## UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., et al.,

Plaintiffs, . Case No. 23-cv-20964

\_

vs. . Newark, New Jersey

. February 21, 2024

AMNEAL PHARMACEUTICALS OF NEW

YORK, LLC, et al.,

Defendants.

TRANSCRIPT OF HEARING
BEFORE THE HONORABLE MICHAEL A. HAMMER
UNITED STATES MAGISTRATE JUDGE

APPEARANCES (the parties appeared via teleconference):

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                     (Commencement of proceedings)
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                         Sorry. I'm trying to determine -- it
              THE COURT:
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   must be recording --
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         (Simultaneous conversation)
              MALE SPEAKER: Yes, that it's recording.
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              THE COURT: Okay. Great. Thanks. Still getting
   used to Teams a little bit.
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              All right.
              So this is Teva Branded Pharmaceutical Products R&D
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    Inc., Norton Ltd., and Teva Pharmaceuticals U.S.A. Inc. v.
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   Amneal Pharmaceuticals in New York, Amneal Ireland Ltd.,
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   Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc.,
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   Civil No. 23-20964. We are here for a Rule 16 scheduling
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    conference in this Hatch-Waxman Act litigation.
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              Can I have appearances, please, beginning with
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    Teva.
                        Sure. Good afternoon, Your Honor.
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              MR. RUIZ:
   Hector Ruiz and Christine Clark from Walsh Pizzi O'Reilly
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20
    Falanga for Teva.
21
              And with me I have my colleagues from Goodwin
22
    Procter, and they can introduce themselves.
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              MR. WIESEN: Good afternoon, Your Honor, Daryl
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   Wiesen from Goodwin Procter in Boston. And with me are Tom
25
   McTique and Eva Monteiro from my office.
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1 THE COURT: Okay. Welcome. 2 And how about on behalf of Amneal? MS. CONROY: Good afternoon, Your Honor. For the 3 4 Amneal defendants, it's Rebekah Conroy from Stone Conroy. 5 And if me today is Jeremy Edwards from Procopio. All right. Welcome. 6 THE COURT: 7 All right. So I've reviewed complaint, the joint 8 discovery plan. 9 To me, I think the big-ticket item -- and I am 10 happy to hear whether there are any issues that the parties 11 want to discuss, I'm certainly aware that you have the 12 conference with Judge Chesler on March 5th. I'm going to 13 assume that is probably to talk about the motions and the 14 anticipated Rule 12(c) motion. 15 But the concern I have -- and I certainly 16 understand, it's Hatch-Waxman Act, always take the deadlines 17 seriously given that the 30-month stay expires in just over 18 two years, and while that may seem a lot, you folks don't 19 need me to tell you there's a whole lot of work that has to 20 get done between now and then. 21 The concern I have, unless I'm misreading it, 22 concerns Section 9(b) where the parties agree the discovery 23 concerning the antitrust counterclaims would be bifurcated 24 and stayed until after resolution of the claims for patent 25 infringement, understanding that, you know, a bench trial, at

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least as proposed in the joint discovery plan for September 2025, I have real concerns that the prospect of just starting discovery on antitrust claims, you know, about two years or so out from now. So I don't know if I'm misreading that or if we can mutually find some other way to have that perhaps give some degree of primacy to the patent infringement side of things but not put all antitrust discovery off for two years, assuming also, quite honestly, that Judge Chesler would find that acceptable. But if somebody wants to speak to that, I'm all ears. MR. WIESEN: Your Honor, maybe I can take the first shot at it. It's Daryl Wiesen. THE COURT: Yes. MR. WIESEN: I think our view -- and Mr. Edwards can agree or disagree -- is that until we know whether -part of their allegations are that this is sham litigation, that there's no basis to bring the claim --THE COURT: Right. MR. WIESEN: -- we'll know something about that through the patent case. In other words, if we win the patent case, that piece, at least, of the antitrust claim goes away. If we lose the patent case, maybe it's alive, but we'll know a lot of more about it.

