

**\*CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER\***

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MERCK SHARP & DOHME LLC,  
Petitioner,

v.

HALOZYME, INC.,  
Patent Owner

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PGR2025-00003 (Patent 11,952,600)  
PGR2025-00004 (Patent 12,018,298)  
PGR2025-00006 (Patent 12,152,262)  
PGR2025-00009 (Patent 12,123,035)

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Held: March 2, 2026

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BEFORE: JEFFREY N. FREDMAN, SUSAN L. C.  
MITCHELL, and CYNTHIA M. HARDMAN, Administrative  
Patent Judges.

The above-entitled matter came on for hearing on March 2,  
2026, commencing at 1:00 p.m.

PGR2025-00003 (Patent 11,952,600), PGR2025-00004 (Patent 12,018,298),  
PGR2025-00006 (Patent 12,152,262), PGR2025-00009 (Patent 12,123,035)

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P R O C E E D I N G S

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JUDGE FREDMAN: Good afternoon. We are convened for oral argument in PGR2025-00003, -0004, -0006, and -0009 pertaining to patentability challenges in U.S. Patents 11,952,600, 12,018,298, 12,152,262, and 12,123,035. I am Judge Fredman. And I'm joined by Judge Mitchell in this hearing room. Also, soon to hopefully be appearing remotely is Judge Hardman. And Judge Valek is joining us for arguments regarding the motion to terminate the PO's panel of involved cases.

Before we go further, I just want to check with the two lead attorneys, is everyone in the room capable of staying for the confidential hearing?

MR. KUSHAN: Yes, Your Honor.

MR. SUMMERS: Yes, Your Honor.

JUDGE FREDMAN: All right. Thank you very much. So welcome to the USPTO's Alexandria Office. We understand that in every case that comes before us, the parties have a lot at stake. The judges before you take our role in deciding the dispute seriously. We've reviewed the briefs and evidence. And we're prepared today probably with some questions that will help us decide the issues in this case.

We're going to limit our consideration to arguments and evidence already presented on the record. We have the briefs and

1 evidence available to us on our computer. But it's helpful for our  
2 remote judges if you point to any of the slides as you do it. So if  
3 we do look away or look at something, we may be looking at the  
4 documents on the record.

5 For everyone here, recording of a PTAB hearing is  
6 prohibited. The court reporter will provide a transcript of the  
7 hearing that will become part of the record in the proceeding at a  
8 later date. To ensure that the transcript is clear, we ask you to  
9 speak directly to the microphone to identify specific slide numbers,  
10 numbering and figures, and other pertinent identifying information  
11 when referring to demonstratives.

12 We'll begin with 30 minutes of the confidential session  
13 devoted to Patent Owner's motion to terminate with Patent Owner  
14 beginning with 15 minutes and Petitioner with 15 minutes. We  
15 will allow Patent Owners to reserve up to five minutes for rebuttal.  
16 Public line will obviously not be available.

17 Once we complete the confidential session, we'll segue  
18 into the main argument. The parties will have 75 minutes in the  
19 main argument session. Petitioner will open that argument and  
20 may reserve rebuttal time, which may not exceed more than half of  
21 Petitioner's total argument time. Patent Owner will then respond  
22 to Petitioner's argument and may reserve surrebuttal time, also not  
23 to exceed more than half of Patent Owner's total argument time.

24 As the parties know, Petitioner has the ultimate burden of  
25 establishing patentability by a preponderance of the evidence. I'll

1 try and maintain the clock and endeavor to give each party a five-  
2 minute warning during their arguments.

3 Let us get started with appearances for both parties for  
4 opening arguments. So I guess we're going to -- and I should note  
5 that you can identify everyone who's with you if you want. Given  
6 the large number of people, I'm not sure, you may just want to  
7 identify the attorneys with you. But if you want to identify  
8 everyone, that's fine.

9 Following the hearing, you can confer with the court  
10 reporter to ensure that there's no questions of the spelling of either  
11 names or terms. She would appreciate that so we can get an  
12 accurate transcript. So let's start with appearances for Petitioner  
13 and rebuttal.

14 MR. KUSHAN: Thank you, Your Honor. Jeff Kushan  
15 for Petitioner. I'm with Sidley Austin. With me is Amy Mahan  
16 from Sidley Austin. Also, there are a number of other attorneys  
17 present, but I won't go through all of them. For the merits  
18 argument, we will reserve 30 minutes for our rebuttal.

19 JUDGE FREDMAN: Thank you. And for Patent  
20 Owner?

21 MR. SUMMERS: Good morning, Your Honor. Zach  
22 Summers, Quinn Emanuel for Patent Owner, Halozyne, Inc. With  
23 me is Lauren Martin, also Quinn Emanuel and Elliot Choi. And  
24 Ralph Powers will be arguing the RPI issue from Sterne Kessler.  
25 We also have Eldora Ellison with us.

1 JUDGE FREDMAN: Sure.

2 MR. SUMMERS: And then we also have some  
3 members from our client here, Mark Snyder, Aubrey Haddach, and  
4 Josh Mack and then some other colleagues from Sterne Kessler.

