

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**TEVA BRANDED PHARMACEUTICAL
PRODUCTS R&D, INC.,**

CIVIL NUMBER:

2:23-CV-20964 (SRC)

Plaintiff,

v.

**AMNEAL PHARMACEUTICALS OF
NEW YORK, LLC,**

Defendant.

**MARTIN LUTHER KING BUILDING & U.S. COURTHOUSE
50 WALNUT STREET, NEWARK, NEW JERSEY 07101
THURSDAY, JUNE 13, 2024
COMMENCING AT 10:55 A.M.**

B E F O R E:

**THE HONORABLE STANLEY R. CHESLER,
UNITED STATES DISTRICT JUDGE,**

A P P E A R A N C E S:

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**Proceedings recorded stenographically.
Transcript produced by computer-aided transcription.**

A P P E A R A N C E S: - CONTINUED

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(PROCEEDINGS held in open court before

The Honorable STANLEY R. CHESLER,

United States District Judge, at 10:55 a.m.)

THE COURTROOM DEPUTY: *Teva Pharmaceuticals v. Amneal
Pharmaceutical, LLC, et al., 23-20964.*

Please note your appearances for the record.

MR. RUIZ: Good morning, Your Honor. Hector Ruiz.

THE COURT: We are going to stop right here.

THE COURTROOM DEPUTY: Speak into the microphone.

THE COURT: The acusticus in this place are horrible.
What is more, as I candidly admitted on the prior proceeding,
I'm getting older. I'm using hearing aids. Speak slowly and
clearly into the microphone.

You can stand where you want at the podium or at the
desk. But you want me to hear you. Go ahead.

MR. RUIZ: Hector Ruiz for the plaintiff's with
Walsh, Pizzi, O'Reilly, Falanga Law Firm. And with me I have
co-counsel from Goodwin Proctor.

MR. WIESEN: Good morning, Your Honor. Daryl Wiesen,
from Goodwin. And with me and my partner Willie Jay, who has
not yet appeared pro hac, but ask that he sits with me at
counsel table.

THE COURT: Welcome.

MR. RUIZ: Thank you, Your Honor.

THE COURT: Let me hear from the defendants.

1 MR. STONE: Good morning, Your Honor. Shalom Stone,
2 Shalom Conroy for the Amneal defendants, and with me is my pro
3 hac colleagues.

4 MR. MADDOX: Good morning, Your Honor. Steven Maddox
5 for the defendants.

6 THE COURT: Good morning to you.

7 All right. We all know what I ruled. We all know
8 that Teva disagrees with me. I'm not surprised. Indeed if
9 you had agreed with me, when the FTC sent out the letter
10 asking for delisting, you would have delisted. So you will be
11 appealing my decision.

12 MR. WIESEN: Yes.

13 THE COURT: And the question is whether or not I
14 should grant a stay pending appeal. I will hear you.

15 MR. WIESEN: Thank you, Your Honor. And I think our
16 -- we did read your ruling. As you said we've already filed
17 our notice of appeal. And we will be appealing the injunction
18 against us immediately, which we believe is appropriate.

19 THE COURT: Okay. Let me just stop one second.

20 Does everybody agree that, in fact, my decision in
21 this is immediately appealable and constitutes an injunction?

22 MR. MADDOX: Yes.

23 THE COURT: Okay. Good. Quite frankly, if you
24 didn't, I'm perfectly willing to satisfy it under 54(b) for an
25 immediate appeal, because indeed it disposes of the entire

1 significant aspect of this case, but if you are all in
2 agreement, then we will go ahead.

3 All I will tell you is this: Sometimes circuit
4 courts have interesting views of what constitutes a final
5 appealable order or what constitutes an injunction. Indeed I
6 had a case earlier where I issued a ruling on a declaratory
7 judgment on coverage. The defendant in that case appealed it
8 as having been an injunction, and dismissed it for lack of
9 jurisdiction because it wasn't an injunction.

10 So, as I said, and quite frankly I suspect that
11 Amneal will not object to my certifying it under 54(b) if that
12 was appropriate.

13 MR. MADDOX: If you found it appropriate, no
14 objection.

15 THE COURT: Okay.

16 MR. WIESEN: We think it is unnecessary, Your Honor.
17 The *Jazz v. Avadel* case by the Federal Circuit had an
18 immediate appeal.

