is a very narrow provision. What we're -- we're

1 parsing, by the way, two clauses in one sentence of a
2 statute. The 2003 amendments were 415 pages long. The
3 Hatch-Waxman Act is thousands of provisions long. Very
4 delicate balance between lots of competing interests,
5 billions of dollars at stake. And we have to be
6 careful. When Congress creates a new cause of action,
7 the law of unintended consequences kicks in here.

8 We know this is not -- that this case is not
9 what Congress intended. The counterclaim we don't
10 believe can be read it all to it, even if it's
11 ambiguous. Putting it in context and looking at what
12 FDA has actually said about these matters in its
13 rulemakings when faced with the same challenges by the
14 generic industry that Mr. Hurst presents here, it has
15 rejected them over and over again as a policy matter.

16 JUSTICE ALITO: To come back to Justice
17 Kagan's question, your position is really nothing can be
18 done by a generic that is blocked from marketing a drug
19 for a nonpatented use by a use code that -- that is --
20 that seems to cover that use.

21 MR. PERRY: In this case, Justice Alito,
22 there were two points: First, FDA rejected Caraco's
23 administrative challenge to the use code. They could
24 have taken that to the D.C. Circuit under the APA.
25 Second, they have indicated a rejection of their section

1 (viii) carve-out because of the use code. They could
2 take that to the D.C. Circuit under the APA. That is
3 the usual course for challenging agency action.

4 If there are any problems here -- our
5 position is we have complied in every respect at every
6 moment with every bit of FDA's regulations. And, again,
7 that -- that's what the evidence in this record shows.

8 So, again, I need to push back a little on
9 extensions and monopolies and so forth, because that's
10 not what this case is about. This case is about a
11 properly working administrative process, and should --
12 in private litigation between two parties in which the
13 FDA will not be a party, should that regulatory regime
14 be dismantled. You know -- and we actually asked to
15 bring the FDA in, in this case. Novo did. And Caraco
16 resisted that.

17 You know, we think that if you're going to
18 debate the administration of the Orange Book, it should
19 be under the APA --

20 JUSTICE KAGAN: But --

21 MR. PERRY: -- with the FDA as a party.

22 JUSTICE KAGAN: But here's what we know
23 about Congress's intent, and it goes back to the Mylan
24 suit: What we know about Congress's intent is that
25 Congress wanted to give a generic manufacturer in this

1 situation a remedy when there was a completely
2 irrelevant patent. And the question is why we should
3 consider this to be any different. In some respects,
4 this makes -- this is worse from the generic
5 manufacturer's point of view because the generic
6 manufacturer doesn't even have a defense in an
7 infringement suit.

8 MR. PERRY: Your Honor --

9 JUSTICE KAGAN: So, why should we think that
10 the Congress that really cared about the result in Mylan
11 does not care about this?

12 MR. PERRY: Mylan, in the response, gives
13 the generic a one-shot remedy, and you're out of it
14 altogether. And it's a black-and-white decision. It's
15 an on/off switch. Either the patent is properly listed
16 or not. A use code in the Orange Book -- there are over
17 a thousand of them. They are shades of gray. There
18 are -- there are very specific ones, very general ones.
19 I read to the Court some of the ones that FDA itself
20 wrote.

21 You would get into these long involved
22 questions about compliance and so forth -- to the
23 effect, Congress wanted to make generic approvals
24 quicker in the Mylan situation. FDA itself -- and I
25 started out my argument reading from that page, page 24a

1 of the reply brief, where the FDA said increased
2 litigation over use codes -- patent listings -- would
3 not assure faster generic entry because you'd spend
4 years and years, as we all have, litigating these very
5 issues.

6 So, the Congress hadn't focused on this,
7 which it never did. There's not one word in the
8 thousands and thousands of pages of legislative history
9 about use codes. Had it focused on this, it would never
10 have gone this way because it didn't need to. And when
11 it did have the broader bill, S. 812, it failed.

12 Thank you.

13 CHIEF JUSTICE ROBERTS: Thank you, counsel.

14 Mr. Hurst, you have 4 minutes.

15 REBUTTAL ARGUMENT BY JAMES F. HURST

16 ON BEHALF OF THE PETITIONERS

17 MR. HURST: Thank you.

18 I'd like to start by asking the Court, if I
19 can, to turn to the Joint Appendix, second volume, 484.
20 And I want to address two issues: the argument that the
21 use code is disconnected from the patent itself and it
22 -- it may relate to the indication regardless of what
23 the patent says, and whether or not the information is
24 being submitted under subsection (b) and (c).