5 JUDGE FREDMAN: Okay. Thank you. And so do you  
6 want to reserve for the RPI issue? Perhaps we should ask the other  
7 --

8 MR. KUSHAN: Yes, Your Honor. We'll reserve two  
9 minutes for the RPI.

10 JUDGE FREDMAN: Two minutes for RPI. And for the  
11 regular?

12 MR. SUMMERS: I anticipate reserving 15 minutes.

13 JUDGE FREDMAN: Okay. I guess, Patent Owner, you  
14 can begin the arguments on the RPI when you're ready.

15 MR. POWERS: Thank you, Your Honor. Just make  
16 sure the AV is working here. Let me just see if they're charging  
17 this here.

18 UNKNOWN SPEAKER: Yes. I can hear you. I  
19 understand. Oh, there we go. I see the video now.

20 MR. POWERS: Okay. Great. All right. Your Honors,  
21 Ralph Powers from Sterne Kessler on behalf of Halozyne.  
22 Evidence, Patent Owner uncovered after the de-designation of  
23 SharkNinja and designation of Corning, including through  
24 additional discovery provided at the end of December, led Patent  
25 Owner to pursue this motion. And through this evidence, it

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1 became clear that Merck & Co is a real party of interest in these  
2 cases and they should have been named as such.

3 If you move to Slide 4. Now, Your Honors know this,  
4 but just to review, naming RPI is a part of the statutory  
5 requirement for filing IPRs and PGRs. The statutory provisions  
6 are identical between IPRs and PGRs on this point and use  
7 identical language.

8 The analysis of an RPI requires a flexible approach, and  
9 it comes from the expansive common law meaning of real party of  
10 interest. There are three main avenues discussed in the case law  
11 on RPI, one is control or opportunity to control the proceedings;  
12 one is blurred corporate lines; and another is clear beneficiary.

13 Now, the tribunal determining RPI should consider all of  
14 the facts before it. But any one of these avenues can lead to a  
15 determination that an entity should have been named as an RPI.  
16 When RPI is challenged, as here, the burden is on the Petitioner to  
17 show that it has properly named in the RPI, all RPIs. This doesn't  
18 appear to be in dispute between the parties here.

19 Now, Your Honors, here, all of these categories of  
20 considerations weigh in favor of finding that Merck & Co should  
21 have been named as an RPI in each of these proceedings. I'd like  
22 to turn to the first control.

23 Moving to Slide 6. Merck & Co, in its SEC filings,  
24 defined Merck & Co., Inc. as Merck for the company. This is  
25 from Merck's SEC filing -- Merck & Co's SEC filing from

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1 November 5th, 2025. Here, we see the cover page, and it clearly  
2 says Merck & Co., Inc. defined as Merck or the company.

3 Moving to Slide 7. And Merck & Co in this -- in these  
4 SEC filings told investors that it filed these PGRs. The MDASE  
5 portfolio referenced here is Halozyme's patent portfolio that Your  
6 Honors are here to discuss with us today. And they're the ones that  
7 are attacked in these PGRs before the Board now.

8 As you can see, Halozyme is also identified in this SEC  
9 document. And by Merck & Co's own statements, it controls these  
10 PGRs. Now, Petitioner tries to downplay these statements by  
11 saying it was really talking about --

12 JUDGE VALEK: Mr. Powers --

13 MR. POWERS: Yes, Your Honor?

14 JUDGE VALEK: -- can I interrupt you for a second,  
15 please? The slide you have here from the SEC filings also refers  
16 to, I guess, a District Court litigation in the District of New Jersey.  
17 Can you explain for us just by way of background the relationship  
18 between these PGRs and that District Court litigation?

19 MR. POWERS: Yes, Your Honor. Before the District  
20 Court litigation was filed, the Petitioner filed a few of the PGRs  
21 before the PTAB now. Then in late April of last year, Halozyme  
22 filed suit in District Court naming Merck Sharp Dohme as the  
23 defendant because Merck Sharp Dohme owns the BLA to the  
24 accused product in that litigation.

25 Then over the course of the year last year, Petitioner filed

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1 several other PGR proceedings for the Court. Does that get into  
2 the question?

3 JUDGE VALEK: So the litigation was filed after the  
4 first of the PGRs, the ones that are being heard later today on the  
5 merits; is that correct?

6 MR. POWERS: Yes, Your Honor. That's right.

7 JUDGE VALEK: Okay. And why isn't Merck & Co  
8 named as a defendant in that District Court litigation?

9 MR. POWERS: I think the primary reason there, Your  
10 Honor, is that the BLA for the accused product -- biological  
11 license -- is owned by Merck Sharp Dohme, LLC. That's the  
12 primary reason. But I do want to -- I hasten to add that that  
13 litigation is in its infancy, has been stayed, and Halozyme is well  
14 within the time to amend the pleadings to name additional  
15 defendants and may do so.

16 JUDGE VALEK: Is Merck currently selling the accused  
17 product, this Keytruda QLEX product, or is that not on the market  
18 yet?

19 MR. POWERS: It is on the market, Your Honor.

20 JUDGE VALEK: Okay.

21 MR. POWERS: It is.

22 JUDGE VALEK: And so in your motion, you say that  
23 it's Merck & Co that's actually selling the accused product --

24 MR. POWERS: It's certainly --

25 JUDGE VALEK: -- but you're not -- let me finish my

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1 question.