19 THE COURT: Okay.

20 MR. WIESEN: And we believe that is the model for
21 what we should be doing here with the stay.

22 THE COURT: I understand that.

23 MR. WIESEN: That being said --

24 THE COURT: Except for the District Court, in fact,
25 having denied that stay.

1 MR. WIESEN: Correct. The District Court denied the
2 stay. The Federal Circuit then granted it.

3 It is also true if you deny the stay, we will take
4 the motion to the Federal Circuit. In fact, given the timing,
5 as I think we all agree under the regulations we have 14 days
6 from your order to delist.

7 THE COURT: Unless I stay it.

8 MR. WIESEN: Unless you stay it. And therefore we
9 will need to go to the circuit quickly if you deny the stay or
10 if the motion remains pending.

11 When you look at the balance of the harms here, there
12 is harm to Teva if it is not stayed. And there is no harm to
13 Amneal if it is. When you combine that with the de novo
14 standard of review on appeal, which I think we would all agree
15 applies to the statutory interpretation question, we believe
16 that raises a substantial question of the merits.

17 I don't want to get into -- I had my shot to convince
18 you on the merits, I won't go near that.

19 THE COURT: You don't have to. Let me put it this
20 way: It obviously is an issue. I obviously concluded that
21 the Second Circuit and the First Circuit had decided it
22 correctly. I understand you disagree. We will stop there for
23 a second.

24 As I understand it, Amneal contends that the standard
25 is not whether or not there is a substantial issue, but a

1 likely probability of success on appeal. Correct?

2 MR. WIESEN: I think that is Amneal's argument that
3 we need to make a strong showing which I think they would
4 probably say is greater than 50 percent at least.

5 THE COURT: Okay. And, essentially, you've argued
6 that the strength of the showing can be less where the harm to
7 the appellant is more severe. Correct?

8 MR. WIESEN: Correct, Your Honor.

9 Under the standard *Haven's* case from the Federal
10 Circuit a number of other district court cases applying that
11 standard, they apply for an injunction pending appeal. They
12 have clearly said that if there is at least a substantial
13 question or Judge Robinson in the *Butamax* case basically said
14 when there is de novo review, if the harm to one party greatly
15 out weighs the harm to the other party, the stay pending
16 appeal is appropriate.

17 THE COURT: Okay. Now Amneal essentially says, Hey,
18 if I don't grant a stay, and they go on the market at risk,
19 you can always seek a PI. What is the fallacy in that
20 argument?

21 MR. WIESEN: The fallacy in that argument,
22 Your Honor, is that the protections that come from the
23 Hatch-Waxman Act, the 30 month stay, is a procedural
24 protection to avoid the need to get to that. Amneal's
25 argument is functionally if we don't infringe or the patent is

1 invalid, then there should be no 30 month stay.

2 But we all know the way the Hatch-Waxman statute is
3 set up, we don't have to deal with that for 30 months. That
4 is the compromise.

5 They get to rely on our data. They don't have to do
6 clinical trials, but they have to wait 30 months if the patent
7 is properly listed.

8 THE COURT: Okay. Let me ask you a few questions.
9 As I understand it the Orange Book has an additional three
10 patents covering this particular product.

11 MR. WIESEN: The Orange Book has nine total patents
12 for ProAir, so four additional patents that we did not sue
13 Amneal on and are not a subject of that motion for that
14 reason.

15 THE COURT: I'm just curious did they file paragraph
16 four certifications with regard to them?

17 MR. WIESEN: They did. And we got the offer of
18 confidential access, analyzed it, and determined that we did
19 not have a basis to sue them and therefore did not.

20 THE COURT: Okay. Fine.

21 So we are left with a situation where once, if my
22 order goes into effect, once they get approval from the FDA
23 they can go on the market. Correct?

24 MR. WIESEN: If they get approval from the FDA. If
25 and when.

1 THE COURT: Okay.

2 MR. WIESEN: That is correct.

3 Without a preliminary injunction, which, as I said,
4 turns us to the merits. And I think, Your Honor, as you know,
5 a preliminary injunction doesn't actually ask whether we are
6 right or wrong, asks whether they have a substantial defense.
7 So that is not even a full merits analysis. It has got a
8 little bit of a thumb on the scale in the defendant's favor
9 because of the equities in the preliminary injunction.

10 THE COURT: Yes and no. And the reason being, among
11 other things, because on validity to the extent it is changed,
12 the patent is presumed to be valid. And, in fact, then they
13 have to demonstrate ultimately on the merits by clear and
14 convincing evidence that it was not valid. Correct?

