

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BLUEBIRD BIO, INC.,  
Petitioner,

v.

SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH,  
Patent Owner

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IPR2023-00070 (Patent 7,541,179 B2)  
IPR2023-00074 (Patent 8,058,061 B2)

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Record of Oral Hearing  
Held: January 24, 2024

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Before JAMES A. WORTH, SHERIDAN K. SNEDDEN, and CYNTHIA  
M. HARDMAN, *Administrative Patent Judges*.

IPR2023-00070 (Patent 7,541,179 B2)

IPR2023-00074 (Patent 8,058,061 B2)

APPEARANCES:

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The above-entitled matter came on for hearing on January 24, 2024, commencing at 9:00 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P R O C E E D I N G S

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3 JUDGE SNEDDEN: Okay. Good morning. This is the consolidated  
4 oral hearing in IPR2023-00070 and 00074. I'm Judge Snedden, and with me  
5 on the panel today are Judges Worth and Hardman. We'll begin with  
6 appearances. So starting with Petitioner, please stand and introduce  
7 yourself, and who you have with you today.

8 MR. MODI: Good morning, Your Honors. Naveen Modi from Paul  
9 Hastings on behalf of Petitioner Bluebird. With me I have my colleagues  
10 Eric Dittmann, Krystina Ho, and Max Yusem. And Mr. Yusem will be  
11 presenting the argument for Bluebird today.

12 JUDGE SNEDDEN: Okay. Thank you.

13 MR. YUSEM: And, Your Honors, I have copies of our  
14 demonstratives. If I can approach, I provide them if you need them.

15 JUDGE SNEDDEN: Sure. I'll take one.

16 MR. YUSEM: Okay.

17 JUDGE SNEDDEN: Thank you.

18 MR. SUH: Good morning, Your Honors. My name is Howard Suh  
19 from the law firm of Fox Rothschild, and we are representing San Rocco  
20 Therapeutics on behalf of Patent Owner Sloan Kettering Institute. And with  
21 me are my colleagues Dr. Joe Chen and Ms. Wanda French-Brown. We  
22 also have, I believe, Dr. Michael Glynn calling in by remote.

23 JUDGE SNEDDEN: We welcome you. Thank you.

24 MR. SUH: Thank you.

IPR2023-00070 (Patent 7,541,179 B2)

IPR2023-00074 (Patent 8,058,061 B2)

1 JUDGE SNEDDEN: We, the judges, do have electronic versions of  
2 each of the parties' slides. As you proceed through your presentations today,  
3 we ask that -- remind you to refer to the slide number as you move through  
4 your arguments today so we can more easily follow along, and also for the  
5 benefit of the record.

6 As set forth in our hearing order, each party will have 90 minutes of  
7 total time to present its arguments. Patent Owner is granted an additional 15  
8 under our LEAP Program. Petitioner will open the hearing with its  
9 argument. Patent Owner will have the opportunity to respond. And each  
10 party may reserve time for rebuttal. Any questions before we begin?

11 MR. YUSEM: No, Your Honor.

12 JUDGE SNEDDEN: Okay. Very good. Sir, can you repeat your  
13 name one more time?

14 MR. YUSEM: Max Yusem, Y-U-S-E-M.

15 JUDGE SNEDDEN: All right. Thank you, Ms. Yusem. When  
16 you're ready, you may begin. And would you like to reserve time for  
17 rebuttal?

18 MR. YUSEM: Thank you, Your Honor. Yes. If I can reserve 30  
19 minutes for rebuttal.

20 JUDGE SNEDDEN: When you're ready.

21 MR. YUSEM: Good morning, Your Honors. May it please the  
22 Board. My name is Max Yusem from Paul Hastings, LLP representing  
23 Petitioner, Bluebird Bio. The patents at issue here, the 179 and 061 patent  
24 relate to work that Memorial Sloan Kettering did in the mid to late 90s  
25 regarding a vector that they call TNS9.

IPR2023-00070 (Patent 7,541,179 B2)

IPR2023-00074 (Patent 8,058,061 B2)

1           If we turn to Slide 2, you can see here representative claims from the  
2 179 and 061 patents. Claim 1 from both. The named inventors published  
3 their TNS9 work in 2000 but waited until mid-2001 to file very limited  
4 provisional applications, only a few pages. They then waited another year to  
5 file a non-provisional application, that's the 221 application, pursuing  
6 broader claims. Publicizing their TNS9 work while seeking a longer patent  
7 term resulted in the inventors' own work becoming invalidating prior art.

8           As seen here, the focus of these IPRs, the challenges in these IPRs is  
9 the language seen in both Claim 1's functional globin highlighted here on  
10 Slide 2. Functional globin lacks priority supports to provisional. The same  
11 argument applies to both the 179 and 061 patent. The rest of the claim  
12 language identified here, whether the HS2-, HS3-, and HS4-spanning  
13 nucleotide fragments that are part of the claimed locus control region, or  
14 LCR, whether or not those would have been obvious over the inventor's own  
15 prior art is the other central focus of the arguments today.

16           And as I explained earlier, for the purpose of today's arguments, the  
17 arguments for both the 179 and 061 patents are the same. As Patent Owner  
18 noted, San Rocco Therapeutics or SRT is the one that responded on behalf  
19 of the Patent Owner. So at times in our papers and today I might refer to  
20 them as SRT. That also is the Patent Owner here.

21           Turning to Slide 3. Petitioner presented various invalidity grounds for  
22 these two patents which you can see here on Slide 3, where Ground 3 for the  
23 179 patent, and Ground 4 and 5 for the 061 patent are what resulted in the  
24 institution of these two IPRs. As you can see for Ground 3, that's based on  
25 an obviousness argument based on what we refer to as the May article which  
26 is an article that the inventors published in Nature. And the background

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