UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R & D, INC., NORTON (WATERFORD) LTD., TEVA PHARMACEUTICALS USA, INC.,	**CIVIL ACTION NUMBER: 2:23-cv-20964-SRC**
Plaintiffs,	**MOTION**
v.	
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS INC, PHV ROBIN P. SUMNER,	**Pages 1 - 55**
Defendants.	

Frank Lautenberg Post Office & U.S. Courthouse.
2 Federal Square
Newark, New Jersey 07102
Wednesday, May 22, 2024
Commencing at 10:09 a.m.

B E F O R E: **THE HONORABLE STANLEY R. CHESLER, UNITED STATES DISTRICT JUDGE**

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(PROCEEDINGS held in open court before The Honorable STANLEY R. CHESLER, United States District Court Judge, at 10:09 a.m.)

THE COURTROOM DEPUTY: All rise.

THE COURT: Be seated. Good morning, everybody.

THE COURTROOM DEPUTY: This is *Teva Branded Pharmaceutical R&D Products, Inc., et al., v. Amneal Pharmaceuticals of New York, LLC,* Civil Number 23-20964.

Please note your appearances for the record.

MR. WIESEN: Good morning, Your Honor. Daryl Wiesen from Goodwin Procter on behalf of Teva. With me are Chris Holding and Thomas McTigue from my office, and Liza Walsh from the Walsh law firm.

THE COURT: Good morning to all of you.

MR. EDWARDS: Good morning, Your Honor.

Jeremy Edwards from Procopio on behalf of the Amneal defendants. I'll let my co-counsel introduce themselves.

MS. SUMNER: Good morning, Your Honor.

Robin Sumner from Troutman Pepper on behalf of Amneal.

MS. O'DONNELL: Good morning, Your Honor.

I'm Melissa O'Donnell from Troutman Pepper also, also on behalf of Amneal.

MS. CONROY: Good morning, Your Honor.

Also on behalf of Amneal, Rebekah Conroy from Stone

Conroy.

THE COURT: So, we have Teva's motion and then a cross-motion from Amneal.

Let me first hear from Teva.

MR. WIESEN: Thank you, Your Honor.

Can I use the podium, if that's okay?

THE COURT: Wherever you're comfortable. All I will tell you this, you may not be able to see at this distance, but I am wearing hearing aids. And nevertheless, as good as they are, the acoustics in this courtroom are horrible. I guess it's an inverse ratio to how magnificent the courtroom physically is.

So please speak slowly and clearly and into the mic. Okay?

MR. WIESEN: I will do my best, Your Honor.

We have copies of slides, if you would like.

THE COURT: I'll be able to look at them up there.

MR. WIESEN: Good morning, Your Honor.

As you just noted, what we are here to argue is Teva's motion to dismiss the delisting counterclaims and the related antitrust counterclaims and Amneal's motion for judgment on the pleadings.

We believe the four patents that are continued to be at issue are properly listed, and so the delisting counterclaims should be dismissed, and Amneal's motion should

be denied.

I want to start with the language of the statute because I think what we're here really to do is to interpret the statute. We have it up on the slide. It's 21 U.S.C. 355 (b)(1)(A)(viii).

And I want to note, Your Honor, that in 2003, Congress adopted the statute for the delisting counterclaim. And since that time, only one patent has ever been delisted. That was in the *Jazz v. Avadel* case last year, and it was on a very different theory than the one presented by Amneal.

The request from Amneal is that you be the first judge to delist a patent on this theory, and we think that's just incorrect as a legal matter.

In fact, until recently, Amneal thought it was incorrect as a legal matter. As we noted in our pleadings, Amneal itself had listed a very similar patent until the FTC wrote letters to both Teva and Amneal a couple months ago.

At that time, Amneal delisted. But until that time, and even since that time, they've noted that the interpretation is reasonable to list patents of these types.

We also in this case, Your Honor, received -- you received an amicus brief from the FTC.

I just want to note I think there is no dispute that there is no deference to the FTC here. They are an independent agency advocating for a position, but if any

agency was to receive deference, it would be the FDA, and they are not here before you taking a position. We've talked and we'll talk some about what the FDA has said in writing, but the FTC deserves no deference. They are like a party simply arguing the statutory interpretation.

So what I wanted to do this morning, Your Honor, is to run through the claims of the patents and explain why using those claims, we believe they are properly listed.

And I was going to use as an example Claim 1 of the '289 patent. It claims an inhaler, the entire inhaler, including the main body, a medicament canister and a dose counter. And we want to run through, based on the statute, why we think that's properly listed.

We'll go back to the statute, and the first phrase that is in dispute is the phrase "claims the drug," in little (viii)(1), "claims the drug for which the applicant submitted the application." And the question is, what does that require as a matter of statutory interpretation?

It's actually quite straightforward, Your Honor. And we'll start -- we'll break it down even word by word. We'll start with the word "claims." That was interpreted by the Federal Circuit in *Jazz v. Avadel* and it means claims in a patent sense, reads on something.

Everybody, I think, agrees on that. There's been no argument from Amneal or the FTC for a different

interpretation, any argument that *Jazz v. Avadel* is wrong. And, in fact, the FTC took that same position in the *Jazz v. Avadel* case. We cited an amicus brief they filed there where they argued that "claim" means, in a patent sense, does the claim cover the product.

And Amneal, I think, finally agreed in their reply brief. At page 5 they wrote "The statutory language is focused on what the patent actually claims." We agree.

So the question then is you would look at the claim, you would apply it.

Now, for this phrase, "claims the drug for which the applicant submitted the application," you would look at whether the claim covers Teva's branded product. So does -- would Teva's ProAir® practice the claim. If it does, it meets this requirement.