15 MR. WIESEN: Correct.

16 THE COURT: So at least on validity issues, there is
17 a thumb on the scale in favor of the patentee. Right?

18 MR. WIESEN: Correct. Based on the prosecution and
19 the assumption that the patent office did its job. Yes, that
20 is correct.

21 THE COURT: Okay. Now you make an argument about
22 this impacting another Hatch-Waxman case, which I gather I am
23 fortunate enough not to be presiding over. Is that correct?

24 MR. WIESEN: I believe you are presiding over.

25 THE COURT: That just shows you that I don't keep

1 track of all of the cases which I'm presiding over.

2 MR. WIESEN: It is in the very early stages. There
3 has been no answer yet, so there would be no reason you would
4 be aware of it. The answer is coming in a few weeks I
5 believe.

6 THE COURT: Okay.

7 MR. WIESEN: That is another case against another
8 generic filer. On that one, we did sue on online patents, as
9 Amneal points out, as the complaint makes clear. In that case
10 we tried to negotiate the offer of confidential access and
11 were unable to.

12 So we will have to go under the New Jersey rules, get
13 the disclosure of the ANDA, and then determine which if any
14 patents we can proceed on. It may only be the patents that
15 are at issue here.

16 It may be other ones, each of the patents covers
17 slightly different things. And we've done a real analysis
18 before pushing forward with litigation on any of them.

19 THE COURT: As you know under New Jersey's rules, you
20 should get that information pretty quickly.

21 MR. WIESEN: Yes.

22 THE COURT: Frankly, I was the chair, I think I still
23 am the chair of the local rules committee. One of the rules
24 we did put into effect, was that although an ANDA applicant
25 does not have to demonstrate that it does not infringe because

1 the burden of proof on infringement is on the plaintiff, the
2 patentee. Nevertheless, if they have filed an ANDA which
3 asserts that they did not infringe, then there should be no
4 reason why they should not disclose early on what their
5 contentions are, with regard to noninfringement.

6 And I will candidly tell you all that is because this
7 court focuses like a bullet on the 30 month stay. And as far
8 as I'm concerned, in my cases, I expect that case to be ready
9 for trial at least six months before the 30 month stay is
10 going to expire. That is the reason for the rule. You should
11 get that information expeditiously.

12 MR. WIESEN: Yes. We expect we will once they answer
13 and we move into that phase. And representing Teva, I can say
14 I've been on both sides of that rule, and we are well familiar
15 with it.

16 THE COURT: Okay. Their argument is: So under any
17 circumstances there are three patents, which have not been --
18 where they filed a paragraph four certification and the
19 30 month stay as to those patents would nevertheless bar that
20 company from going on the market until the 30 month stay
21 expired or alternatively until they, in fact, achieve success.

22 MR. WIESEN: Or until we see their ANDA and determine
23 we can't proceed with pursuing those patents. And that is the
24 fallacy in that argument, is that given the different scope of
25 the different patents, each patent, as in this case we may

1 determine some patents can be asserted, some patents can't.

2 That is why with it is important that we be allowed
3 to list all of the patents. And the harm comes from delisting
4 really any one of them, because it will cover different claim
5 scope.

6 THE COURT: Okay. Anything else you wish to add?

7 MR. WIESEN: If you have no other questions, I will
8 cede the floor.

9 THE COURT: No.

10 Let me talk to counsel for Amneal.

11 MR. MADDOX: Good morning, Your Honor.

12 THE COURT: Good morning. Let me ask a few
13 questions. As I understand it you have not received tentative
14 approval. Correct?

15 MR. MADDOX: That is correct.

16 THE COURT: And as I understand it from
17 correspondence with the FDA, the possibility of your receiving
18 tentative approval is either November of 2024 or January of
19 2025 depending on whether or not they have to do an inspection
20 of the facility. Is that correct?

21 MR. MADDOX: That is the expectation of the FDA.
22 Yes.

23 THE COURT: Okay. So until you get tentative
24 approval, what harm is there in staying my decision?

25 MR. MADDOX: Sure. The harm would come from staying

1 the decision until the court of appeals ultimately got around
2 to deciding it. Which would, frankly, come up against the
3 30 months likely.

