1 UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA
2

3 REGENERON PHARMACEUTICALS, INC.,

4 Plaintiff,

5 vs. CASE NO.:
1:22-CV-61
6 MYLAN PHARMACEUTICALS INC.,

7 Defendant.

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9 Proceedings had in the status conference of the above-styled action on Wednesday, September 28, 2022, before
10 the Honorable Thomas S. Kleeh, Chief District Judge, at Clarksburg, West Virginia.
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Wednesday Afternoon Session
September 28, 2022, 2:59 PM
- - -

THE COURT: Madam Clerk, would you be kind enough to call our next case, please.

THE CLERK: Regeneron Pharmaceuticals, Inc., versus Mylan Pharmaceuticals, Inc. Civil Action Number 1:22-cv-61.

Will counsel, beginning with Plaintiff's counsel, please note your appearance for the record.

MR. RUBY: Good afternoon, Your Honor. Steve Ruby -- Carey, Douglas, Kessler & Ruby -- for Plaintiff, Regeneron. And also with me I have David Berl of Williams & Connolly, who's been admitted pro hac vice and will be primarily handling the matter for Plaintiff today.

We also have a couple of Plaintiff representatives from in-house counsel with Regeneron, Petra Scamborova and James Evans, Your Honor.

THE COURT: All right. Good afternoon, counsel.

MR. COPLAND: Good afternoon, Your Honor. This is Gordon Copland, Steptoe & Johnson, appearing for the Defendants.

Also appearing are William Rakoczy of the Rakoczy Molino firm. Mr. Rakoczy will be addressing the Court on the issues we expect.

Furthermore, Mylan is also appearing through two

in-house attorneys, Thomas Jenkins and Matthew Greinert, who are attending the hearing.

THE COURT: All right. Understood. Good afternoon to you as well, counsel. And, again, my apologies collectively to everyone for being a bit behind schedule here today.

We convene to discuss some scheduling issues as there seems to be quite a divergence as to not only when we should set trial but also under what statutory vehicle we proceed.

Plaintiff's counsel, the floor is yours first.

MR. BERL: Thank you very much, Your Honor. David Berl of Williams & Connolly representing Regeneron.

Your Honor, in our view this is not a garden variety patent infringement case. In particular, there are two important differences between this case and the typical case that comes before Your Honor in terms of patent infringement.

The first key difference is that this case, a BPCIA case -- BPCIA is an acronym for the biosimilar statute passed as part of Obamacare -- includes with it a series of voluminous exchanges that occur before the case is filed, colloquially referred to as the "patent dance." And that patent dance includes Regeneron's assertions about what claims are infringed and why, Mylan's assertions about why its product and manufacturing process don't infringe those claims, Mylan's assertions for why the claims are invalid, and Regeneron's responses as to why it believes its claims are valid.

1 That all happened via an exchange of many hundreds of
2 pages of information going both ways all before this case was
3 filed. And that's important in our view because this case does
4 not begin at the same posture as most cases. We're part of the
5 way down the runway -- I would submit much of the way down the
6 runway -- toward knowing what we would generally not know until
7 that discovery has occurred.
8 We've seen their aBLA -- that's their FDA
9 application -- to sell their biosimilar version of Regeneron's
10 flagship Eylea product. We've seen additional information as
11 well. And we are prepared to move forward, given that
12 information, on an accelerated schedule.
13 Which brings me to the second distinction between
14 this case and the typical patent infringement case is that this
15 case, pursuant to the BPCIA, provides more particular statutory
16 relief that Congress included when it passed the BPCIA. And
17 that statutory relief is a mandatory injunction precluding the
18 Defendant, here Viatris, from marketing and selling its product
19 in the United States until expiry of any patent that Your Honor
20 finds to be valid and infringed following trial as long as
21 there's what's called in the statue a final court decision,
22 which is defined as a judgment that is either not appealed or
23 appealed and then ruled on by the court of appeals, here the
24 Court of Appeals for the Federal Circuit.
25 So we can be flexible, Your Honor, with respect to

1 how this case proceeds and even with respect to how many
2 patents move forward at this juncture. But we cannot be
3 flexible -- because the statute does not permit us to be
4 flexible -- as to the timing of the case, as to the timing of
5 the trial and the ultimate disposition of the case, which in
6 our view needs to occur before May 18th, 2024, in order to
7 avail ourselves of the statutory relief that Congress provided.
8 So that's why, in our view, we've proposed a schedule
9 we think is feasible. We think it's reasonable. We think it's
10 within the scope and balance of what other courts and
11 administrative bodies have ordered in circumstances that we
12 view are -- as analogous.
13 But the fundamental point here is that it is not
14 appropriate for Viatris, the defendant, to moot our claim for
15 statutory relief, our primary request for relief, simply by
16 running out the clock. But irrespective of the merits of
17 opposition on validity and infringement, we are not permitted
18 to obtain statutory relief. So that's why we provided the
19 schedule we've provided.
20 The Defendant, Viatris/Mylan, has provided a few
21 responses, largely that our schedule isn't feasible. We don't
22 believe that to be true. They are a large company as Your
23 Honor knows. Eleven lawyers on their side already have entered
24 an appearance. And we think we can move forward, given what we
25 already know, on the schedule that we have provided for.