The second word -- we'll skip over the "the," if we can, and we'll talk about the word "drug." The "claims of the drug."

That, again, no dispute is defined in the statute. It's 21 U.S.C. 321(g)(1), defines the word "drug." And, again, I think we have agreement from Amneal in Footnote 3 of their opening brief that this definition applies.

Interestingly, Amneal spends a lot of time talking about sort of common and colloquial meanings of the word "drug." But we know in statutory interpretation when the term

is defined, we don't use the common meaning or the colloquial meaning of a term; we use the defined term. And here, the defined term is not just what we might all think of the active substance or the active ingredient or the medicine, it's much broader than that. And that's the definition that we need to apply here as we figure out whether something claims the drug.

It's also worth noting what "drug" used to be defined to mean, Your Honor. Before 1990, there was an additional phrase. We put it up on slide 7. "But does not include devices or their components, parts or accessories." And then that was struck out.

So it used to have a definition that sort of Amneal argues for now but Congress explicitly amended the statute and in doing so, expanded it.

Now, why would you make this change? Why would you go about and say "drug" could include a device?

It really gets at exactly what we're talking about in this case, Your Honor. It's a combination product. It's a product that has both an active ingredient and a device that work together to treat the patient.

And the question, the FDA and Congress had to ask is, how are we going to regulate those things?

The conclusion in the amendment here was that we're going to look at the overall product, and we're going to decide, does it work mainly as a drug or does it work mainly

as a device, and we're going to regulate the whole thing under one set of rules.

For a metered-dose inhaler, the FDA has been quite explicit that is going to be regulated as a drug, and all the parts of the metered-dose inhaler therefore fall within this definition of "drug" because their article is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.

And if we look at (D), it is includes the components of that product. Each meet the definition of "drug" separately.

So Amneal spends a lot of time arguing that a device can't be a drug. Quite frankly, not so when it comes to the definition of "drug" that explicitly applies in the Food, Drug, and Cosmetic Act.

Amneal spends a lot of time talking about the *Genus Medical* decision to try and distinguish drugs from devices, but *Genus Medical* is talking about not combination products like we have here. It's talking about either a drug product, like a pill or a capsule, or a device like a knee brace or a stent that has no drug involvement.

It's not talking about a product like the metered-dose inhaler. That whole thing can be defined as a drug and treated and regulated as such.

So then if we go back to Claim 1 of the '289 patent,

we ask ourselves, does this claim the drug? As we've just gone through, the answer is clearly yes. The drug includes the device that's an integral part of the combination product, and that's clearly what is claimed here.

There's no argument from Amneal that if you applied this claim to Teva's ProAir® product, Teva's product would not practice this claim. And that means it claims the drug for which the application was filed.

THE COURT: Let me stop you there.

The FDA and the *Lantus* opinion both focus on, in part, the word "claim" and the language of a drug product.

Now, your contention is that your product is a drug product and has been approved by the FDA as a drug product, correct?

MR. WIESEN: Correct, Your Honor.

THE COURT: Okay. That's because it's a combination -- a combination drug product.

MR. WIESEN: Right.

THE COURT: Okay?

Now, the FDA, the FTC and *Lantus* both seem to focus on some language that the FDA has focused on as to whether or not a patent should be listed. And apparently their guidelines are that the focus should be a drug product -- it's stated, "The key factor is whether the patent being submitted claims the finished dosage form."

Now, not being a lexicographer, and, frankly, not being a patent lawyer, the question that strikes me is whether or not that language means that the patent has to claim the complete dosage form in order to be listed in the Orange Book.

And *Lantus* obviously said yes. The FDA says yes.

Amneal doesn't quite agree with that, by the way, because they say that a device can never be something which is listed in the Orange Book.

The FDA, FTC, respectfully, disagrees with their position and says yes, it can be if the patent claims the entire dosage form. Which means active ingredients, the machinery and, indeed, any excipients that might be included, correct?

That's the FTC's position, correct?

MR. WIESEN: I think it's -- I'm not sure whether the FTC would require, for example, all of the excipients. I think there's some ambiguity.

In other words, if a claim said an the inhaler with albuterol sulfate but didn't mention the propellant, it's not clear to me what the FTC would say.

But I do think you are right, that Amneal and the FTC are -- they come to the same place in this case but their reasoning is definitely different, and their logic is.

THE COURT: Okay. And *Lantus* clearly indicates that it's got to be a patent which essentially fully covers the

finished dosage form.

MR. WIESEN: I think *Lantus* wants -- I read *Lantus* as requiring the name of the active drug at the very least in the claim.

THE COURT: There is no doubt about that.

MR. WIESEN: Again, what else would be required I think is a little unclear from *Lantus*, but they seem to want the magic words of, in our case, albuterol sulfate.

THE COURT: Okay. And they are using the word "claim" differently from what you are defining it as, and, frankly, what the Federal Circuit would define as a claim for purposes of patent infringement, correct?

MR. WIESEN: I believe that's right. I think that *Lantus* -- *Lantus*, which is before *Jazz v. Avadel*, talks about "claim" and they seem to think that "claim" means, uses the term -- uses the name of the drug. And I think the Federal Circuit has told us that is incorrect.

THE COURT: Okay. So if I understand your argument, it is essentially that any patent which Teva has which could reasonably be viewed as being infringed if the ANDA applicant's application was approved is properly listed in the Orange Book?

MR. WIESEN: I think not quite, Your Honor, in that I think the phrase "claims the drug" has to focus on, first, whether Teva's ProAir® product, the NDA product, is covered by

the claims.

THE COURT: Okay. So let's stop there. All right.