2 MR. POWERS: Sorry. Of course.

3 JUDGE VALEK: But you're not actually accusing them  
4 of infringement yet?

5 MR. POWERS: Well, that is late breaking news, Your  
6 Honor. That hasn't happened yet because the District Court side is  
7 stayed. So there's no action pending these PGRs at the District  
8 Court side.

9 And as I mentioned, Halozyme is within the time to  
10 amend its pleadings and name additional defendants and may do so  
11 naming Merck & Co.

12 JUDGE VALEK: Before the District Court action was  
13 stayed, was Merck & Co already selling the accused product or it  
14 had not been launched?

15 MR. POWERS: No. Not to my knowledge, Your  
16 Honor. No. It had not been launched. The information leading to  
17 the conclusion that Merck & Co is selling came from SEC filings  
18 late last year.

19 JUDGE VALEK: And when was the case stayed?

20 UNKNOWN SPEAKER: January of 2026 roughly. It's  
21 a little bit more complex procedurally than that. But we've been  
22 discussing with the ALJ there whether or not we go forward in  
23 discovery and the parties have agreed that we would not be going  
24 forward with discovery until after conclusion of these proceedings.

25 MR. POWERS: Okay. I'd like to move on to Slide 9.

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1 Indeed, when Merck & Co wanted to attribute action to Merck  
2 Sharp Dohme, LLC, it knew how to do so. Merck & Co clearly  
3 does not include LLC in this document. This comes from the very  
4 same SEC filing that Merck points to, alleging that when Merck or  
5 the company is referred to, it refers to its subsidiaries.

6 But you can see here in this document -- this is on Slide 9  
7 -- that when Merck wanted to specifically call out Merck Sharp  
8 Dohme, LLC, it could and did. And that cannot include the  
9 company as the language appears in the very same SEC document  
10 that Merck points to for its evidence.

11 Moving to Slide 10. Going back to the first SEC  
12 document that I pointed to, Exhibit 2400, Merck & Co, right under  
13 the passage that discussed these PGRs from Merck & Co's SEC  
14 filing discusses funding its legal action, including these PGRs -- it  
15 discusses the company's -- and therefore, Merck & Co's best  
16 estimate for the cost associated with its ongoing litigation  
17 activities, including these PGRs mentioned directly above.

18 And this shows that Merck & Co told the SEC and the  
19 investing public that Merck & Co is funding these PGRs. It's also  
20 participating in strategy even under Petitioner's reading of this  
21 passage. And Merck's opposition is telling when it attempts to  
22 address this point. Petitioner says that these reserves are kept in  
23 order to protect against legal losses to ensure Merck & Co., Inc.  
24 and its subsidiaries are adequately capitalized. And that's under  
25 opposition 14. But Petitioner does not make any allegation --

1 JUDGE FREDMAN: Can I ask a question?

2 MR. POWERS: Of course, Your Honor.

3 JUDGE FREDMAN: I'm just curious. A little bit off  
4 topic, but -- so is there any doubt that Merck & Company, the  
5 parent company, [REDACTED] doesn't engage in the  
6 manufacturing distribution of the drugs?

7 MR. POWERS: I think there is some doubt based on  
8 what they say in their SEC filings.

9 JUDGE FREDMAN: So you're saying that they  
10 manufacture the drug or you're saying they control the  
11 manufacture?

12 MR. POWERS: I'm not 100 percent sure of that. But it  
13 looks like they are attributing sales of the QLEX product to  
14 themselves at Merck & Co., Inc. And they also pay licensing fees  
15 for the QLEX products and its related product, Keytruda. They  
16 haven't disputed that at all in their opposition.

17 JUDGE FREDMAN: So they're paying fees to Merck  
18 Sharp & Dohme?

19 MR. POWERS: Their third party licensors in order to  
20 maintain the product. Moving along to Slide 13. And this is a key  
21 point. We learned through additional discovery that Ms. Zachary,  
22 general counsel at Merck & Co, signed the engagement letters with  
23 counsel representing Petitioner in these PGRs. And there's no  
24 dispute that these letters -- and I'm showing you the signature page  
25 here -- govern the relationship with outside counsel and provide all

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1 the guidelines for engagement for both firms representing  
2 Petitioner in these PGRs. Petitioner does not dispute in its  
3 opposition that Ms. Zachary is compensated by Merck & Co, even  
4 if she's also paid by Petitioner.

5 Moving to Slide 15.

6 JUDGE VALEK: Mr. Powers, before you move on --

7 MR. POWERS: Yes, Your Honor.

8 JUDGE VALEK: -- according to the signature block on  
9 your Slide 13, Ms. Zachary signed these on behalf of Merck Sharp  
10 & Dohme, the Petitioner. So why can't she wear two hats as GC  
11 for both Petitioner and Merck & Co?

12 MR. POWERS: Well, you're right, Your Honor. She did  
13 sign on behalf of Merck Sharp Dohme. But she's also -- she has  
14 the same exact titles at Merck & Co. And her -- there's a lot of  
15 information to show that she has a very controlling interest in the  
16 strategy related to Merck & Co's legal strategy global. So I can  
17 take you to her bio from The Merck & Co website, which shows  
18 that she leads the Office of General Counsel at Merck & Co and  
19 sets the company's global legal strategy.