1 Their second primary response --
2 THE COURT: Mr. Berl.
3 MR. BERL: -- is the fact --
4 Yes.
5 THE COURT: If I could interrupt you there before you
6 transition.
7 What would Plaintiff's position be on the remaining
8 discovery or other issues necessary to occur before trial
9 given -- and I'll borrow your phrase -- the patent dance work
10 that's already occurred?
11 MR. BERL: Yes. So, Your Honor, there are no
12 documents for us to produce. Mylan has already produced its
13 FDA application. There are some additional documents that we'd
14 like them to produce. We provided them requests back in August
15 for those documents. So they understand what we need. And
16 that's largely what we need. There may be a few follow-ups,
17 but that largely is what we need.
18 In terms of what needs to happen from our
19 perspective, from what we need to produce, we have prepared a
20 substantial document production that includes the most
21 important documents in my client's possession; that is the
22 relevant portions of its FDA application for its Eylea product,
23 the laboratory notebooks that reflect the conception of the
24 invention at issue, scientific reports that reflect information
25 about the research and development that led to the inventions

1 that are disclosed in claims here, as well as the patents and
2 their file histories. We will be prepared to furnish all of
3 that information, all of those documents to Mylan within 48
4 hours of Your Honor's entry of a protective order.
5 And by way of update, we have received a response
6 from Mylan. We're conferring with Mylan tomorrow. And we're
7 hopeful that by the end of the week the parties will be able to
8 present for Your Honor's signature a stipulated protective
9 order. And within 48 hours of that being executed by The
10 Court, as I said, we will produce the lion's share of the
11 information that Mylan would need.
12 At that point, obviously, they would review the
13 documents; we would review the documents they have produced;
14 and we would proceed to depositions.
15 We're mindful, Your Honor, of the fact that we are
16 requesting an accelerated schedule. And what that means is
17 that this should not be a case in which 50 depositions happen
18 on both sides. This is not a four-year schedule. This is a
19 nine-month schedule. Again, starting from today nine months
20 rather than from the date of the exchanges that have preceded
21 the filing of the complaint.
22 And so we will obviously have depositions. They will
23 be able to learn about the discoveries and the research and
24 development that led to them. We'll need to take depositions
25 to understand a little more of what their FDA application means

1 and their product. And following that we would proceed to
2 expert discovery.
3 Mylan has suggested that the expert discovery will be
4 unwieldy, that we'll have innumerable experts. Just to be
5 clear, Your Honor, that's not the case. We will not present to
6 Your Honor anything like the boogeyman of a case that Mylan has
7 presented in its papers. I've been doing this for two decades
8 now. I have never presented to The Court 655 claims, or
9 whatever the number is, for adjudication at trial. I would be
10 shocked if we present more than a dozen claims to Your Honor
11 for adjudication at trial.
12 No fact finder, no matter how experienced and how
13 intelligent, can keep 655 claims straight in his or her mind.
14 And we don't pretend that you should be the first. So we will
15 narrow the case substantially before trial. We think that
16 should be done in a reasonable manner. We shouldn't have to
17 pick and choose at this point, essentially playing roulette,
18 before we have a claim construction proceeding and we have
19 discovery. But following that fact discovery and claim
20 construction proceeding, we will be prepared to narrow the case
21 substantially, down to a small number of patents, somewhere in
22 the range of four patents. And at that point we can proceed to
23 trial on a small number of claims. Nowhere close to the
24 hundreds of claims. Somewhere in the range of a dozen or two
25 claims at that point. And we'll further narrow before trial.

1 So we think this can be done and managed, given what
2 we already know, in an efficient manner. We will litigate the
3 case in recognition of the schedule. We're not going to have
4 25 experts come in in a nine-month schedule. That's
5 unreasonable. We wouldn't do that upon asking Your Honor for
6 this schedule. It has to be litigated in a commensurate and
7 reasonable way. And we're prepared to do that.
8 THE COURT: All right. Thank you, Counsel.
9 Mr. Rakoczy. And I'm sorry if I'm not pronouncing
10 your name correctly, sir. Is that -- am I close?
11 MR. RAKOCZY: That is correct, Your Honor.
12 Mr. Rakoczy. William Rakoczy.
13 THE COURT: All right. Thank you, sir. Go right
14 ahead.
15 MR. RAKOCZY: Thank you, Your Honor.
16 I'd like to start first with the remedy issue. So
17 point one, Your Honor: Regeneron will not be left without a
18 remedy here. There's no dispute that they can seek a
19 preliminary injunction if the emergent need arises and that
20 they can seek a permanent injunction under the patent laws,
21 just like any litigant can do, and under Supreme Court case
22 law.
23 As for the statutory issue, Your Honor, they are not
24 interpreting it how the statute has been applied. For one
25 thing --