4 And the harm could start to flow that harm could
5 start to flow from November. We don't know when we are going
6 to get approval. We don't expect to get it this week. But we
7 would --

8 THE COURT: I'm not going to get a PI?

9 MR. MADDOX: Not that I know of.

10 THE COURT: Okay.

11 MR. MADDOX: So that is the harm. And the harm for
12 the 30 days is just it enlarges the delay. It kicks the can
13 down the road.

14 THE COURT: Let's take the 30 months -- I'm sorry,
15 the 30 day delay.

16 MR. MADDOX: Sure.

17 THE COURT: If I were to deny a stay, then Teva as
18 night would follow day would go up to the Federal Circuit and
19 seek that stay. Correct?

20 MR. MADDOX: Correct.

21 THE COURT: Would you be surprised to know that
22 circuit judges, like district judges, do not like being
23 presented with applications on complex issues which they have
24 to decide with remarkable speed? Would you be surprised about
25 that?

1 MR. MADDUX: I would not.

2 THE COURT: So if I were to grant a stay of 30 days
3 to give Teva and you reasonable time to argue it before the
4 Federal Circuit whether or not that stay should be continued,
5 you would not be harmed at all. Right?

6 MR. MADDUX: There would be no immediate harm. We
7 wouldn't know what the knock-on effect turned out to be.

8 THE COURT: Well, you don't know what the
9 Federal Circuit would decide. Right?

10 MR. MADDUX: Right.

11 THE COURT: But you could make all of those arguments
12 to the Federal Circuit. Right?

13 MR. MADDUX: Yes.

14 THE COURT: And it could be done in an orderly
15 fashion. Right?

16 MR. MADDUX: Yes.

17 THE COURT: And, in fact, my colleagues on the
18 Federal Circuit would not be presented with having to make a
19 decision about whether or not to grant a stay based upon two
20 days worth of briefing. Right?

21 MR. MADDUX: Correct.

22 THE COURT: And indeed also would have the
23 opportunity to at least do a preliminary analysis of whether
24 or not I was off the wall or absolutely correct in deciding
25 that I was going to follow the Second and First Circuits.

1 Right?

2 MR. MADDUX: Correct.

3 THE COURT: So if I were to do that -- and let's just
4 take a look at factors here: Strength of the appellant's
5 case; and obviously if I felt that they were really strong, I
6 wouldn't have issued the opinion that I did. Right?

7 MR. MADDUX: Correct.

8 THE COURT: On the other hand, there are essentially
9 only two decisions in the country at the appellate level
10 dealing with this issue. Right?

11 MR. MADDUX: Yes.

12 THE COURT: And both have turned out to be in your
13 favor. But they were not decided by the Federal Circuit.
14 Right?

15 MR. MADDUX: Yes.

16 THE COURT: So at a minimum there is at least a real
17 substantial issue about whether or not I was right or wrong.
18 Although, as I've indicated, if I had any concerns about
19 whether or not I was right or wrong, I wouldn't have ruled
20 what I did.

21 But the Federal Circuit in other circumstances and
22 the Third Circuits and have, unfortunately, and sometimes in
23 my view incorrectly, disagreed with me. That is life. And it
24 is not inconceivable that they might disagree with me again.
25 Indeed, to put it bluntly, there are occasions when what the

1 Federal Circuit does is totally unpredictable. Right?

2 MR. MADDUX: Yes.

3 THE COURT: And any patent lawyer practicing before
4 me knows that, as does any district judge in the country.

5 So at least there is a real issue. So let's get to
6 the harms. One is, from their point of view, if I deny a
7 stay, then within 14 days they have to ask the FDA to, in
8 fact, delist those patents. Correct?

9 MR. MADDUX: Yes.

10 THE COURT: And that means that unless there is an
11 emergent application to the Federal Circuit for a stay, you
12 are going to be free to go on the market whenever approval is
13 given by the FDA. Right?

14 MR. MADDUX: Yes.

15 THE COURT: On the other hand, if I grant a 30 week
16 -- a 30 day stay, the court, which is ultimately going to
17 decide this issue is given a reasonable opportunity to
18 evaluate the positions of the parties including the strength
19 of their appeal and the likelihood that my reasoning is
20 correct or not can also be evaluated along with those other
21 factors. Right?

22 MR. MADDUX: Right.

23 THE COURT: And indeed as we all know in the *Jazz*
24 case where the district court denied any stay whatsoever, the
25 losing party went up to the Federal Circuit, and the

1 Federal Circuit, in fact, granted a stay pending disposition.
2 And indeed if I recall correctly, extended the stay.

3 MR. MADDOX: They granted a stay pending expedited
4 disposition, which of course is something in the court of
5 appeal's control.