And so often in these cases, the antitrust is 1 2 bifurcated for that reason, because it's not totally 3 unrelated. Once we know what happens with the patent case, 4 we will have a lot of insight on what might happen or what 5 might not be viable in the antitrust case. And the same, I 6 think, is true with the delisting count, which, as we go 7 through that in the first six months -- and Mr. Edwards and 8 Amneal actually filed that 12(c) motion last night --9 THE COURT: Right. MR. WIESEN: -- when it was due, so we're now in 10 11 the heart of briefing that. 12 And, again, we haven't bifurcated the discovery on 13 the delisting issues if we get past motion practice. 14 So I do think that, although we would have 15 bifurcated the discovery on market power and some of the 16 antitrust-specific issues, a lot of the fact discovery on 17 antitrust will overlap with the other issues. And the idea, 18 I think, of the bifurcation was just to postpone the 19 antitrust-specific discovery that would be additional and may 20 not be necessary and, I think, we all feel when we would 21 learn a lot about that through the patent and delisting 22 discovery. 23 THE COURT: Okay. 24 Anybody else want to be heard on that? 25 MR. EDWARDS: Yes, Your Honor. This is Jeremy

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Edwards for Amneal. 1 2 We're largely aligned, which is why the parties 3 agreed to bifurcate. So recognizing, of course, your 4 hesitation, you know, there's a whole layer of investment 5 that I think the parties would wish to put off to get some 6 clarity as we go through the patent case. 7 THE COURT: But that clarity is going to Right. 8 only come at the end of the patent case. Right? 9 MR. EDWARDS: Yes. So that's a problem. 10 THE COURT: 11 Let me ask this. I think counsel just referenced 12 that -- and I'd anticipated this too -- a fair amount of the 13 antitrust discovery will be necessarily tied up in or 14 encompassed by the patent infringement discovery.

Can you give me any sense in terms of time frame or otherwise what additional antitrust-specific discovery would look like? I mean, if we start to get into things like market share, acts that were undertaken concerning the alleged sham litigation -- and, obviously, this is something that, you know, this Court in particular has dealt with over the course of some years now in other cases, my experience, at least, has been the antitrust side of discovery alone could take several years. I've had other cases where after all the patent infringement litigation had been, you know, brought to resolution, there were still two to three years of

1 antitrust-specific discovery. 2 I'm sure some of you folks are in those cases; so you know exactly what I'm talking about; right? 3 4 MR. WIESEN: Yes. Yes, Your Honor. 5 THE COURT: Right. So you understand my concern, 6 naturally. 7 MR. WIESEN: Yes, I mean, we do appreciate that, Your Honor. And I think it is fair. 8 9 I think to Mr. Edwards' point, part of the question 10 is the investment for the companies at this stage, including 11 the question of when there would be even any antitrust 12 causation and damages, depending on when Amneal could get 13 either tentative or final approval. And that hangs over all 14 of this as well. At the moment, the ANDA's in its early 15 stages. There are representations in the counterclaims and 16 otherwise for when they might get approval. But I think the real answer is none of us know. And the value even of the 17 18 antitrust claim, until we have more certainty on that, raises 19 questions. 20 I don't think we can or would dispute that there 21 could be somewhat substantial discovery on the antitrust 22 issues if or when it came to that. 23 THE COURT: Right. 24 MR. WIESEN: But I think that that might be 25 necessary almost no matter what because some of the -- and