So it would be whether or not if one were to, in fact, replicate the ProAir® atomizer that by doing so if it infringed any claim that was covered by the atomizer, then it should be listed in the Orange Book?

MR. WIESEN: I think that's right, Your Honor. Although, I will note, I don't actually think you have to get to that question, given the claims we have here. But I do think we agree that that is the interpretation of the statute.

THE COURT: Okay. Now, that would mean that any time one proposed a NDA for a product which arguably infringed the ProAir® atomizer, it would be subject to the 30-month stay and be properly listed in the Orange Book?

MR. WIESEN: Correct. If there was a good faith basis to bring a claim for infringement of those patents, then there would be a 30-month stay that would attach to that lawsuit if it was brought within 45 days.

THE COURT: Okay. Now let me ask you this. As a logical corollary of that, if Teva were to modify the ProAir® atomizer and get patents on the modifications to the ProAir® approval and get NDA approval for that newer modified atomizer containing albuterol -- is that the active ingredient?

MR. WIESEN: Albuterol sulfate, yes, Your Honor.

THE COURT: I'm wonderful at mangling chemical names.

But if Teva were to do that, your view would be it could properly list that new patent in the Orange Book for the new NDA, and generics would be barred from getting any ANDA which covered that active ingredient?

MR. WIESEN: If they used -- if they used the dose counter that we alleged in good faith practiced that limitation in that patent, then yes.

But we would presumably, if we changed the dose counter, have to take out of the Orange Book the old patents and put in the new patents because we could only keep in the Orange Book patents that cover the current product.

THE COURT: Well, your old product would not have been -- let me put it this way. It's possible for you to have two inhalers with different delivery systems simultaneously approved by the FDA, correct?

MR. WIESEN: Correct. If we kept both of them on the market, then presumably we could keep patents in the Orange Book -- separate patents for each of the two inhalers. Of course, that's not what we've done, but that's a hypothetical.

What happened here is that the FDA actually told us we had to add a dose counter, which we did, and then after designing it, we have patents on that dose counter which we listed.

THE COURT: Okay. Now, could a generic file for a ANDA for an inhaler which had the same active ingredient but

used a different delivery system without being subject to the 30-month stay?

MR. WIESEN: If they used a dose counter that did not practice the patent that we didn't have an allegation, then yes, they could -- they could proceed with a different, as you called it, atomizer or inhaler, with a different dose counter.

And if it was different enough -- there are, Your Honor, for example, patents that are listed in the Orange Book that we did not sue them on because when we reviewed the OCA or the materials, we concluded that we could not sue them on those patents.

THE COURT: But if you, in fact, had this new patent and they filed for an ANDA, they would be required to file a paragraph IV certification.

MR. WIESEN: Correct, Your Honor.

THE COURT: It would have to be either that we don't infringe or that your patent is invalid, correct?

MR. WIESEN: Yes.

THE COURT: And either way, the 30-month stay would apply as long as you concluded that you were going to file a Hatch-Waxman lawsuit within the 30-day period that you're allowed to do it after the paragraph IV certification is made, correct?

MR. WIESEN: Correct. If we had a good faith basis to sue them and we did within 45 days, then there would be a

30-month stay in place.

THE COURT: So potentially by continuing to improve your inhaler, you could essentially, in your view, continue to list new patents covering the active ingredient from now until forever, correct?

MR. WIESEN: I think the answer, Your Honor, is we could with a couple of caveats. Which the first is that's like when people redesign a -- come up with a new delivery dose mechanism for a drug, an extended release formulation or the like.

The other thing is once the first set of patents are expired on the dose counter, for example, Amneal could simply use that and wouldn't then be infringing, presumably, the new patents. So there would be an option for them to avoid infringement.

THE COURT: There would be, but as a marketing practice, one would expect that Teva would, in fact, do its best to induce practitioners to prescribe its new improved product, correct?

MR. WIESEN: I think certainly if there were improvements, Teva would probably want to encourage people to use the improved device.

But with the automatic substitution laws in place in the U.S., I'm not sure that that would make much of a difference. If a -- if a doctor writes a prescription for

ProAir® HFA, it could be filled with the generic no matter what Teva encouraged them to do.

THE COURT: Not if, in fact, they wrote "no substitutions" on it, right?

MR. WIESEN: Correct. If they wrote "dispense as written," then they would need to continue to use just the branded product.

THE COURT: Okay. I'm sorry I interrupted you. Please continue.

MR. WIESEN: What I wanted to turn to, Your Honor, then was the question of whether the claims here claim the drug.

And here, and to the point you were asking about, unlike in *Lantus*, these claims are not to just a portion of the product, it is to the inhaler as a whole. And so that is actually a very different situation than *Lantus*, and we'll get to that with the drug product claim -- with the drug product patent phrase.

But in terms of whether this claims the drug, I think the answer is clearly it claims the entire device. And there are requirements as well that there be a medicine here, that there be an active drug substance.

One of the limitations here is the inhaler. And an inhaler, obviously, you have to inhale something. It's the drug. And there's a medicament cannister, and the medicament

canister must have a medicine in it. That's albuterol sulfate. So it doesn't use the words "albuterol sulfate," but an active ingredient is required.

If I can turn, then, Your Honor, to the next statutory phrase, and I think you were asking about this as well, the drug product formulation or composition patent, and focus on why that, too, is met by the claims.

As we were just talking about, there is a regulation, "finished dosage form contains a drug substance." And when the FDA adopted these regulations, they specifically discussed drug products and included metered-dose inhalers.

