

REGENERON PHARMACEUTICALS, INC. vs.  
MYLAN PHARMACEUTICALS INC.

09/28/2022

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF WEST VIRGINIA

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

vs.

CASE NO.:  
1:22-CV-61

MYLAN PHARMACEUTICALS INC.,

Defendant.

- - -

Proceedings had in the status conference of the  
above-styled action on Wednesday, September 28, 2022, before  
the Honorable Thomas S. Kleeh, Chief District Judge, at  
Clarksburg, West Virginia.

- - -

APPEARANCES:

On behalf of the Plaintiff via Zoom:

David I. Berl  
Williams & Connolly LLP - Washington  
680 Maine Avenue, SW  
Washington, DC 20024  
dberl@wc.com

Steven Robert Ruby  
Carey, Douglas, Kessler & Ruby, PLLC  
707 Virginia Street, East  
Suite 901  
Charleston, WV 25301  
sruby@cdkrlaw.com

James Evans  
Petra Scamborova  
Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, NY 10591-6717  
james.evans@regeneron.com  
petra.scamborova@regeneron.com

APPEARANCES CONTINUED ON NEXT PAGE

Realtime Reporters, LLC  
schedulesrealtime@gmail.com 304-344-8463



REGENERON PHARMACEUTICALS, INC. vs.  
MYLAN PHARMACEUTICALS INC.

09/28/2022

1 On behalf of the Defendant via Zoom:

2 Gordon H. Copland  
3 William J. O'Brien  
4 Steptoe & Johnson PLLC - Bridgeport  
5 400 White Oaks Boulevard  
6 Bridgeport, WV 26330  
7 gordon.copland@steptoe-johnson.com  
8 william.obrien@steptoe-johnson.com

9 William Rakoczy  
10 Neil B. McLaughlin  
11 Rakoczy, Molino, Mazzochi & Siwik, LLP  
12 6 W. Hubbard Street, Suite 500  
13 Chicago, IL 60654  
14 wrakoczy@rmmslegal.com  
15 nmclaughlin@rmmslegal.com

16 Matthew Greinert  
17 Thomas Jenkins  
18 Viatrix Inc.  
19 1000 Mylan Boulevard  
20 Canonsburg, PA 15317  
21 matthew.greinert@viatrix.com

22 Proceedings recorded utilizing realtime translation.  
23 Transcript produced by computer-aided transcription.  
24  
25

REGENERON PHARMACEUTICALS, INC. vs.  
MYLAN PHARMACEUTICALS INC.

09/28/2022

1 Wednesday Afternoon Session

2 September 28, 2022, 2:59 PM

3 - - -

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

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

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

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

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

18 THE COURT: All right. Good afternoon, counsel.

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

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

25 Furthermore, Mylan is also appearing through two

REGENERON PHARMACEUTICALS, INC. vs.  
MYLAN PHARMACEUTICALS INC.

09/28/2022

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

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

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

9 Plaintiff's counsel, the floor is yours first.

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

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

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

REGENERON PHARMACEUTICALS, INC. vs.  
MYLAN PHARMACEUTICALS INC.

09/28/2022

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 statute 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

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.