6 THE COURT: I certainly don't.

7 MR. MADDOX: Right.

8 THE COURT: But they did. And, in fact, they did
9 extend the stay.

10 MR. MADDOX: Yes.

11 THE COURT: Okay. So the final factor is the public
12 interest. And, again, I'm dealing with a 30 day stay.

13 MR. MADDOX: Okay.

14 THE COURT: Okay. How would granting a 30 day stay
15 impact negatively on the public interest of this case?

16 MR. MADDOX: It is difficult to see how a 30 day stay
17 would.

18 THE COURT: So, and I hate to put you on the spot,
19 but when we go through these factors, it looks like there is
20 every reason in the world to, in fact, grant the stay for
21 30 days. And let you folks indeed come up with a briefing
22 schedule, which you can present to the Federal Circuit for
23 dealing with that, their application for an extension of that
24 30 day stay. And the court, which will ultimately decide this
25 case, can determine whether or not it makes sense to them

1 whether or not stay should be granted. Correct?

2 MR. MADDUX: Certainly that is, there are aspects of
3 that that is correct. I'm not sure there is every reason, but
4 there is a lot of reason.

5 THE COURT: Okay. I'm satisfied that the reasons
6 which I just gave you --

7 MR. MADDUX: Sure.

8 THE COURT: -- are more than adequate to justify
9 granting a 30 day stay of my order to permit you folks to
10 indeed apply to the Federal Circuit for an extension of that
11 stay. That will not harm Amneal in any way, shape, or form.

12 There is no possibility you are going to get
13 tentative approval within 30 days; and that we are all agreed
14 about. Right?

15 MR. MADDUX: Yes.

16 THE COURT: Okay. So in short, no harm to you. Harm
17 to them is at least an issue. And the public interest is not
18 harmed at all by granting that stay. Correct?

19 MR. MADDUX: True.

20 THE COURT: Good. I apologize for cross-examining
21 you. I do tend to, in fact, want to focus on the issues that
22 are really presented. And to put it bluntly, that is what I
23 find, which is: Number one, there is a substantial issue.

24 Two, there is substantial harm to Teva if this
25 decision is not stayed at least for enough time for them to

1 present it to the Federal Circuit court of appeals.

2 There is no harm to Amneal because they can't
3 conceivably go on the market.

4 And the public interest, as you have conceded, is not
5 harmed in any way, shape, or form by granting that stay.

6 Now I can also tell you, quite candidly, just like I
7 indicated that the Federal Circuit and the district courts do
8 not appreciate being presented with urgent applications
9 without adequate time to consider them. Your proposal that we
10 proceed to a preliminary injunction on this instead, quite
11 frankly, is one which is indeed anathema to the undersigned,
12 meaning me. All right.

13 There is nothing worse than having to deal with
14 complex legal and factual issues on an expedited basis because
15 a generic has gone on the market at risk and a branded
16 manufacturer, therefore, is compelled to seek a preliminary
17 injunction. It creates havoc with the court's docket and it
18 delays handling other cases. And the court is satisfied that
19 granting that stay will obviate that possibility.

20 So for the reasons that I just discussed, the
21 alternate application by Teva for this matter to be stayed for
22 a period of 30 days from today is granted. I will direct Teva
23 to submit a form of order.

24 I am also going to direct you folks to consult and
25 agree upon a briefing schedule for any such application, which

1 will grant the Federal Circuit more than adequate time to
2 consider your positions and evaluate the merits of your
3 claims. Okay?

4 MR. MADDOX: Understood.

5 THE COURT: Good. Submit an order. It is great
6 seeing you. Let me see folks at sidebar.

7 (Sidebar conference held off the record.)

8 THE COURT: Thank you very much counsel. Have a
9 great day.

10 (The proceedings are concluded at 11:29 a.m.)

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FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE

14

15 I, **Laurie A. Engemann, CCR, CRCR, RPR**, Official Court
16 Reporter of the United States District Court for the District
17 of New Jersey, do hereby certify that the foregoing is a
18 correct transcript from the record of proceedings in the
19 above-entitled matter.

20

21

22

23 /S/ Laurie A. Engemann CCR, CRCR, RPR

June 14, 2024

24 *Signature of Official Court Reporter*

Date

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