IN THE SUPREME COURT OF THE UNITED STATES

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CARACO PHARMACEUTICAL :

LABORATORIES, LTD., ET AL., :

Petitioners : No. 10-844

v. :

NOVO NORDISK A/S, ET AL. :

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Washington, D.C.

Monday, December 5, 2011

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

APPEARANCES:

JAMES F. HURST, ESQ., Chicago, Illinois; for Petitioners.

BENJAMIN J. HORWICH, ESQ., Assistant to the Solicitor General, Department of Justice, Washington, D.C.; for United States, as amicus curiae, supporting Petitioners.

MARK A. PERRY, ESQ., Washington, D.C.; for Respondents.

C O N T E N T S

P R O C E E D I N G S

(10:05 a.m.)

CHIEF JUSTICE ROBERTS: We'll hear argument first this morning in Case 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?

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

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

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

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

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

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

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

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

MR. HURST: Justice Scalia, there --

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

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

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

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

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

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

was satisfied, wasn't it?

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

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

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

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

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

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

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

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

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

(Laughter.)

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

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

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

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

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

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

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

MR. HURST: I could not.

JUSTICE ALITO: Why -- why is that?

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

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

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

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

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

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

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

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

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

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

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

JUSTICE KENNEDY: I mean, we can ask the

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

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

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

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

JUSTICE SOTOMAYOR: Counsel --

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

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

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

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

JUSTICE SOTOMAYOR: Counsel --

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

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

MR. HURST: But --

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

MR. HURST: You have --

JUSTICE SCALIA: It's conceivable.

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

JUSTICE SOTOMAYOR: Counsel --

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

JUSTICE SOTOMAYOR: I'm sorry. Finish answering.

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

correction and the deletion remedy.

JUSTICE SOTOMAYOR: I'll wait for your rebuttal.

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

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Mr. Horwich.

ORAL ARGUMENT OF BENJAMIN J. HORWICH

ON BEHALF OF THE UNITED STATES,

AS AMICUS CURIAE, SUPPORTING THE PETITIONERS

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

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

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

But more to the point --

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

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

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

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

And we do think that -- we do think that

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

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

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

JUSTICE KENNEDY: Yes.

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

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

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

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

JUSTICE ALITO: If a patent holder --

MR. HORWICH: So, the third choice --

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

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

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

JUSTICE ALITO: Well, what about after --

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

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

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

CHIEF JUSTICE ROBERTS: What about --

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

regard.

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

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

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

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

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

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

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

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

JUSTICE SOTOMAYOR: Except that --

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

JUSTICE SOTOMAYOR: Except, counsel --

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

JUSTICE SOTOMAYOR: I'm sorry.

JUSTICE KAGAN: Go ahead.

CHIEF JUSTICE ROBERTS: Justice Sotomayor.

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

MR. HORWICH: Well, it tells parties --

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

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

Let me also point out --

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

MR. HORWICH: I'm sorry.

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

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

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

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

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

going to lose --

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

JUSTICE SOTOMAYOR: -- because --

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

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

MR. HORWICH: Because it includes the metformin use.

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

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

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

MR. HORWICH: Well, the --

JUSTICE SOTOMAYOR: -- the act of

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

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

JUSTICE SOTOMAYOR: All right. How about --

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

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

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

JUSTICE SOTOMAYOR: It will not even --

MR. HORWICH: It's not permissible.

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

MR. HORWICH: FDA will not permit -- does

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

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

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: Finish your statement.

MR. HORWICH: Thank you.

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

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Mr. Perry.

ORAL ARGUMENT OF MARK A. PERRY

ON BEHALF OF THE RESPONDENTS

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

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

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

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

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

MR. PERRY: Page 522, Your Honor.

CHIEF JUSTICE ROBERTS: Thanks.

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

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

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

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

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

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

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

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

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

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

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

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

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

JUSTICE SOTOMAYOR: What odds would you put --

MR. PERRY: I'm sorry?

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

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

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

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

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

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

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

MR. PERRY: Yes, Your Honor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

to eat your time up.

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

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

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

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

MR. PERRY: Justice Breyer --

JUSTICE SCALIA: I don't really care.

(Laughter.)

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

(Laughter.)

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

MR. PERRY: Yes.

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

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

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

JUSTICE BREYER: You know, I know that argument.

MR. PERRY: Right. So --

JUSTICE BREYER: You don't need that argument.

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

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

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

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

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

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

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

that had lots and lots of additional patent information.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. PERRY: Your Honor, the transposition is

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. PERRY: Your Honor --

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

MR. PERRY: Your Honor --

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

(Laughter.)

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

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

MR. PERRY: Correct.

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

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

MR. PERRY: It is certainly --

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

So, what's the parade of horribles?

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

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

MR. PERRY: Yes.

JUSTICE SOTOMAYOR: What's the parade of horribles?

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

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

This Court is familiar with that and the parade of horribles from the Buckman case.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

JUSTICE KAGAN: But --

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

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

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

MR. PERRY: Your Honor --

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

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

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

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

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

Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Mr. Hurst, you have 4 minutes.

REBUTTAL ARGUMENT BY JAMES F. HURST

ON BEHALF OF THE PETITIONERS

MR. HURST: Thank you.

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

If you're at 484, this form went through

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

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

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

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

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

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

cites 505.

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

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

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

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

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

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

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

MR. HURST: Sure.

JUSTICE SOTOMAYOR: As I read the record, in

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

MR. HURST: Yes.

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

MR. HURST: The question is did we --

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

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

CHIEF JUSTICE ROBERTS: Thank you, counsel.

MR. HURST: Thank you, Your Honor.

CHIEF JUSTICE ROBERTS: The case is submitted.

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