In fact, Amneal argues that we've seen no statements from the FDA that refer to a metered-dose inhaler as a drug product itself because it's a device, but Amneal's own Exhibit 4 is a statement from the FDA in 1993 that specifically says, "Therefore, if a device is intended to deliver a specific drug or if the labelling references a specific drug product, the device will be considered a drug product and regulated by CDER," which is part of the FDA that regulated drugs.

And so the distinction between drugs and devices that Amneal focuses on, the FDA has explicitly rejected. They've said that if it is overall a product that treats the patient through an active ingredient that's delivered, we're going to treat all of the parts, even the device parts, as drug

products.

We can see that in the Orange Book as well, Your Honor. If you look at Exhibit 3 of our papers, and it's page C-1 from the Orange Book, it's we have on the top here, it's a Drug Product list of Dosage Forms, and the one second on the list is metered aerosols.

What's interesting about this, and we've cut some of it off on the slide, but you can see the next one down is Capsule, these are exactly the types of dosage forms that you might think about: A capsule, a tablet, a pellet, a pill.

And the FDA treats a metered-dose inhaler in exactly the same way. It, too, is a drug product. And they say the same thing about ProAir® HFA. It is a metered-dose inhaler which is a dosage form in a drug product.

In fact, when the FDA adopted the control of regulations, they specifically listed types of patents that could not be included in the Orange Book, and they did not include patents such as the ones that are at issue here. They could have. It was raised in the comments. And when they made their list of things to exclude, they did not exclude the types of patents we're dealing with here.

So if we turn, then, back to the question of in the claims, is it a drug product claim, again, what we see is that there's an inhaler for metered-dose inhalation, comprising, and it includes a medicament canister. That is, to the

question you were asking, the entire drug product. The inhaler is the drug product.

Now, is every specific element explicitly called out? It's not. But when we look at the FDA's definition -- or the Federal Circuit's definition of claims, we don't need to have listed off albuterol sulfate, the HFA propellent, the different excipients. As long as this claim reads on our product, it claims our drug product.

THE COURT: Let me stop you there. Suppose instead of having a patent which covered the entire inhaler device you had a patent which covered one tiny portion of the device, which the FDA approved. Let's say, for example, a dose counter and only the dose counter, is it your position that that patent would have to be listed in the Orange Book?

MR. WIESEN: Your Honor, I think it would have to be listed in the Orange Book based on the definitions of the terms and the way they are used.

Again, I think that's not our case, and you don't have to decide that, and I can go through the other patents and show you why. But I think it is -- I do think it would have to be listed.

Interestingly, Your Honor, that really means that the question would be about how people went about drafting the claims rather than the big-picture policy questions that Amneal or the FTC want to talk about. And what I mean by that

is the distinction would apparently be whether you claimed an inhaler with a dose counter or just the dose counter.

And that is, in the end, really a strategic question for the patent prosecutors.

And if this had been clearly defined 20 or 25 years ago, people would have drafted claims strategically to accomplish what you're suggesting.

The fact that this question has been left open is part of what leads us to this question. But it doesn't become, then, a big-policy question. It becomes, did the patent prosecutors write a strategically smart claim or not.

THE COURT: Now, let me ask you this. All right?

After *Lantus*, the Second Circuit decided a somewhat similar issue. And as I understand it, and I will admit this particular opinion can cause one's eyes to go blurry, but as I understand it, they very specifically distinguish between the use of the word "claim" in the FDA Orange Book listing as to claim the approved product, and the word "claim" for whether or not use of the product might create a viable claim for infringement. Or, I don't know if they say viable, but a probable or possible.

And as I understand, that opinion echos *Lantus* in terms of saying that word "claim" means different things when used in the different parts of the statute.

Was the Second Circuit also wrong?

MR. WIESEN: We've spent a lot of time talking about that very decision, Your Honor. I think that I read that decision a little bit differently, both the district court and the Second Circuit decision, in the following way.

I think that the way to understand that, I think *United Commercial Workers v. Takeda*, about the drug Actos, is that the drug that -- the patent that Takeda had, the NDA was on Actos which had one active ingredient in it.

The patents require two active ingredients. And so if you applied the test of, does the NDA itself practice the patent, the answer was no. Because the NDA itself was only one drug and the patent was two drugs.

What *Takeda* tried to argue is even though the NDA doesn't practice the patent, the generic might because the generic drug, even though it was only one drug, might be given with the second drug to infringe.

And what the Second Circuit said was, no, for the "claims the drug" phrase, we are going to look at whether the NDA practices the patent. And since the NDA is only one drug, it does not and it shouldn't be listed, or whether the antitrust case about that go forward, was not a delisting counterclaim.

I actually read that as consistent with our interpretation that "claims" means, does the NDA product practice the patent, not just speculating about whether the

ANDA product in the future might practice the patent.

THE COURT: Well, look. The opinion obviously is a convoluted one because actually, as I understand it, the Second Circuit said, actually, this should have been listed as a method of use patent, and the generics could have filed I think what's called a skinny ANDA application, which means carving out the patented usage from their application and seeking only an ANDA approval for the unpatented or expired patents.

MR. WIESEN: That is my understanding as well. And I think that was because the label had a method of using the drug in combination but might have infringed as a method claim, but it wasn't the composition claim that physically had both drugs within the same capsule or pill.

THE COURT: Okay. Let me ask -- sorry to interrupt you. But let me ask Amneal a couple questions. Okay?

MR. WIESEN: Thank you, Your Honor. I'm going to try to switch the source over to their slides.

THE COURT: Wherever you're comfortable. Just make sure you speak into the mic.

MR. EDWARDS: Good morning, Your Honor.

THE COURT: Good morning.

MR. EDWARDS: You had questions for me?