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   much of that discovery may need to get pushed off depending
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    on where Amneal ends up with -- when they could come to
   market will impact a lot of that damages-related discovery
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 4
    and otherwise.
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              MR. EDWARDS:
                            Your Honor, if I may --
              THE COURT: Yeah.
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              MR. EDWARDS: No qualms with what Mr. Wiesen is
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    saying.
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              Might propose a path forward here only if we do
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   have this motion that if Amneal prevails on this motion, this
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    case won't be --
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              THE COURT: You're talking about the Rule 12(c)
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   motion?
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              MR. EDWARDS: Yes, Your Honor.
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              THE COURT: The severance. Right.
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              MR. EDWARDS: Yeah, if that motion is granted and
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    all the asserted patents are delisted, this won't be a
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   Hatch-Waxman case anymore.
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              THE COURT:
                         Right.
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              MR. EDWARDS:
                            There won't be a stay. And, perhaps,
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    it makes sense to table the question of bifurcating antitrust
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    discovery until that motion is decided or some later date, if
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   we aren't getting traction in having that motion decided and
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   we feel the pressure mounting to begin antitrust discovery in
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    earnest.
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MR. WIESEN: I guess I might add to that, Your Honor, that as part of our 12(b)(6) motion on the counterclaims, we did move to dismiss antitrust counterclaims. THE COURT: Right. And so, again, to Mr. Edwards' point, maybe one question is -- one possibility is to let those motions get resolved and then revisit the question of discovery once we see what does or does not remain in the case, both on the listing issue, whether it's a Hatch-Waxman case, and whether there are antitrust claims. THE COURT: Yeah, it's funny you say that. Going into -- coming into the conference, I was thinking of doing exactly that. I was a little hesitant because I'm, like, well, am I really just kicking the can down the road, but sometimes kicking the can down the road a little bit isn't the worst thing. So I think I'm -- I think that's a fair approach. And then we revisit the issue. Obviously, I am not making any promises as to whether I'm going to formally bifurcate, but at the same time, I certainly will be happy to talk to the parties, hear your input, and we'll just basically continue the conversation. I think makes a lot of sense. And it also lets the parties -- I mean, obviously, nobody's proposing to hold off on infringement discovery

because of the Rule 12 motions; right? 1 2 UNIDENTIFIED SPEAKERS: That's correct. THE COURT: Right. So it also has the collateral 3 4 benefit of letting you folks focus on the infringement side 5 of discovery for at least a few months, you know, which, of 6 course, given the 30-month stay deadline has inherent value 7 as well. 8 Okay. That's -- that has resolved sort of my real 9 concern coming into the conference. 10 Do the parties have any particular concerns you 11 want to raise on the patent infringement side of discovery? 12 MR. WIESEN: Not from Teva or from the plaintiff's 13 perspective, Your Honor. We worked well together to figure 14 out the schedule. And we've done this before, so ... 15 THE COURT: Well, I'll tell you what. I have a lot 16 of parties who have done this together, things like this 17 together before, and they don't agree on anything; so it's 18 testament to counsel that you folks work so as well together 19 and were able to agree on all of the deadlines, for which I'm 20 certainly grateful. 21 Any other counsel --22 MR. EDWARDS: And no issues. Yeah, sorry, 23 Your Honor. No issues for Amneal. 24 THE COURT: All right. So what we'll do is, then, 25 we'll get the scheduling order up. That'll basically set the

get some rest.

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antitrust side of discovery off to the side and stay that, at
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    least pending the Rule 12 motions. And then I'll have the
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   deadlines that the parties propose.
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              So thank you, folks, for making life easy today.
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   It's always a pleasure to work with all of you.
              UNIDENTIFIED SPEAKERS: Thank you, Your Honor.
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             MR. WIESEN: And we appreciate you doing this
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   remotely. I was before Judge Arleo for the last two weeks
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   down in Newark. So --
              THE COURT: Oh, you're on that trial?
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             MR. WIESEN: On the Pacira versus Fresenius trial,
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   yes, Your Honor.
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              THE COURT:
                         Right. Right.
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             MR. WIESEN: I was on the generic side on that one.
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    I was representing Fresenius.
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              THE COURT: Okay. All right. Okay. Is that
    resolved?
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             MR. WIESEN: No. We finished trial, and now we're
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    doing posttrial briefing. So.
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              THE COURT: Oh, that's right. That's a bench
    trial.
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             MR. WIESEN: It's another Hatch-Waxman case; so
23
   it's a bench trial.
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              THE COURT: Right. Okay. Good. Well, I hope you
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|Hearing |23-cv-20964, February 21, 2024

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1	Thank you, folks. Have a great day.
2	UNIDENTIFIED SPEAKERS: Thank you.
3	(Conclusion of proceedings)
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