20 So it's undisputed that she's paid by Merck & Co, even if  
21 also by MSD, LLC. And it's undisputed that she has a fiduciary  
22 duty to act on behalf of Merck & Co. So that's plenty to show that  
23 she has a controlling interest in these PGRs here, like the common  
24 leaders in both Galderma and Zoll cases.

25 JUDGE VALEK: Other than her signature on these

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1 engagement letters, which she signed on behalf of Petitioner, not  
2 Merck & Co, do you have any evidence -- specific evidence of Ms.  
3 Zachary's involvement in these PGRs?

4 MR. POWERS: In these specific PGRs, it's difficult  
5 without, you know, additional discovery that might get to privilege  
6 here, Your Honor. But we do --

7 JUDGE VALEK: But do you have any evidence,  
8 though?

9 MR. POWERS: Evidence --

10 JUDGE VALEK: Specific to these PGRs -- apart from  
11 her setting the -- what it says here, the company's global legal  
12 strategy, do you have any evidence that shows she has been  
13 specifically involved in these PGRs, other than her signature on  
14 these engagement letters?

15 MR. POWERS: No direct evidence, Your Honor. But  
16 we -- I don't think we need that. If we look at cases like Zoll and  
17 Galderma, you can see that the opportunity to control is enough.  
18 You don't need the actual evidence of control. Opportunity to  
19 control is enough.

20 And the point is that if Ms. Zachary called up outside  
21 counsel and gave them an instruction, they would have had to  
22 follow that instruction. And that could come from either of the  
23 two entities that she represents. And outside counsel wouldn't  
24 even know. She has --

25 JUDGE VALEK: What is the evidence of that? Of what

1 you just said, that if she called them up -- this hypothetical  
2 scenario where she calls them up, what evidence do you have that  
3 she gets to call that shot?

4 MR. POWERS: Well, Your Honor, I think the  
5 engagement letters go right to that. She signed outside counsel  
6 engagement letters that govern these proceedings. And that is  
7 highly probative evidence of her ability to call the shots.

8 I see that I'm almost out of time. And I'd like to jump  
9 ahead, if I may, because I didn't get to cover a lot of evidence that  
10 we briefed, and Your Honors will see.

11 But if I may go to Slide 35. Here's a summary of the  
12 evidence that we have on the three sort of prongs that I talked  
13 about before. We have evidence of control listed here, evidence of  
14 blurred lines, which includes also the evidence we discussed about  
15 control and also the specific benefit where it appears that Merck &  
16 Co sells Keytruda.

17 It attributes the sales of Keytruda to itself, referencing  
18 specifically Merck & Co., Inc. It's undisputed. It pays royalties to  
19 cover Keytruda and additional evidence that Your Honors have  
20 seen in our brief.

21 Finally, I'd like to spend a little bit of time addressing --

22 JUDGE FREDMAN: Are you going to run into your  
23 rebuttal time or --

24 MR. POWERS: Just a tiny bit.

25 JUDGE FREDMAN: Okay.

1 MR. POWERS: Well, I'll scratch that. I'll -- it'll be safer  
2 and --

3 JUDGE FREDMAN: Go ahead.

4 MR. HACKMAN: I'll be right with you, Your Honors.  
5 So I'm Blaine Hackman on behalf of Petitioner Merck Sharp &  
6 Dohme, LLC. Sometimes I'll refer to them as MSD, LLC. And  
7 there are really three headlines that we want the Board to take  
8 away today: first is that MSD, LLC, is the only party that has been  
9 controlling upon these proceedings; second is that MSD, LLC, and  
10 MCI have maintained corporate separateness and that MCI does  
11 not even have the capability to practically control these  
12 proceedings; and finally --

13 JUDGE FREDMAN: Do you have the evidence that  
14 they can't practically control the proceedings?

15 MR. HACKMAN: Sure, Your Honor. So why don't we  
16 go to Slide 14, please? So Slide 14 is evidence that's been  
17 produced by MSD, LLC. And this refers to the corporate position  
18 of Merck & Company as a parent company. And so in this  
19 instance, there's not really a structure that Merck & Co has in order  
20 to oversee these proceedings.

21 [REDACTED]  
[REDACTED] I  
23 know that my colleague was -- or my counterpart was referring to  
24 the fact that Ms. Zachary signed for -- who gave them counsel  
25 hearing for -- on behalf of MSD, LLC, to be represented for

1 matters just generally.

2 But that doesn't go to this specific proceeding. And it  
3 was done in Ms. Zachary's capacities in MSD, LLC. So we're not  
4 serving MCI. So there's really no ability for MCI to approach this  
5 from the perspective of running this procedure.

6 JUDGE VALEK: Mr. Hackman, what evidence is there  
7 to support the factual assertions you just made [REDACTED]  
[REDACTED]

9 MR. HACKMAN: So, Your Honor --

10 JUDGE VALEK: Where does that evidence come from?

11 MR. HACKMAN: Yes, Your Honor. So first, we  
12 submitted, I believe it's Exhibit 2401, several interrogatory  
13 responses. In fact, we can go to Slide 2 -- Slide 3, excuse me. So  
14 we submitted several interrogatory responses that describes the  
15 nature of Merck & Company's operations.