1 THE COURT: And, Mr. Rakoczy, you're speaking
2 specifically about the BPCIA? Is that right?
3 MR. RAKOCZY: Yes, Your Honor.
4 THE COURT: Okay.
5 MR. RAKOCZY: I want to speak about that issue.
6 So the first issue is there's no dispute they can
7 seek a permanent injunction if they win it. All patent
8 applicants can do that. All people that sue as a patent owner
9 can do that.
10 On that specific statutory issue, Your Honor,
11 mentioned, my point is this: The majority of all BLAs, or
12 biosimilars, in the past have been approved years before there
13 was ever a District Court, much less a Federal Circuit appeal,
14 decision. And the only courts to redress this issue have, in
15 fact, granted the permanent injunctive relief under that
16 statute even though the BLA was approved years before those
17 final judgments. So this interpretation of Regeneron just does
18 not come to pass.
19 Beyond that, Your Honor, the interpretation doesn't
20 make sense. Because under their view of the world of this
21 statute whether that relief is available is based on things
22 like court schedules, the vagaries of litigation, appellate
23 schedules, when applicants filed their applications. And so
24 this is a great case in point. In this case they're saying
25 they need a superfast schedule against Mylan to get that

1 relief. But there's a dozen other filers coming down the pipe
2 after Mylan who will be nowhere near court decisions before
3 they get BLA approval. And yet they would say it wouldn't
4 apply to them. That makes no sense.
5 So point one, Your Honor, they do have a remedy.
6 They will not be left without a remedy.
7 But number two, putting all that aside, that issue
8 should not be used to deprive Mylan of the due process and a
9 full and fair opportunity to defend itself with full discovery,
10 Your Honor. A full and fair discovery. And the schedule that
11 they are proposing is not feasible, it's not fair, and it's
12 unprecedented.
13 We're talking about 24 patents, Your Honor, they've
14 sued us on. Twenty-four patents, hundreds of claims,
15 11 different patent families, numerous subject matter like
16 protein purification, recombinant manufacturing methods,
17 formulations, indications. I can go on. Thirty-three unique
18 inventors.
19 And here we hear from Regeneron today that maybe if
20 we go through all this discovery we'll have all of this somehow
21 reduced. Well, it hasn't been reduced, Your Honor. And this
22 is an unprecedented schedule. In all of the biologic
23 litigation of this type to date, we're talking about 24-month
24 to 41 1/2-month schedules for two patents. Not 24, not
25 hundreds of claims, not 33 unique inventors. No one has done a

1 biologic case like this in this amount of time, and for good
2 reason, because it prejudices the defendant in a huge, huge
3 way. We don't think this remedy should override that.
4 Now, something else I want to mention -- point three,
5 Your Honor -- is the futility of the proposal from Regeneron.
6 Even if we mapped out their proposal, we're talking about one
7 and a half months for Markman proceedings. And let's think
8 about that. Twenty-four patents in suit. Briefing on Markman,
9 hearing on Markman, and Your Honor writing up an opinion on
10 Markman in one and a half months. Let's just assume even that
11 was feasible. Then we're talking about three months of fact
12 discovery on 24 patents. In Your Honor's other patent actions,
13 Hatch-Waxman actions, we're talking over 24-month schedules for
14 two to six patents. And again, as I said, in other biologic
15 actions it's gone years, 41 months for two patents.
16 Let's assume that could all happen. Then we do three
17 months of expert discovery. And a point -- I want to make a
18 point on Regeneron's issue on experts, Your Honor. More than
19 one of these patents has already been challenged in the patent
20 office. One patent. And Regeneron had five expert witnesses
21 for one patent. Now we're talking about 24 patents, 11 subject
22 matters. So I -- I question the amount of expert witnesses
23 that will be necessary here.
24 But, again, let's assume we get all that done in
25 three months. Even if we go to trial in June 2023 as Regeneron

1 says, the parties -- even if in July of next year we did all
2 post-trial briefing and then Your Honor drafting an opinion on
3 24 or even 12 patents in the month of July, they still wouldn't
4 get this Federal Circuit appeal decision anywhere near in time
5 before that date in May of 2024. Federal Circuit run rate for
6 a simple appeal is 12 months. I'm not aware of any Federal
7 Circuit appeal ever getting done on 12 to 24 patents in less
8 than 12 months.
9 And, in fact, if they want a final decision, we have
10 to factor in rehearing proceedings. So they would need a
11 Federal Circuit decision in eight months. That's not going to
12 happen. It's unrealistic, Your Honor. So even under their
13 schedule it's futile and it's not going to work and it's
14 certainly not a reason to take away Mylan's due process rights.
15 Point four, Your Honor: This whole emergent
16 circumstances or expediency they're raising is undermined by
17 their conduct in that so-called "patent dance" they just
18 mentioned. They sat back for 209 days, 120 days of which they
19 control. They solely could have expedited 120 days. They
20 never did anything. They let the time go by, and then they
21 ambushed Mylan after the complaint was filed, waiting 30 days
22 to file the complaint, and then they raised the fact that they
23 want this expedient schedule. If they wanted expediency, Your
24 Honor, they could have shaved many, many months off of this.
25 But, instead, they let the time go by.

On that same issue, on the patent dance, no court has ever held and no statute says that that is a substitute for litigation and discovery. Quite the contrary, Your Honor. The courts have held that nothing in that binds the defendant like Mylan. Mylan is entitled to defend itself in any way, shape, and form that is reasonable and proper. It's entitled to seek the discovery to do that.

Point five, your Honor. And I'll try and be brief. We've still gotten no answers as to how this schedule could even possibly happen from Regeneron. We don't have any indications on claim reductions, patent reductions, except for what I just heard was we could go through all discovery and then maybe we might get a reduction. We have no indications on fact witnesses. We have 33 unique inventors, no indication of who will come to trial, who they have control over, whether we have to go overseas, to The Hague, for foreign inventors. We've not gotten anything in that regard from them. We've gotten no limits on expert witnesses, no explanation for how we do Markman, much less an opinion on Markman in one and a half months. And, again, this would be super, super expedited. It's unprecedented.