THE COURT: Yes. As I understand it, on the antitrust counterclaim, you contend in the brief, and I know

the FTC quoted you -- I'm sorry, not in the brief, in the complaint -- that you could go on the market as early as April of this year if the 30-month stay were not in effect, correct?

MR. EDWARDS: Yes, Your Honor. That was true at the time. There have been some developments since.

THE COURT: Okay. Now, let me ask you -- I'm here to be educated. And my understanding is that, for example, when a paragraph IV certification is made, the ANDA applicant can proceed to have the FDA review its application, and if the FDA concludes that except for the 30-month stay it issues what's called a tentative approval? Is that correct?

MR. EDWARDS: Yes, Your Honor, that's correct.

THE COURT: And that tentative approval means that as soon as the 30-month stay expires, or alternatively, as soon as the patents which are listed in the Orange Book are determined to either be invalid or uninfringed, the ANDA product can go on the market, correct?

MR. EDWARDS: Yes, with some exceptions that are not relevant.

THE COURT: Okay. Now, as of the filing of these briefs, had a tentative approval from the FDA been issued?

MR. EDWARDS: No, Your Honor. Tentative approval is currently expected November 4th of this year.

THE COURT: Okay. So I've read your papers about the argument that the antitrust claims can or cannot apply where

there is a statutory basis for seeking to delist Orange Book listings. And it's obvious that both you and Teva have radically different views of the existing law. And, of course, the FTC has a further different view from Teva's.

But let me ask you a simple question. Until you have tentative approval, what antitrust -- what antitrust damages or injury have you suffered?

MR. EDWARDS: Your Honor, it's the existence of the stay. It is a simple question. However, Amneal has my co-counsel, who is a specialist in antitrust, and if you would like a more complete answer, I would defer to them for a moment.

THE COURT: I would be interested because, quite frankly, as I was sorting through this, I'm saying to myself, they say they could, but they can't until they get FDA approval. And the tentative approval is the equivalent of a final approval as long as there is no blockage, right?

MR. EDWARDS: A tentative approval is tentative and becomes final when there are no longer any barriers to that.

THE COURT: Okay. Which means either a 30-month stay or a pediatric exclusive or some other provision which would stop you -- stop the FDA from authorizing it.

But in terms of being found to be pharmacologically equivalent to the NDA, the FDA has made that determination, correct?

MR. EDWARDS: Upon granting tentative approval, yes, they've made that decision.

THE COURT: Okay. Let me hear from your antitrust expert.

MR. EDWARDS: Yes, Your Honor.

MR. WIESEN: Your Honor, if I could clarify one point from Mr. Edwards.

THE COURT: Sure.

MR. WIESEN: He indicated that they expect tentative approval as of a certain date. My understanding is that's when they expect the next response from the FDA, but we don't know whether that will be a rejection or approval.

THE COURT: And the answer is, at this point it's largely irrelevant because, quite frankly, I want to know whether I have a case of controversy.

MR. EDWARDS: Your Honor, where would you like to go from here? Would you like to hear from antitrust counsel?

THE COURT: Yes.

MS. SUMNER: Good morning, Your Honor. Robin Sumner from Troutman Pepper on behalf of Amneal.

Your Honor has asked a very good question, and I have an answer for it.

Failure to obtain tentative FDA approval is not a bar, as a matter of law, to an antitrust claim at the motion to dismiss stage.

And I'm happy to point Your Honor and your clerks to four cases that --

THE COURT: Hold on. My law clerk writes the notes.

MS. SUMNER: -- that will bear that out. The first one is *In re: Wellbutrin*, and the cite is 281 F. Supp. 2d 751. It's an Eastern District of Pennsylvania case from 2003.

Bristol-Myers Squibb v. Ben Venue Labs, 90 F. Supp. 2d 540. It's a District of New Jersey case from 2000.

Takeda Pharmaceuticals v. Zydus Pharmaceuticals, 358 F. Supp. 3d 389. It's a District of New Jersey case from 2018.

And the last one is *In re: Metoprolol*, and the citation for that is 2010 Westlaw 1485328 and that is a District of Delaware case from 2010.

And the reasoning in all of those cases is that at the motion to dismiss stage, you cannot determine whether the delay in obtaining FDA approval is attributable to the allegedly improper conduct. And here, that is both the 30-month stay and the bringing of what we contend is baseless infringement litigation or something else. That's a fact issue that can only be decided at the motion to dismiss stage.

For example, it's perfectly plausible, and has been recognized that multiple cases, that once the patent litigation is brought, generic manufacturers have every incentive, and, in fact, often do, shift their resources away

from obtaining approval and invest them in defending the litigation.

It's also -- so that's one form of antitrust harm and injury that gives plaintiffs like counterclaimants, like Amneal, at this stage standing to bring these claims.

It's also indisputable, I think, at this point in the case law that I've just cited, several of which are out of the District of New Jersey and Third Circuit, that costs incurred in defending sham litigation occasioned by these improperly listed patents also was cognizable antitrust injury that gives claimants like Amneal standing at this juncture to bring those counterclaims.

THE COURT: But the fact remains that the Orange Book listing has not been what prevented Amneal from going on the market, correct?

MS. SUMNER: Well, I think that at this point we don't know that because we don't know, and discovery is needed to show, what would have happened had there been no Orange Book listing, had Amneal not had to file the paragraph IV litigation, had it not had to shift to defending improper patent litigation. That's a fact question that can't be decided on a motion to dismiss.

THE COURT: I've listened very carefully to your cites. Interestingly, none of them are quasi-appeal citations, correct?

MS. SUMNER: No, they are not, Your Honor.

THE COURT: And three of them are F. Supp. and one is a non-published.

Now, in a real world, of course, non-pubs for district court decisions are the same as published decisions.