16 And in addition, if we go to Slide 4, we note that there's  
17 four in-house counsel that have been managing this proceeding.  
18 And they are all MSD, LLC, employees. Through them, MSD,  
19 LLC, has been the only party in control of these proceedings. And  
20 there's no evidence in the record and no evidence that we're aware  
21 of with Ms. Zachary that's been directing these proceedings from  
22 her wearing the hat of MCI.

23 The only way these proceedings have been run is through  
24 MSD, LLC. And they're the only company with, really, an interest  
25 in this. They're the company that's selling the product. So there's

1 really -- we have to prove a negative here. But there's really no  
2 evidence that MCI even has that lever of control that they could  
3 step into these proceedings for control.

4 JUDGE VALEK: Let me push back on that a little. Ms.  
5 Zachary is the general counsel of MSD, right?

6 MR. HACKMAN: That's correct, yeah.

7 JUDGE VALEK: And so all these people presumably  
8 report up to her at some point, maybe not directly. Doesn't she  
9 have the power to pull the plug on these PGRs if she wanted?

10 MR. HACKMAN: Well, Your Honor, we're certainly  
11 not aware of anything in the record suggesting that she does have  
12 the ability through the capacity of MCI. That would involve, I  
13 think, a situation that we don't see the structure being there for. I  
14 think we have to go to the case law to, really, distinguish what's  
15 going on here.

16 We look at cases like Galderma. We look at cases like  
17 Corning. There's a lot of direct involvement from the parent. For  
18 example, the parents have IP departments. The parents are the  
19 ones signing the engagement letter. So we have to just contrast the  
20 practicality. Sure. There's this theoretical issue. And that's dealt  
21 with the Daifuku case.

22 JUDGE FREDMAN: Let me ask you, for someone  
23 who's not as familiar with this, like myself, as some of my  
24 colleagues, in a corporate situation, obviously as the general  
25 counsel, she can order the -- for MSD, she could order the

1 recommendation to proceed. In the situation with MCI, would she  
2 be able to do it herself? Or would she basically have to arrange a  
3 corporate meeting and have the officers all vote? Is that what  
4 would have to happen?

5 MR. HACKMAN: To our awareness, there's no  
6 mechanism by which she could step in as MCI. It's wearing her  
7 MCI hat in order to do determination.

8 JUDGE FREDMAN: So presumably the officers could  
9 appoint her to some position. I mean, they would have to do  
10 something. And my question is, would it require a decision by the  
11 entire board of the corporation, or is there something individually  
12 she could do?

13 MR. HACKMAN: Your Honor, I don't know the answer  
14 about --

15 JUDGE FREDMAN: Okay.

16 MR. HACKMAN: -- what the corporate government  
17 structure would require. But this is, I think, why the Board's law  
18 addresses this issue. As you're getting into kind of -- we're getting  
19 into a theoretical here.

20 JUDGE FREDMAN: Okay.

21 MR. HACKMAN: Could there be a situation where  
22 MCI can step in? But we have to judge the RPI issue from the  
23 practical nature. And that's what they talked about in the Daifuku  
24 case, for example, that we cite that, you know, if we look at this  
25 from the perspective of could a parent come in and order

1 something? Maybe.

2 But we don't, you know, have any evidence that that's  
3 happened here. That's on Slide 17. It's just worth noting that this  
4 is the sort of situation that the evidence has been presented as if  
5 this theoretical possibility.

6 JUDGE MITCHELL: So how do you explain the SEC  
7 filings?

8 MR. HACKMAN: Yeah. So why don't we discuss  
9 those? So let's go to Slide 14 for a moment. Let's go to Slide 12.  
10 Yeah. So the SEC documents that Halozyme is relying upon here  
11 to connect MCI to the PTRs, they really can't do so. So the  
12 Petitioner has relied a lot in their papers on Exhibit 2400, which is  
13 a 10-Q filing from Merck. And they argue that these refer to the  
14 financial statements of MCI and MCI alone, the actions of MCI.

15 But actually, if we look at those documents, they say that  
16 it's MCI and its subsidiaries. If we look at the audited document,  
17 that's Exhibit 2415, that's the auditor's interpretation of what the  
18 SEC documents are disclosing. And again, it refers to the  
19 company and its subsidiaries.

20 And so it strains, really, credibility that the auditors to  
21 look at these filings and they would interpret them as the company  
22 being MCI and its subsidiaries, and then deciding, you know, this  
23 is how we interpret the documents, if the documents weren't  
24 actually meant to be that way. And so to us, there's every reason  
25 to believe that these are just generalities. It's referring to the parent

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1 company and all of its subsidiaries. It's not just the parent  
2 company.

3 And for these reasons, for example, both the Board and  
4 Article III courts have been skeptical about these sort of  
5 documents to link a parent company as the actioner, as the  
6 company that's actually had -- really, either had jurisdiction or in  
7 the context of RPI's real control and could go in to control. And so  
8 that's really the situation with the SEC documents.