And by the way, Your Honor, the examples they put in their papers -- the Twitter example, the Telecom example, ITC examples -- none of those had anything to do with a 24-patent biologic case.

And lastly, Your Honor, kind of the elephant in the room, which is we have no explanation on what's going to happen with all these other patents. The whole point of this action is to try and get some type of patent certainty with 24 patents. They're suggesting trying 12 patents and then holding these other 12 back. What does that mean? Can they assert them after the first trial? Can they assert them in serial fashion after that? We have no explanations on that. None whatsoever.

So what we've done is made a -- what we believe is a cooperative and accommodating proposal, Your Honor, two part. If Regeneron insists on asserting 24 patents and they will not drop them, give us covenants not to sue or dismiss them with prejudice, we are proposing a standard 24-month schedule, which in and of itself would be ridiculously fast for 24 patents. That's part one of our proposal.

If Regeneron doesn't like that, if they won't give us certainty -- meaning they'll drop most of these patents with covenants, dismissals with prejudice, what have you -- and we could get it down to a manageable number, say eight, and they reduce the claims, then Mylan is willing to do a 15-month schedule, which gets us to trial, I believe, by December of 2023.

So Mylan is willing to be reasonable. We're willing to move quick. But we are not willing to move so quick that,

1 again, it deprives us of the ability to fully and fairly defend
2 ourself, Your Honor.
3 And I should say, lastly, Mylan is not trying to run
4 out the clock. Regeneron tried to run out the clock during the
5 patent dance. If they really wanted to move fast, they could
6 have self-expedited and not wasted those many months.
7 Thank you, Your Honor.
8 THE COURT: All right. Thank you, Counsel.
9 Mr. Berl.
10 MR. BERL: If I could respond to the six points that
11 Mr. Rakoczy just made.
12 First he said that there is other relief in the BPCIA
13 other than the statutory relief. He's right, of course. But
14 the ability to obtain other relief does not moot the statutory
15 relief that Congress provided. And his view of the law is that
16 Congress provided statutory relief for no reason; it's a dead
17 letter and a biosimilar applicant, like Mylan today, can come
18 into the court and run out the clock. That's exactly what's
19 going on here. Make no mistake. A December 2024 trial date --
20 or a December 2023 trial date deprives us of any opportunity
21 for statutory relief. They don't have to face it on the
22 merits. They just run out the clock. That's exactly what's
23 going on here.
24 And to be clear, we didn't run out the clock during
25 the patent dance. We had to review their materials. And we

1 did self-expedite and serve our submissions before they were
2 due.
3 With respect to his due process sort of arguments,
4 number one, I'd note that there's no citation anywhere in
5 Mylan's papers about the proposition that a court setting a
6 trial date nine months after a scheduling conference somehow
7 deprives a party of due process. That's because it's not true.
8 All of his arguments that you just heard from Mr. Rakoczy
9 depend on a fallacy. And that fallacy is that we are proposing
10 to proceed all the way to trial on 24 patents. That's not
11 true. We are proposing to proceed on a subset of those
12 patents, 12 patents now. And if Your Honor thinks that's too
13 much to accommodate Mylan's needs, we're prepared to be
14 flexible on that and we're prepared to move forward with this
15 first phase with fewer than that. We could do even six patents
16 if that's more palatable.
17 But at the end of the day, this notion that we're
18 going forward on 24 patents with 11 different families simply
19 is not true. There are 12 patents that we have identified for
20 the first part of litigation. There are only 4 patent
21 families, not 11. And we'd be prepared right now to go down to
22 3 patent families to make the burden even lower on the parties
23 and on The Court. That's not so much. That's not nearly as
24 many as in the papers. And we're cutting out all of the time
25 for document production by having already reviewed and

1 collected the lion's share of the documents. And we're
2 prepared to produce them with alacrity.
3 With respect to the futility argument, respectfully,
4 it's the same fallacy, Your Honor. There's not fact discovery
5 on 24 patents. There's fact discovery on far fewer than that,
6 three or four patent families. That's it.
7 And the Markman hearing? Courts frequently limit the
8 number of Markman disputes in order to prevent an unwieldy
9 process. It's common in other courts, from Texas to California
10 and elsewhere, for The Court to pronounce that it will
11 adjudicate eight or ten different Markman disputes. We can
12 choose five; they can choose five. If there are fewer than
13 ten, there are fewer than ten. And that ensures that it won't
14 be an unwieldy Markman process.
15 And by the way, Mr. Rakoczy is not correct that we
16 provided some time limit for the Markman decision. We would
17 not suggest that Your Honor has some deadline. That's for Your
18 Honor to decide the Markman issues after they're presented.
19 We've obviously provided a deadline for the parties to submit
20 their papers and to present the Markman issues to The Court,
21 and we would hope that Your Honor would rule on them after
22 that. But it's not true that everything has to be decided in
23 six weeks under our schedule, let alone 24 patents in
24 11 families, let alone some innumerable number of claim terms.
25 We think that that could be done in an expedited fashion by