A colleague of mine once described the federal supplements as the book in which federal judges get published at their own expense and at their own option. And as we all know, any judge, district judge who wishes his or her publication or opinion to be published in the F. Supp. need merely send it in to West publication and they do it automatically, correct?

MS. SUMNER: I believe that's right, Judge Chesler.

THE COURT: Okay.

MS. SUMNER: In addition, if I may, there's one additional case that also is directly on point and covers many of the other issues here, and that's the gabapentin patent litigation which is also out of the District of New Jersey, and that's at 649 F. Supp. 2d 340, and that's a 2009 case.

THE COURT: Was that Judge Hochberg's decision?

MS. SUMNER: Yes.

THE COURT: I lived with that case for 20 years.

MS. SUMNER: Well, in that case, the issues that Your Honor has wisely questioned about were not a bar to the antitrust claims which were permitted to proceed in the

absence of FDA tentative approval for the same reasoning that has been endorsed by the other court decisions that I've referenced.

THE COURT: Okay. On that issue, I'd like to hear from Teva.

MS. SUMNER: Thank you, Your Honor.

THE COURT: By the way, I understand that you folks actually asked that the antitrust claims be severed or essentially stayed pending disposition of the underlying case.

Is that correct?

MS. SUMNER: That is correct, Your Honor. I believe there's an agreement between the parties to that effect.

THE COURT: And my understanding also is that regardless whether of not I order delisting of the Orange Book patents and, indeed, grant judgment on the pleadings for Amneal, that, nevertheless, there are declaratory judgment counterclaims asserting that the patents were invalid.

Is that correct?

MS. SUMNER: I believe that that's correct, Your Honor. And there also would still remain a pending sham litigation antitrust counterclaim.

THE COURT: Okay. Now the sham antitrust litigation claim would potentially hinge on two issues: One is whether or not the delisting provisions in effect preempt the antitrust claims to the extent that they are based upon Orange

Book listings, correct?

MS. SUMNER: To the extent the monopolization claim and attempted monopolization claim is based on improper listing, there -- Teva has raised an argument that it is, in effect, preempted. I'm not sure they use that word, but that's the idea under *Trinko*.

THE COURT: Okay. That's the *Trinko* argument.

MS. SUMNER: Yes.

THE COURT: And I haven't looked at the tail end of your complaint since it goes on forever, but is there also a claim that the infringement claims themselves are a sham litigation?

MS. SUMNER: Yes, Your Honor. There is a separate sham litigation monopolization claim.

THE COURT: Okay. And that claim would hinge on initially, at least, the validity or invalidity or infringement or noninfringement of Teva's patents, correct?

MS. SUMNER: It hinges on whether or not a reasonable litigant could have expected success on infringement.

THE COURT: Thank you. Let me hear from Teva.

MR. WIESEN: Your Honor, I'm going to ask Mr. Holding to respond as he is our antitrust expert.

THE COURT: Thank you.

MR. HOLDING: Good morning, Your Honor. Chris Holding for Teva.

Just on your last point, because you raised the question of bifurcation, part of the reason I think the parties agreed to bifurcate the antitrust is what you just said: To a large degree, whether or not there is a viable antitrust claim will turn on what happens in the patent phase of the case. So as often said, let's just sort of put that aside for now.

I believe your question originally was given the status and the lack of a tentative approval, has Amneal suffered any injury or damages? And the general answer to that is no, because they can't have suffered any damages until they are validly on the market, and you cannot be validly on the market until you have FDA approval, obviously.

I think you then asked is there a cognizable claim yet in the absence of tentative.

I agree that there are some cases that have said at the motion to dismiss phase you have to look at what that's going to be.

Typically, it's because it may be, first of all, that there's a declaratory claim now, and that you might have damages if you get tentative down the road and you are delayed but we don't know and will have to see and have you adequately pled that.

But in terms of the question of, is there a basis now to think they might have been delayed, I think counsel cited

gabapentin, cited Wellbutrin and some others. Those are class-action cases where the question is, does the evidence -- would discovery show that somehow the pendency of the patent lawsuit slowed down the plaintiff.

Amneal doesn't need any discovery on that. This isn't a class case. Amneal knows what it's doing. They are not standing in front of you today saying, you know what, Teva sued us, we stopped trying hard. We've turned our attention somewhere else.

You didn't hear any of that.

What they actually, I think, tried to tell you in their briefs is that they are going back and forth and back and forth and back and forth with the FDA. And they keep telling you, we expect to hear from them this month or in that month and that month.

So in terms of what's in front you, there's absolutely no basis to conclude at this point that the pendency of litigation, the fact that we listed these patents and that there is a 30-month stay is slowing them down or that they've suffered any injury at all.

THE COURT: Let me ask -- and I'm sorry. I'm horrible at names. I'm almost as bad at names as I am pronouncing drugs.

But counsel who was arguing the antitrust issues for Amneal, could you step up for a second?

MS. SUMNER: Robin Sumner, Your Honor.

THE COURT: Thank you.

MS. SUMNER: And I'm equally terrible with names.

THE COURT: It's why I went into this business as opposed to politics. You can't be a politician unless you can remember everybody's name and look them straight in the eye and make them think that you are the most important person in the world. I've never been good at that.

But let me ask you this. Assuming that the antitrust claims survive, wouldn't an element of the viability of an antitrust claim be the willingness of Amneal to go on the market at risk?

And even if the Orange Book listings were stricken, if you went on the market and the validity and infringement of those patents had not been litigated, you would either have to design around or have designed around the inhaler, or you would, in fact, have to, in fact, use the inhaler which the FDA approved, correct?