9 JUDGE VALEK: Let me ask you a question about that,  
10 Mr. Hackman.

11 MR. HACKMAN: Sure.

12 JUDGE VALEK: Because there's also in the same  
13 documents, for example, the same one you're citing, Exhibit 2415,  
14 it also has the pages that the Patent Owner was referring to where  
15 it has Merck & Co., Inc., and then in parentheses it says Merck or  
16 the company. So in those same documents where you're saying it  
17 carefully defines them as Merck & Co and its subsidiaries, it also  
18 kind of defines them the way that Patent Owner would like to read  
19 them. So which statement do we believe --

20 MR. HACKMAN: Yeah. So --

21 JUDGE VALEK: -- from the same document?

22 MR. HACKMAN: Your Honor, there's ambiguity -- you  
23 can read ambiguity in that. It's also worth noting, though, there's  
24 exhibits that are missing from a lot of these SEC filings that have  
25 certifications in. They clarify. The language is a little bit muddy

1 in the SEC documents, which is why they're not really very  
2 reliable.

3 I think the more reliable evidence is part of the things  
4 like the tax filing are the actual operations. The fact that every  
5 action that's been taken with regard to this case, including things  
6 not related to the case directly but -- you know, for example, the  
7 engagement of outside counsel, that was all done from MSD, LLC.  
8 There's nothing that's done by MCI.

9 And next slide -- I think we were talking about this a bit,  
10 or Your Honors were talking about with my counterparts is on  
11 Slide 13, which we have the litigation in the District of New  
12 Jersey. Oh.

13 JUDGE MITCHELL: Sorry. Yeah.

14 MR. HACKMAN: Need to call a timeout?

15 JUDGE FREDMAN: We'll just pause for one second.

16 JUDGE MITCHELL: Thank you.

17 JUDGE FREDMAN: We can do that.

18 JUDGE VALEK: Am I back?

19 JUDGE MITCHELL: Yes.

20 JUDGE FREDMAN: You're back. We were just trying  
21 to find you.

22 JUDGE VALEK: Okay. I lost --

23 JUDGE FREDMAN: So I'm going to give you another  
24 minute or so back.

25 JUDGE VALEK: I apologize, Mr. Hackman. You were

1 responding to my question. And I got cut off right then before I  
2 even heard the first word.

3 MR. HACKMAN: Okay.

4 JUDGE FREDMAN: I'll give you two minutes --

5 MR. HACKMAN: I noticed --

6 JUDGE HARDMAN: I can hear everything. I don't see  
7 my video. There we go.

8 JUDGE FREDMAN: What's happening is you're both  
9 on both screens. So when you speak, we'll see -- you know, you  
10 two are a little picture in picture version.

11 JUDGE HARDMAN: Okay.

12 JUDGE FREDMAN: Probably it's just -- whatever, it'll  
13 be fine. So I'm going to start the time again, maybe go back a little  
14 bit in time. Can you repeat your question, Judge Valek?

15 JUDGE VALEK: Yeah.

16 JUDGE FREDMAN: And then we'll let him answer  
17 your question there.

18 MR. HACKMAN: Sure, Your Honor.

19 JUDGE VALEK: Sure. Let me know when we're back  
20 on.

21 JUDGE FREDMAN: We're on.

22 JUDGE VALEK: Okay. So, Mr. Hackman, I was  
23 wondering how do we reconcile the somewhat inconsistent  
24 statements in the SEC filings where in one part of the document it  
25 seems to refer to just Merck & Co as the company, and in other

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1 parts, it also includes the subsidiaries in the definition of  
2 company?

3 MR. HACKMAN: Well, Your Honor, first, take a little  
4 issue with inconsistencies. I mean, it's not a document that's meant  
5 to be read specific to the parent versus the subsidiary. It's meant to  
6 be read consolidated. So it's always referring to the consolidated  
7 companies.

8 But to the extent there's any need to reconcile -- if we go  
9 to the next slide, Slide 13 -- we address this, for example, in the  
10 litigation that we have here, which is in New Jersey, which we  
11 discussed -- or which you discussed with the Patent Owner  
12 previously. And so this suit relates to most of the PGR challenged  
13 patents.

14 And if we notice in the SEC filing, sometimes they just  
15 refer to the company and they referred to these PGRs and they  
16 referred to this litigation as sort of a related thing. But Halozyme's  
17 argument suggests that MCI is saying is the company is the party  
18 involved in this litigation. But the reality of it is MSD, LLC, is the  
19 only party that's in this litigation.

20 And in terms of the launch of QLEX, we know it was  
21 late 2025. We don't have the exact time frame with respect to the  
22 stay. But it was certainly a live issue. Certainly, Halozyme was  
23 aware of the corporate parentage. There was corporate disclosures  
24 in July 2025, well before any stay was discussed.

25 So there's no question that if MCI was a relevant party,

1 there was a lot of time for Halozyme to add them in. And this  
2 issue didn't even arise until November when they started raising  
3 the RPI issue. So we think here there's really clear evidence  
4 Halozyme was able to distinguish the two entities and which entity  
5 is doing what. And that's an indication that, again, the separation  
6 of these two entities.

7 JUDGE FREDMAN: Is MCI the one selling Keytruda or  
8 is it --

9 MR. HACKMAN: It's MSD, LLC. It's the company --

10 JUDGE FREDMAN: Is MCI involved in any way?

11 MR. HACKMAN: [REDACTED]

13 Our understanding is there's no -- [REDACTED]

14 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

19 JUDGE FREDMAN: Okay.

20 JUDGE HARDMAN: Can I ask, Counsel, Patent Owner  
21 mentioned that MCI has a license to the QLEX product; is that  
22 correct?