1 selecting ten claim terms at most and having the parties work
2 out which those are that require adjudication by The Court.
3 Same thing with respect to fact discovery. It's not
4 24 patents. Nor is it for an expert discovery. We're not
5 going to have five experts on one patent, Your Honor. We're
6 not going to do that having requested this schedule. We will
7 be reasonable as to the number of experts that will be present.
8 If we go forward on three patents, it's very unlikely that
9 we'll have more than five experts in total in the case, let
10 alone one patent, smaller than the typical case of this size.
11 With respect to the Federal Circuit and the futility,
12 I would respectfully disagree with Mr. Rakoczy. Upon Your
13 Honor's ruling we will, of course, make the Federal Circuit
14 aware of the timing issue so that this will not be a typical
15 appeal. And we will explain to the Federal Circuit that
16 justice delayed is justice denied, that we would self-expedite
17 our briefing, and that we would submit that the Federal Circuit
18 should issue a decision by May 18th, 2024, so that we have
19 the relief that Congress provided.
20 Now, obviously, I don't control what the Federal
21 Circuit does in that regard. But having practiced before that
22 court a substantial number of times, it's my strong belief that
23 they would treat this case differently given the statutory
24 deadline that Congress has imposed here in order not to moot
25 the relief that Regeneron is entitled to.

1 Now, Mr. Rakoczy suggests that this relief doesn't
2 really matter because in other BPCIA cases innovators have not
3 received that relief. And I want to be very clear about this,
4 Your Honor. Because he's half right, but he's not revealing
5 what matters. The BPCIA, as I've said, was passed as part of
6 Obamacare. So the first wave of BPCIA cases related to old
7 biologic products. These are typically products that you've
8 seen advertisements on TV while you watch football games, like
9 Keymyra and Enbrel. These are old products approved generally
10 in the 1990s. And what happened is that Congress provided in
11 the BPCIA 12 years of regulatory exclusivity, plus some
12 additional exclusivity in certain cases. That was all expired
13 before Obamacare was even enacted, let alone the BPCIA
14 litigation regarding those products or patents. In a sense,
15 those were all grandfathered into the statute. So this
16 regulatory exclusivity and the statutory remedies were, per se,
17 unavailable in those old grandfather cases.
18 That's the past. This is now. This is a case, the
19 first of its kind -- and there will be others over and over and
20 over -- where the statutory remedy is in play. And the notion
21 that Congress provided for this statutory remedy but then allow
22 defendants to have a get-out-of-jail-free card by complaining
23 that it's just going to take too long and their dozens of
24 lawyers aren't going to be able to do discovery fast enough,
25 well, that beggars belief, Your Honor. That's not Congress's

1 thought. Congress introduced that statutory relief because
2 they thought it meant something. Because you can't just moot
3 it by saying, "I want a slow schedule, and I'm going to try the
4 case too late for the statutory relief to be in place, and I'm
5 going to force them to get a permanent injunction or a
6 preliminary injunction." That's not what Congress intended.
7 And respectfully, Your Honor, I don't think that's fair.
8 Finally, Your Honor, the last point that Mr. Rakoczy
9 made related to claim reductions and what happens with the rest
10 of the patents. We are prepared, Your Honor, to reduce the
11 number of patents now. We've already said we'll reduce it to
12 12 in our papers. If Your Honor is more comfortable with a
13 lower number, as I said, we can be flexible on that. And we're
14 happy to limit it to three patent families and as few as six
15 patents now, this week.
16 We will do further reduction with respect to the
17 number of claims at an appropriate time. We would submit that
18 that appropriate time is after we've had fact discovery and
19 after Your Honor rules on the claim construction issues.
20 Because, as I said, this isn't roulette. It can't be that we
21 select the number of claims now, then they say, "Oh, we have
22 this Markman issue," and that kicks us out of infringement on
23 that claim, and Your Honor agrees with Mylan, and then a claim
24 that doesn't have that issue is left on a cutting room floor
25 before we ever knew what the Markman ruling was and what the

1 fact discovery would show.
2 So we will be prepared to limit it down to fewer
3 patents, even fewer than six, after we have a Markman decision
4 and after fact discovery, and a reasonable number of claims.
5 We would submit at that juncture something like two dozen
6 claims is appropriate. Far fewer than the hundreds of claims
7 about which Mylan raises as specter. And certainly, before
8 trial, we will narrow it further. I'm not going to come before
9 Your Honor asking you to adjudicate even 24 claims. It will be
10 fewer than that. And so there will be no futility. Your Honor
11 will not have to decide the validity and infringement of
12 25 claims. We're going to make it manageable for Your Honor in
13 view of the schedule we're proposing.
14 And with respect to the rest of the claims, with
15 respect to those, what I can say, Your Honor, is that Mylan
16 raises this possibility, this boogeyman again, of we're going
17 to ask for a preliminary injunction on the eve of their launch
18 with one of these other patents that is not one of the ones
19 that we're proposing to move forward with now, and then all of
20 a sudden there's going to be some difficult proceeding before
21 Your Honor. Not so. That's not so. To be clear, the reason
22 that this schedule we're proposing makes sense is that it
23 prevents the preliminary injunction process that Mr. Rakoczy
24 just spoke of.
25 Mylan's schedule is missing something. Because if