MS. SUMNER: I'm sorry, could you restate the question?

THE COURT: Sure.

MS. SUMNER: I'm not sure I entirely followed the whole thing. I thought I was with you but --

THE COURT: Look, and let me rephrase it.

I assume that your ANDA application, in fact,

includes an inhaler device which is essentially identical to Teva's device.

Would that be a correct assumption?

MS. SUMNER: I think I'm going to defer to my patent colleague here, but I think that is not a correct assumption.

THE COURT: Okay. Then let me hear from him.

MR. EDWARDS: Would you like me to approach, Your Honor?

THE COURT: Wherever you're comfortable. Wherever I can hear you.

MR. EDWARDS: The short answer is, the short answer is absolutely not. We have noninfringement positions as to these patents, and the inhalers are not the same as the NDA product.

THE COURT: Okay. But you're going to have to show that your application, including an inhaler, is bioequivalent to Teva's product, correct?

MR. EDWARDS: Yes, Your Honor. And there are many ways to skin a bioequivalence cat.

THE COURT: And that includes not infringing their patents.

MR. EDWARDS: Absolutely. That's the decades of Hatch-Waxman litigation.

THE COURT: Okay. But for me to evaluate -- and I'll go back to you.

MS. SUMNER: Okay.

THE COURT: For me or a trier of fact to evaluate, A, whether or not there is any antitrust violation, or the extent of the injury that occurred from an antitrust violation, one would have to, in fact, include an evaluation of whether or not Amneal was willing to go on the market in the face of the potential infringement suit, and the likelihood that Amneal would be hit with either a preliminary or permanent injunction from going on the market under standard injunctive rules, correct?

MS. SUMNER: I think, Your Honor, if we got to a point where Amneal could launch at risk, that it had all the necessary approvals and there was nothing blocking it from launching at risk, then what it does at that juncture might go to whether there is a continuing harm and or the quantum of damage or harm that Amneal has incurred. But it certainly would not erase the harm that was occasioned by the delay in approval up to and including that point, as well as the sunk litigation costs which are also cognizable antitrust injury in a case like this.

THE COURT: And if Teva, in fact, became aware that you were going to launch at risk and filed the preemptive preliminary injunction suit and then got a permanent injunction, would you have suffered any antitrust damages except for your sunk costs in terms of attorneys' fees?

MS. SUMNER: I think that the continued delay from that injunction would -- would still be cognizable injury.

THE COURT: Why? The delay would be by court order because a court determined that, in fact, your product did infringe a valid patent and the court, using the four standards, four or three, depending upon the phase of the moon, that a court is required to consider in determining whether or not to issue an injunction, concluded that injunction was appropriate.

Would that court order, barring you from going on the market, result in an antitrust violation?

MS. SUMNER: I think if we had a basis to claim, which we do here in this particular factual situation, that bringing such an injunction was, in fact, objectively baseless, that we would have to go the whole way through, you know, a court decision where there was no further chance to appeal on the merit before you could make that determination.

THE COURT: Okay. And assuming arguendo that I was foolish enough to issue such an injunction, and if that circuit was foolish enough to affirm me, what damages then?

MS. SUMNER: If at the end of the day it is determined, I think, without sort of appeal to further recourse, that the litigation was, in fact, not objectively baseless and it were determined that these patents were not improperly listed in the Orange Book, then I think at that

point, there would be no cognizable antitrust violation.

THE COURT: But let's assume that they were improperly listed, but you still tried to go on the market after you got tentative approval and they got a permanent injunction and the fed circuit affirmed it and, incredibly enough, the Supreme Court denied cert, where are you then?

MS. SUMNER: I see what you're saying. You're saying they enforced them outside of the Hatch-Waxman regime and just enforced them because of our attempt to go on the market without having gotten approval.

THE COURT: Right. They have the right to do that no matter what happens with delisting or not delisting, correct?

MS. SUMNER: Yes. I mean, I think in that particular factual situation, again, if you got the whole way to the end and it was found that the patents, in fact, did present a bar to Amneal marketing its ANDA products, then, again, at that juncture there would be no antitrust injury.

But that is not the situation we are in right now. I mean they have listed them, and we are in a 30-month stay situation.

THE COURT: Okay. Thank you. Any further -- I'm sorry. Go ahead.

MR. EDWARDS: I beg your pardon, Your Honor. May I be heard as to the listing issue?

THE COURT: Yes. I don't want you to be bored.

MR. EDWARDS: Thank you, Your Honor.

THE COURT: Although remember, sometimes the wisest thing to say is nothing.

MR. EDWARDS: Understood, Your Honor.

There was quite a bit of discussion about the statutory language in the delisting requirements themselves.

Let's pull up the statutory language, slide 26.

Teva is contending that the ordinary meaning of claims in patent law should apply here. We think that's actually intention -- quite a bit of tension with the words of the statute.

There's not been much discussion about, although Your Honor did allude to, the idea of, well, what if you could reasonably assert. That's dealt with in the introductory proportion of the listing requirements.

If "claims the drug," if all that means is any little piece of it which if you marketed the NDA product would infringe, then it would mean no more than what's already included in the opening clause, a patent for which a claim of patent infringement could reasonably be asserted.

"Claims the drug" must mean something more, Your Honor. That's the underlying premise in *In re: Lantus* and in *United Food* adopting the reasoning of *In re: Lantus*.

And, of course, you must give effect to the statutory language that follows that.

There's been also quite a focus here on "claims the drug." And we sort of stop there.

The statute doesn't stop there. It's "claims the drug for which the applicant submitted the application."

That is absolutely critical, and we believe ends the inquiry as to whether these patents are properly listed.