23 MR. HACKMAN: [REDACTED]

[REDACTED]

[REDACTED]

1 JUDGE HARDMAN: Is there affirmative evidence of  
2 that in the record?

3 MR. HACKMAN: In the record, I don't believe we have,  
4 other than -- I'm not sure if we had any interrogatory responses,  
5 but there's no documentation of this. And just sort of on that note,  
6 you know, one of the things is this issue, this motion to terminate  
7 was pretty late in the case and the Board expressed desire to not  
8 delay the case. So we haven't submitted a declaration. If the board  
9 does feel there's an actual question or a declaration or some clarity  
10 would be helpful, we ask for that opportunity to submit that. So --

11 JUDGE MITCHELL: Can I ask you, in just the SEC  
12 filing, are there other activities of other subsidiaries that are also  
13 listed that would help sort of bolster your, you know, argument  
14 that hey, this is all of the family, the parent and the subsidiaries  
15 that are described in that SEC filing?

16 MR. HACKMAN: Certainly. So analogous to this slide,  
17 there's other activities where other subsidiaries are doing -- you  
18 know, things that we know that only one subsidiary is doing, for  
19 example, MCI is not doing. I can't point it out to you right now.  
20 But that -- the way that these documents are formed is that they're  
21 referring to collectively all the subsidiaries. So all the activities  
22 are lumped in together.

23 JUDGE MITCHELL: Thank you.

24 MR. HACKMAN: Just to -- and also a quick note, you  
25 may have seen in the briefing that Halozyme brings up the other

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1 cases that MCI has been listed as an RPI. There are some cases  
2 where listed, some cases where they're not, one of them is an Ono  
3 case. That was an instance where my colleague, Mr. Kushan, was  
4 lead counsel. There had been a litigation that had sued MCI.  
5 Whether or not there was jurisdiction unclear, but they'd sued  
6 MCI.

7           And so as an abundance of caution, MCI was added as a  
8 RPI. There are other cases, for example, where counterpart's  
9 counsel, Quinn Emanuel, the backup counsel, they had not these  
10 specific individuals. But the firm filed RPI statements that  
11 included MSD Corp., which was the predecessor to MSD, LLC,  
12 only. So there are instances where MSD, LLC, or Corp. were the  
13 only RPIs.

14           And then there are some instances where they're both.  
15 But there's no penalty, really, for over listing RPIs. And so in  
16 those instances, we don't think that MCI was ever an RPI. But  
17 looking at the case -- this case and these facts, there's no evidence  
18 of MCI being an RPI.

19           So I just want to go quickly to slide -- the slide of the  
20 comparison to boards, which is Slides 15 to Slide 13. So this is  
21 just one thing we wanted to raise. It's sort of emblematic of a lot  
22 of Halozyme's arguments is that these two boards are the same  
23 board, they're both MCI. One is on a Merck branded page, one is  
24 on an MSD branded page.

25           This arose because there's a trademark dispute with the

1 German Merck. And as a result, Merck in the U.S. and Canada  
2 can represent itself as Merck, can brand itself as Merck. Overseas,  
3 it has to be MSD, LLC.

4 But these are the same boards. If you go to the next  
5 slide, Slide 16, we can see from publicly available documents this  
6 New Jersey filing, the board of managers of Merck Sharp &  
7 Dohme is different from the board of MCI. So again, it shows  
8 these corporate separation -- separateness. There's no blurred lines  
9 between these two entities.

10 Finally, I just want to go to slide -- second -- the third to  
11 last slide. It is Slide 18. Yeah. So just a quick note, any benefit to  
12 MCI is strictly its subsidiaries' benefit. There's no separate  
13 benefit. MCI doesn't have products. It doesn't have any operations  
14 that are at issue here.

15 And so if we were to eviscerate the substance and  
16 disallow any general benefit to allow a party to be -- or force a  
17 party to be named RPI, really, there'd be no distinction between  
18 parent subsidiary and RPI analysis. But this board's precedent has  
19 shown over and over again that unless there's really substantial  
20 involvement or that ability to have substantial involvement with  
21 the RPI, there's no issue -- no RPI issue.

22 And then finally, the last slide, we just want to address  
23 waiver. So here, there were four PORs prior to Corning. There  
24 were several PORs after we produced discovery on this issue.  
25 That RPI issue was never raised in those PORs. So we believe

1 there's a case to waiver this. Thank you, Your Honors.

2 JUDGE FREDMAN: Thank you very much.

3 JUDGE VALEK: I have one question about that before  
4 you step down. How has Petitioner been prejudiced by Patent  
5 Owner not having raised the RPI issue in its patent or responses in  
6 these -- I think it's 10 later filed PGRs if I'm counting right.

7 MR. HACKMAN: Well, the prejudice is actually  
8 evidence of why we're here, why we haven't had the opportunity to  
9 -- for example, you know, have time to put in a declaration to fully  
10 address this issue. Although we think the evidence speaks for  
11 itself. But that's really been, you know, the issue is -- the  
12 proceeding, we could have done it at a different stage of the  
13 proceeding. Now we're briefing it here.