1 they have trial as they've proposed in their Proposal Number 1,
2 in late 2024, and they get approved and are prepared to launch
3 in May of 2024, that schedule is a dead letter. It will be
4 overtaken by preliminary injunction proceedings. So what
5 they're really proposing, sotto voce, is for Your Honor to hold
6 preliminary injunction proceedings in the spring of 2024
7 followed by a bench trial on the same patents. That is
8 wasteful, duplicative, and unnecessary.
9 What makes more sense is for Your Honor to hear this
10 as a full trial on a full record once, without the need for
11 preliminary injunction. So we will agree that with respect to
12 those other patents that we would not move forward with at this
13 juncture, we would not assert those patents for a preliminary
14 or even a permanent injunction so that Mylan can have -- Mylan
15 can have the certainty it desires as to whether it can launch
16 in May of 2024.
17 If Your Honor and the Federal Circuit feels that one
18 of our patents is valid and infringed, Mylan will not be able
19 to launch in May of 2024. There will not be an injunction
20 against their U.S. marketing and sale. If Your Honor and the
21 Federal Circuit rule that one of our patents is valid and
22 infringed and we prevail, in other words, then, by operation of
23 statute, Mylan will not be permitted to launch until the last
24 of those valid and infringed patents expires.
25 And so it's certain for everyone. And it can be done

1 once, and it can be done efficiently, without the need for
2 preliminary injunction proceedings followed by a duplicative
3 trial.
4 And I will submit that with respect to the rest of
5 those patents, Your Honor, we don't know exactly what will
6 happen with them. But it is likely that there won't need to be
7 another trial with respect to those patents. If we prevail on
8 these patents that we're proposing to move forward with now,
9 this small subset of patents, then it's very unlikely that we
10 would feel the need to move forward again with respect to those
11 other patents.
12 And so that's why we think this case can be managed
13 in a way that provides us statutory relief that is reasonable
14 and in conformity with other complicated cases, including those
15 cited in our papers. Mr. Rakoczy is right. Those aren't Mylan
16 Pharmaceutical cases. I don't understand why that matters.
17 The Verizon case we cited related to six patents about
18 complicated telecommunications technology. I don't think
19 that's any less difficult or complicated than
20 biopharmaceuticals.
21 But in any event, this provides us an opportunity to
22 obtain the statutory relief that Congress introduced while
23 providing limits on the number of patents we're asserting at
24 this juncture. We will further narrow the case. And we are
25 accelerating discovery by producing documents immediately and

1 then, also, relative to what's happened to date, which is an
2 exchange of all of the information pursuant to the patent
3 dance.
4 And Mr. Rakoczy says those aren't limiting; they're
5 entitled to raise things that they did not include in their
6 hundreds of pages. But I take Mr. Rakoczy and his client at
7 their word that what they provided to us was a good faith
8 understanding of what their contentions were with respect to
9 noninfringement and invalidity. And we did the same, and we've
10 provided them with a good faith understanding of what our
11 contentions were.
12 So while he may try to advance one new argument here
13 and there, we have to acknowledge that the parties have been at
14 this for months and exchanged information and we know where we
15 are. And the notion that that should be sort of thrown out the
16 window and ignored in that process we don't think is well
17 taken.
18 So, obviously, Your Honor, I'm happy to answer any
19 questions Your Honor may have and respond otherwise. But
20 that's -- that's how Regeneron sees it.
21 THE COURT: Thank you, Mr. Berl.
22 Mr. Rakoczy, is it Defendant's position the BPCIA is
23 not applicable to this litigation and that we're proceeding
24 only under Hatch-Waxman? Or is that oversimplification?
25 MR. RAKOCZY: No, Your Honor. It would -- it is

1 not --
2 Excuse me. William Rakoczy for Mylan.
3 THE COURT: Yes, sir.
4 MR. RAKOCZY: It is not Mylan's position that BPCIA
5 does not apply. It does apply. My point was -- and if you
6 look at our papers, our response brief to the motion to
7 expedite, document 26 at page 11, our point, Your Honor, was
8 that in the majority of these BPCIA cases we are where we are
9 today, which is the BLA where biosimilar gets approved well
10 before a court decision. And in the two cases where that
11 happened in New Jersey involving the Enbrel case, Judge Cecchi,
12 even though the biosimilar had been approved many, many years
13 before, when the biosimilar BLA applicant lost, she entered
14 that mandatory permanent injunction. So the courts that have
15 addressed this have not applied it the way Regeneron is
16 interpreting it. That was my point.
17 THE COURT: Okay.
18 MR. RAKOCZY: And so there is a remedy. There is a
19 BPCIA remedy that the courts have applied in these facts, even
20 if we don't do a rough schedule, and there's a patent remedy
21 that they can seek as a patent defendant -- excuse me -- patent
22 plaintiff that has sued.
23 THE COURT: Okay. What about Mr. Berl's contention
24 that those cases Mylan relies upon are grandfathered in, for
25 lack of a better term?

MR. RAKOCZY: I am not aware of any authority saying they're grandfathered in, Your Honor. The facts are the facts. And there's nothing in the statute, nothing in the legislative history I'm aware of, and certainly no court decision saying that they're grandfathered in. And I've not seen anything that said what Judge Cecchi did in New Jersey was somehow unlawful when she granted that remedy.