The claims of the patent nowhere refer to the ProAir® HFA product, to albuterol sulfate. In fact, the patents themselves never contain the word "albuterol."

Both of subsections, Roman I and II must be satisfied in order to have a listable patent.

I'm sorry. Let's put aside subsection II. Let's go to slide 2, please.

This is where the delisting counterclaim rubber hits the road, Your Honor. These are the two requirements in the listing requirements that the parties are fighting over.

We've already talked about "claims the drug." We believe none of the patents meet that requirement under *In re: Lantus* or and also under *Genus Medical*.

But they also fail on the second requirement because they are not drug product patents according to the FDA's own definition of "drug product" which requires it to contain the active ingredient.

The natural corollary to the FDA's definition of "drug product" in the real world, when you compare it to the

listing requirements, if a real-world product must contain a drug substance, a drug product patent must recite the drug substance.

The claims here do not do that.

THE COURT: That's exactly the same argument that the FTC made.

MR. EDWARDS: Yes, Your Honor. And I would like to classify something on that point. We are entirely aligned with both the FDA's and the FTC's views on the listing issues in this case. There may have been a misunderstanding.

When we say a device patent is not listable, we mean a pure device patent that does not contain any reference to the drug for which the applicant submitted the application. That's what in our parlance and our briefing a device patent is.

We are not taking the position that a claim to a combination drug product that does recite the drug substance is somehow not listable. That position has been attributed to us by Teva, and it is not correct.

THE COURT: Well, it was also attributed to you by the FTC.

MR. EDWARDS: Well, I think they perhaps also misunderstood at the time what we meant when we said a "device patent." We mean a pure device patent that does not recite the drug -- the actual drug ingredient.

THE COURT: Okay.

MR. EDWARDS: I'm mindful of Your Honor's admonition that the best thing to say sometimes is nothing. So unless you have further questions from me, I will step down.

THE COURT: Actually, that was just quoting former Magistrate Judge John Hughes who occasionally has said some words of wisdom.

Anything further from Teva?

MR. WIESEN: Your Honor, if I could respond to just one or two points quickly?

THE COURT: Sure.

MR. WIESEN: And if we could go to slide 2, Mr. McTigue.

I want to start where Mr. Edwards was talking about the language "claims the drug" for which the applicant submitted the application.

I think we see that language as being separate from what's in the preamble in the little viii which is, "for which a claim of patent infringement could reasonably be asserted."

In little viii, the "reasonably be asserted" focuses on the ANDA product. Could you assert infringement against an ANDA product? In one, "claims the drug for which the applicant submitted the application," you look at whether the NDA product, ProAir® HFA, practices the patent.

So those are two separate issues.

And we could, for example, if we had a patent that when we saw their product we didn't practice it, so it wasn't in the Orange Book, but they do practice it, we could sue them for them for that.

It wouldn't be listable because it wouldn't meet the "claims the drug" limitation, but it would be something that we could sue on.

And so we think that the preamble and the little i are distinct requirements and don't have the surplusage problem that Mr. Edwards seems to be relying on.

The second thing I wanted to just briefly touch on, if we could go to slide 4, please, which is Claim 1 of the '289 patent.

Mr. Edwards referenced that this is a pure device patent and there is no reference to any drug.

I think that is actually where the rubber meets the road on some level, Your Honor. Because it is true it doesn't use the name of the drug, albuterol sulfate, but we believe properly construed and understood, this claim does require the presence of a drug. It's, you might think of it as a genus claim of an inhalation drug and albuterol sulfate would fall within that genus.

And if there is a question about the scope of the claims, then the appropriate thing to do would be to have claim construction before we decided whether these patents do

or don't claim the drug.

That's what happened actually in the *Jazz v. Avadel* case. There was a 12(c) motion. It was denied because they made it claim construction. They construed the claims and then they could figure out whether it was properly listable.

Those were the two points I wanted to make, unless you had other questions.

THE COURT: Yes.

What do I do with the FDA's focus on whether to list a drug product patent stated, the FDA states "The key factor is whether the patent being submitted claims the finished dosage form"?

Now, the finished dosage form of this is your aerosol and the active ingredients and whatever excipients may be there.

None of your patents claim -- have claims which cover all of those elements, correct?

MR. WIESEN: I disagree, Your Honor. I think this claim is an example that does. It doesn't explicitly recite each of those elements, but it does cover each of those elements because the inhaler and the medicament canister need to have each of those elements and therefore comprise the complete drug product.

THE COURT: But that simply is another way of saying that if you made the drug product, you will, in all

likelihood, have infringed a claim of this patent. That's all that is saying.

MR. WIESEN: I think not, Your Honor. If they used -- because there are additional limitations, for example, if they used a different formulation, maybe they could get out of it. If they used a different dose counter with different physical parts, they wouldn't infringe the patent. And that's the dispute we're having. But that doesn't go to the question of whether it can be listable.

THE COURT: Okay. Thank you very much.

Anything further?

MR. EDWARDS: Nothing from Amneal, Your Honor.

MS. SUMNER: Your Honor, if I may, I just wanted to respond to one thing that Mr. Holding said about the pleading on antitrust injury.

I would just refer Your Honor to paragraphs 127 through 131 of our counterclaim, and that's where we have pled the injury that I was discussing.

THE COURT: Thank you very much.

Thank you all.

You'll get a decision quite shortly. It's been good seeing you all. Thank you again.

THE COURTROOM DEPUTY: All rise.

(Proceedings concluded at 11:20 a.m.)

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FEDERAL COURT REPORTER'S CERTIFICATE

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/S/ Mary Jo Monteleone, RMR, CCR, CRCR — 05/24/2024
Official Court Reporter — Date

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