14 JUDGE VALEK: But Counsel, we had a call with the  
15 parties before we allowed the motion and specifically asked  
16 whether you wanted to submit a declaration. At that time, you told  
17 us you didn't think you needed to.

18 MR. HACKMAN: This was the call recently?

19 JUDGE VALEK: Yeah.

20 MR. HACKMAN: Our understanding was that the need  
21 -- there was an exigence that we needed to address this before -- or  
22 ideally so we could bring it to the oral hearing. I think the time  
23 was we didn't anticipate needing. Again, we think that the  
24 evidence speaks for itself. But, you know, sometimes, the Board  
25 does find them helpful in this. Thank you very much.

1 JUDGE FREDMAN: Thank you, Counsel. Great. I can  
2 give you four minutes.

3 MR. POWERS: Thank you, Your Honor. Just a few  
4 things before I talk about the timeliness of --

5 JUDGE FREDMAN: Can I ask you a question? I'm just  
6 curious --

7 MR. POWERS: Sure.

8 JUDGE FREDMAN: -- since he raised the declaration  
9 issue. So would you -- presumably, you'd get it deposed -- if we  
10 allow a declaration, you'd get it deposed. Are you opposed to a  
11 declaration?

12 MR. POWERS: At this stage of the proceedings, I think  
13 so, yes, Your Honor, the --

14 JUDGE FREDMAN: You are --

15 MR. POWERS: -- Counsel already agreed that it was  
16 unnecessary for them. But if the Board thinks that would be  
17 helpful, then of course, we're happy to engage in that.

18 JUDGE FREDMAN: Okay. Thank you.

19 JUDGE VALEK: Let me ask a question about that  
20 before we move on. [REDACTED]

22 MR. POWERS: [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

1 [REDACTED] folks that work for MSD, LLC, are very  
2 confused about where they work. Because as we've briefed, there  
3 are a lot of folks that work, according to their OED website and  
4 their registration with the PTO for either Merck or Merck & Co,  
5 and some -- the minority say MSD, LLC.

6 So that goes to blurred lines -- that evidence, I think, is  
7 very compelling for blurred lines. And that's the kind of thing that  
8 -- yes --

9 JUDGE VALEK: But I guess what I'm getting at is do  
10 you have any sort of evidence to the contrary, or do you -- let me  
11 ask you a little differently. Given that there may be some  
12 confusion in the company -- and I agree with you, maybe there are  
13 some blurred lines -- but do you have -- [REDACTED]  
[REDACTED]  
[REDACTED]

16 MR. POWERS: What I think we know, Your Honor, is  
17 based on their own statements is that Merck & Co, and Jennifer  
18 Zachary in particular, operates through, at the very least, control  
19 over the subsidiaries. And that's how she performs her function as  
20 the general counsel.

21 JUDGE VALEK: So again, just looking for an answer to  
22 my question. Do you dispute their assertion?

23 MR. POWERS: Yes, Your Honor, yes.

24 JUDGE VALEK: Thank you.

25 MR. POWERS: And from a practical standpoint, yes. I

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1 also heard counsel equivocate when it comes to whether or not  
2 Merck & Co sells Keytruda QLEX or pays royalties on behalf of  
3 Merck & Co and its subsidiaries. It's undisputed that Merck & Co  
4 compensates Ms. Zachary. Ms. Zachary also said that her primary  
5 role was as general counsel of Merck & Co in SEC filings.

6 I heard Counsel say that SEC documents aren't reliable.  
7 Well, the SEC documents I've shown you today that are in the  
8 record are certified by none other than Ms. Zachary. And they're  
9 certified under Sarbanes-Oxley to be accurate and not have  
10 misstatements. And SEC documents were found reliable to find  
11 evidence of an involved and controlling parent in the Amazon v.  
12 Appistry IPR that's IPR2015-00480, Paper 18. FCC documents  
13 were reliable for that purpose.

14 Ms. Zachary has undisputed -- we all know she signed  
15 the engagement letters that govern these very PGRs. And Ms.  
16 Zachary sets Merck & Co's global legal strategy. Whether she  
17 does that through Merck & Co's own IP department or through  
18 involvement with the subsidiaries, it doesn't matter. She has the  
19 opportunity to control these proceedings and that's all that it takes  
20 under Zoll and Galderma.

21 Now, moving on to the timeliness of Halozyme acting  
22 diligently here. So once SharkNinja was de-designated and  
23 Corning was designated, Halozyme immediately investigated the  
24 RPI issue. Shortly after Halozyme launched its investigation, it  
25 encountered the November 5th SEC filings that we've been

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1 discussing here today. Halozyme contacted Petitioner's counsel on  
2 the RPI issue on November 11, just four business days after the  
3 SEC document came out.

4           Only after the panel authorized Halozyme's motion for  
5 additional discovery did Petitioner produce any of this -- any  
6 documents to Halozyme. And Halozyme learned at that time that  
7 Ms. Zachary signed the engagement letters with Counsel --

8           JUDGE FREDMAN: All right.

9           MR. POWERS: -- at that time.

10          JUDGE FREDMAN: Thank you.

11          MR. POWERS: Thank you, Your Honor.

12          (Whereupon, the confidential portion of the above-  
13 entitled matter concluded.)  
14

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