So we believe there's a BPCIA remedy. They can seek it. We believe there is a permanent injunction remedy. They can seek it. So we think that's all pretext for this what I would call absurd and fast schedule.

And if I may, Your Honor, I have just a couple very brief points --

THE COURT: Go right ahead, sir.

MR. RAKOCZY: -- on a couple things.

So on the fallacy point, Your Honor, there's no fallacy that they have sued us on 24 patents -- excuse me -- sued Mylan on 24 patents. Mylan has repeatedly asked them to drop half with prejudice, to provide covenants not to sue, and they have done none of that.

And so even today we are where we are. We have 24 patents in suit. We have no patent certainty on any of them. And even the suggestion you just heard was not to provide Mylan with patent certainty with dismissals with prejudice or covenants not to sue. What you heard was reduce

1 the number for trial and then they'll figure out what to do
2 with the rest after that. Well, that provides Mylan nothing,
3 Your Honor. That's basically between -- putting Mylan between
4 a rock and a hard place. Mylan agrees to go with a crazy
5 schedule, deprive itself of full and fair discovery, and then
6 have to deal with all these other patents later. So we have
7 not gotten any patent certainty with their proposal whatsoever.
8 A couple of other quick points, Your Honor. The
9 patent dance, it's not a substitute for discovery. Mylan
10 provided the best good faith contentions it could, but Mylan
11 got no discovery from Regeneron during that patent dance.
12 None. We just got statements saying what patents we allegedly
13 infringed and why. But we didn't get discovery from the
14 inventors. We didn't get development documents, lab notebooks,
15 any of the other things we are going to have to have.
16 Now, we heard Regeneron say they're going to give
17 that all to us. Well, that's their view, Your Honor. Your
18 Honor knows how this works. We'll get a document production.
19 We'll review it in good faith. I highly, highly doubt that we
20 will get all of the discoverable information on 24 patents in
21 three months. That's not realistic.
22 Fourth, Your Honor, on the futility point. With all
23 due respect, I don't think we should be predicting and
24 depriving Mylan of discovery based on what the Federal Circuit
25 may or may not do. I've practiced in front of the Federal

Circuit plenty myself. I've never seen an appeal move like this, with this complexity and this many patents in issue. So I do think what they're suggesting is a schedule that even if we adopted it, even if it was possible, that we're not going to see any Federal Circuit decision before that, not on an average run rate, not on run rates of cases this complex.

And lastly, Your Honor, the Markman briefing point. My point in the Markman briefing was we have one and a half months to get that done before final contentions are due. How are we supposed to go through final contentions and expert discovery without a Markman ruling? And so Regeneron is asking Your Honor to do a ridiculous amount of work to get all this done, both with Markman opinions as well as court opinions that are going to have to be done in a matter of days, not weeks, not months. We suggest that's not fair to the parties, not fair to The Court, which is why we offered the proposals -- the accommodations that we did.

Thank you, Judge.

THE COURT: No. Thank you.

Mr. Berl, I'll give you last word, sir.

MR. BERL: Yes, Your Honor. Just briefly.

It's not true that Your Honor has to rule on Markman before expert discovery. I'm presently litigating a case in this very court in which we are finishing up expert discovery before Markman proceedings are finished. And, frankly, the

1 case is against Mylan, pending before Judge Bailey. So that's
2 not the case. We're not imposing any sort of unreasonable time
3 limit on Your Honor. We would never -- we would never deign to
4 do so.
5 Mr. Rakoczy's arguments that you just heard continue
6 to assert that everything is too complicated and there is not
7 enough time for the parties or the Federal Circuit because it's
8 24 patents that they're going to have to rule on. I don't know
9 how many times I need to say this. It's not true. We're not
10 proposing to move forward on 24 patents. We're proposing to
11 move forward on a small subset. And if that small subset that
12 Your Honor considers to be reasonable within this time frame is
13 a half dozen patents, then that's what it will be. And it will
14 be less than that at trial. And it will be less than that on
15 appeal.
16 And so he has sort of constructed a world in which
17 everyone is dealing with 24 patents. That's not our proposal.
18 And, respectfully, he is litigating against a straw man, not
19 our proposal.
20 And one final word on the Enbrel case which
21 Mr. Rakoczy keeps bringing up. I know because I was there and
22 I was counsel of record in that case. In that case the
23 approved product was approved, Enbrel, more than 12 years
24 before the litigation began so that all the regulatory
25 exclusivity was off the table. That's what I mean by

1 grandfathered; that you could file these applications even on
2 old products like Enbrel.
3 And what was at issue in that case, therefore, had
4 nothing to do with regulatory exclusivity and statutory relief.
5 Because that was gone. It was an old product. And he's right.
6 Judge Cecchi did enter a permanent injunction after a finding
7 of validity and infringement. And he's right that that remedy
8 is available to us too.
9 But the point is so, too, is the statutory remedy.
10 And it's not a response to say, "We can ignore what Congress
11 said because Congress provided some other possible relief, too,
12 and I'm allowed to run out the clock on your primary prayer for
13 relief." That's not right, that's not in conformity with what
14 Congress passed, and we submit that's not fair.
15 And with that, if Your Honor has any more questions,
16 I'm happy to answer them. But I think we've stated our
17 position.
18 THE COURT: No. Understood, Mr. Berl. Thank you.
19 Let me ask this question as I'm a little fuzzy on
20 what aba- -- hypothetically, if Plaintiff's proposal is the
21 path we pursue and we're talking about six patents that are
22 selected to be litigated in a first wave, if you will, what
23 becomes of the other patents?
24 MR. BERL: Well, Your Honor, we will not ask The
25 Court for a preliminary injunction as to those patents. So

we're not going to sort of duplicate efforts in that regard.