25 If you're at 484, this form went through

1 notice-and-comment rulemaking before the enactment of
2 the counterclaim. The title, "Patent Information
3 Submitted" -- that -- that is a -- this carries out the
4 regulation 314.53, entitled "Submission of patent
5 information."

6 Now look at right below those two boxes.
7 What does it say -- how does it say the information is
8 being submitted? This is a form Novo signed. "The
9 following is provided in accordance with section
10 505(b)" -- that's 355(b) and -- "(c) of the Federal
11 Food, Drug, and Cosmetic Act."

12 Moreover, when the FDA issued this patent
13 submission regulation in its final rule, it cited 505 as
14 its legal authority. That's at 28J of the Blue Book.
15 It cited -- and it specifically called out subsections
16 (b) and (c).

17 So, this is a regulation that was enacted
18 prior to the enactment of the counterclaim. And now --

19 JUSTICE SCALIA: And what do you say about
20 the -- the section cited by -- by your colleague?

21 MR. HURST: We address -- he's citing
22 something the FDA said in 2007. And if you actually
23 read it, we cited it -- we addressed this in our briefs.
24 It actually says our -- our legal authority for doing
25 this was explained fully in 2003. And in 2003, the FDA

1 cites 505.

2 Can I turn you quickly to 487 now? This
3 addresses quite specifically this notion that the
4 indication can be used even if it's disconnected from
5 the patent. 4.2b. Remember what the regulation says,
6 and Justice Breyer read this before. It's at 127a of
7 the appendix. But the regulation says that the brand is
8 required to, quote, "the description of the patented
9 method of use as required for publication." They're
10 supposed to provide that information.

11 And look what the actual instruction says.
12 It could not be more clear. 4.2b, bottom right side.
13 "The answer to this question" -- this is where the brand
14 supplies the use code -- "The answer to this question
15 will be what FDA uses to create a 'use code' for Orange
16 Book publication. The use code designates a method of
17 use patent that claims the approved indication or use"
18 -- it depends on what the patent claims -- "of a drug
19 product."

20 And then it goes on to explain why you need
21 to do that: "Each approved use claimed by the patent
22 should be separately identified in this section and
23 contain adequate information" -- this refers to section
24 (viii) -- "adequate information to assist 505(b)(2) and
25 ANDA applicants" -- that's us -- "in determining whether

1 a listed method of use patent claims a use for which the
2 ANDA applicant is not seeking." That is precisely the
3 situation we are facing.

4 We have offered a construction of this
5 statute that is fully consistent with its text, its
6 structure, and its purpose. And it really is the only
7 reading of the statute that carries out congressional
8 intent in terms of trying to prevent situations where
9 incorrect patent information is unfairly delaying
10 generic competition.

11 Up to this point right now, Novo has still
12 failed to identify any reason why anybody in Congress
13 would want the system to work as Novo posits, where the
14 brand company gets to supply an overbroad use code,
15 without judicial review, without agency review, that
16 blocks admittedly noninfringing products from the
17 marketplace. And I -- and I submit that given the
18 addition of the correction remedy, that would not be in
19 there if this was not designed to address use codes,
20 because that's the only thing that can be corrected
21 without remedy.

22 JUSTICE SOTOMAYOR: Going back to the
23 question that I had and a more practical question --

24 MR. HURST: Sure.

25 JUSTICE SOTOMAYOR: As I read the record, in

1 April of '08, the FDA rejected your section (viii)
2 application.

3 MR. HURST: Yes.

4 JUSTICE SOTOMAYOR: All right? And it asked
5 you to submit an amended code. Your brief says we did
6 it in September of 2010. Is it anywhere in the record?

7 MR. HURST: The question is did we --

8 JUSTICE SOTOMAYOR: That you submitted what
9 the FDA requested for your claim 4, the amended label?

10 MR. HURST: Oh. Yes, we -- we did, and it's
11 in JA 777, paragraph 20. It's a stipulated fact.

12 CHIEF JUSTICE ROBERTS: Thank you, counsel.

13 MR. HURST: Thank you, Your Honor.

14 CHIEF JUSTICE ROBERTS: The case is
15 submitted.

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

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