What I would propose is what happens in sort of most cases where there's a first wave and then a potential second wave of cases, whether it's products liability cases or any other, which is we'll see what happens with the first wave. And typically what happens, in my experience, is that the first wave takes care of the second wave too.

Now, I can't sit here and promise that that will happen and there will be no further proceedings after Your Honor adjudicates the first wave of patents. But I can predict that it will be substantially narrowed depending on what the world looks like at that point, what the result of the first wave is. And at that point I think it makes sense for us to appear before Your Honor again, having decided the first wave, and say, "Okay. Now what's left here? What's left to do to clean up the remainder of this case?" And we submit it won't be difficult; it won't be complicated; it won't be unwieldy. We won't make it so.

And so, you know, I wish I could predict exactly what will happen with those. But I think we will be in a position to narrow things substantially once we get there and we know what the world looks like. But we can't predict that now.

MR. RAKOCZY: May I address that for 30 seconds, Your Honor?

THE COURT: You may, Mr. Rakoczy. I'm assuming you

1 would object to Mr. Berl's proposal that Plaintiff gets
2 multiple at-bats.
3 MR. RAKOCZY: Exactly, Your Honor. It's not an
4 answer to say it's no answer and that 18 patents, under Your
5 Honor's hypothetical, can be held over our head. The whole
6 point is to get launch certainty so that we don't have to worry
7 about those other 18. So if we're talking about six patents in
8 a super-rushed schedule, that's exactly the reason why those
9 other 18 should be dropped with prejudice or we should get
10 covenants not to sue and we can put them aside. But that is
11 exactly why that proposal is so fundamentally unfair.
12 Thank you, Judge.
13 THE COURT: Well, Mr. Rakoczy, in all fairness to
14 Mr. Berl's position, I realize Defendant's interest is launch
15 certainty; the Plaintiff's is something different than launch
16 certainty.
17 All right. Now --
18 MR. RAKOCZY: Oh, understood.
19 And I'm sorry, Your Honor.
20 THE COURT: No. Go ahead. Go ahead.
21 MR. RAKOCZY: No. I was going to say understood,
22 Your Honor. But the idea here is they sued Mylan. We didn't
23 sue them. They sued Mylan and asserted 24 patents. They're
24 alleging we infringed 24 patents. And so those patents have to
25 be dealt with. And you've heard today there's still no answer

as to what would happen to the overwhelming majority of those patents after a super-rushed schedule and trial.

And I realize Regeneron may think it works to their advantage to hold those over our head and create uncertainty. But that's not the point of this process. If they want to sue on 24 patents, they should be prepared to deal with 24 patents in one way, shape, or another. Either litigate them on a normal schedule or drop them with prejudice and let's do a more quick -- or a quicker schedule, as Mylan proposed in their Proposal Number 2.

THE COURT: Okay. All right. Understood.

Counsel, thank you. I do want to study some of the materials you've submitted to The Court for its consideration. Let me express our collective gratitude for the work you did in preparing us and educating us for today's discussion. But I want to study that a little bit more. But we will get an order out addressing the dispute that exists here, as well as a scheduling order.

Along those lines, I also do need to look at the court's calendar to see when -- and I'm not going to bother asking everyone to look in their crystal ball as to the length of any trial given the variable that is the number of patents we may be discussing depending on how this litigation is ultimately structured. But I do want to get a feel for when we've got a clear patch of grass, for lack of a better term, on

1 our calendar.
2 And some of your -- some -- I won't say some. All of
3 your local counsel have heard me say this before. But one of
4 the many reasons that I was so interested in this position was
5 never having to look at calendars with a group of lawyers
6 again. And I continue to exercise that Article III privilege
7 regularly. So I do also need to look at our book to -- again
8 to find some runway space for however this ultimately looks.
9 With that, Mr. Berl, is there anything further from
10 the Plaintiff's perspective we need to discuss today, sir?
11 MR. BERL: No, I don't believe so. Thank you, Your
12 Honor, for your time.
13 THE COURT: No. Thank you.
14 Mr. Rakoczy, anything further from defense's
15 standpoint?
16 MR. RAKOCZY: Nothing from Defendant, Mylan, Your
17 Honor. Thank you.
18 THE COURT: All right. Thank you all very much.
19 Have a wonderful remainder of your day and week, and you'll
20 hear from us in short order. We'll stand adjourned otherwise.
21 Thank you.
22 (Proceedings concluded at 3:47 PM.)
23
24
25

CERTIFICATE

I, Rachel Kocher, a Registered Professional Reporter, do hereby certify that the foregoing is a true and correct transcript of the proceedings had in the above-styled action on September 28, 2022, as reported by me stenographically, all to the best of my skill and ability.

I certify that the transcript fees and format comply with those prescribed by the Court and the Judicial Conference of the United States.

Given under my hand this 1st day of November 2022.

Rachel Kocher, RPR

Rachel Kocher, RPR

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