

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MODERNA THERAPEUTICS, INC.,
Petitioner,

v.

ARBUTUS BIOPHARMA CORPORATION,
Patent Owner.

IPR2019-00554
Patent 8,058,069 B2

Record of Oral Hearing
Held: April 22, 2020

Before TINA E. HULSE, CHRISTOPHER G. PAULRAJ, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

IPR2019-00554
Patent 8,058,069 B2

APPEARANCES:

ON BEHALF OF THE PETITIONER:

MICHAEL FLEMING, ESQUIRE
C. MACLAIN WELLS, ESQUIRE
Irell & Manella, LLP
1800 Avenue of the Stars, Suite 900
Los Angeles, CA 90067-4276

ON BEHALF OF THE PATENT OWNER:

MICHAEL T. ROSATO, ESQUIRE
STEVEN W. PARMELEE, ESQUIRE
SONJA R. GERRARD, ESQUIRE
LORA M. GREEN, ESQUIRE
Wilson Sonsini Goodrich & Rosati
701 Fifth Avenue, Suite 5100
Seattle, WA 98104-7036

The above-entitled matter came on for hearing on Wednesday, April 22, 2020, commencing at 1:00 p.m., by video/by telephone.

PROCEEDINGS

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3 JUDGE PAULRAJ: Good afternoon, counsel. This is the final oral
4 hearing in IPR2019-00554. I'm Judge Paulraj and with me on the video we
5 have judges Hulse and Majors. As noted in our trial hearing order, in light
6 of the current situation with COVID-19 we'll be conducting this hearing
7 entirely by video conference. So, we do have a court reporter present who
8 will be transcribing this hearing, although the court reporter will not be seen
9 on video. I also understand that members of the public may be listening on
10 this hearing. I'm not aware of any confidential information that might be
11 discussed but wanted to make sure counsel was aware of that. With that,
12 let's start with appearances. Petitioner's counsel first and then Patent
13 Owner's counsel.

14 MR. WELLS: This is Maclain Wells of Irell & Manella on behalf of
15 Moderna, Petitioner. Also, on the line dialed in is Michael Fleming also of
16 Irell and Manella. And from our client Moderna, Debra Milasincic, head of
17 intellectual property.

18 JUDGE PAULRAJ: Thank you, Mr. Wells. And counsel for Patent
19 Owner.

20 MR. ROSATO: Good afternoon, Your Honor, this is Mike Rosato on
21 behalf of Patent Owner. And dialed in should be my colleague Lora Green.
22 And it is possible that in house counsel for the Patent Owner Meagan Young
23 is dialed in as well. And further in the conference room I have at a distant
24 location Franklin Chu and Sonja Gerrard.

25 JUDGE PAULRAJ: Thank you, Mr. Rosato. So, per the terms of our
26 oral hearing order, each side will have 45 minutes to present their arguments

1 and each side may reserve some of that time to respond to the other side's
2 arguments. I'll ask you how much time you want to reserve when it's time to
3 present.

4 We are in receipt of the demonstratives that were emailed to the board
5 so we have that in front of us as well as full access to the record in this
6 proceeding. I want to remind counsel to make sure you do clearly identify
7 the slide number that you're referring to as you make your presentation so
8 we can follow along. Please also make sure to mute yourself if you're not
9 speaking so we avoid unnecessary background noises.

10 I'm not aware of any outstanding objections to the demonstratives that
11 we need to resolve. But I did get a reminder from the court reporter before
12 we started that to the extent that there's complicated terminology please
13 articulate those clearly and if we need to have them spelled out, we may
14 have you do that as well just so we have a clear record. Unless there's any
15 other preliminary matters we need to discuss, we can proceed with
16 Petitioner's arguments.

17 MR. WELLS: Yes, Your Honor. Maclain Wells for Petitioner
18 Moderna and I would like to reserve 20 minutes of our time for rebuttal.

19 JUDGE PAULRAJ: That's fine, Mr. Wells, let me go ahead and put
20 that on the clock here. So, that would give you 25 minutes for your initial
21 arguments. Whenever you're ready.

22 MR. WELLS: Thank you, Your Honor. So, I would like to begin
23 today talking about obviousness, Kendal reference obviousness in view of
24 Patent Owner's own 189 prior art publication. Which disclosed the same
25 lipid carrier systems that are described in the challenged claims of the 069
26 patent.

1 And so, if we could turn to Petitioner slide 20. This is the cover page
2 in the summary of invention from the 189 patent and we're talking here
3 about nucleic acid-lipid particles and three different types of lipid
4 components. A cationic lipid, a non-cationic lipid and a conjugated lipid.
5 And Your Honor's may be aware from the discussions in the papers that the
6 non-cationic lipid can be further subdivided into different types of non-
7 cationic lipids a phospholipid and a cholesterol.

8 So, if we proceed to slide 21, in the 189 patent there's this disclosure.
9 The lipid nucleic acid particles of the present invention, and it provides
10 ranges. And so, we have for the cationic lipid, a 2 to 60 range. This is the
11 mol or percentage. For the non-cationic lipid, which would include
12 potentially the phospholipid and cholesterol we have 5 to 90. For the
13 conjugated lipid, we have .5 to 20 and then it specifically called out 2 as one
14 example. And for the cholesterol, when it's present, we have 20 to 55 mol
15 percent. And if you go to paragraph 0159 of the 189 patent, it discusses the
16 types of non-cationic lipids and gives the examples of a phospholipid, a
17 cholesterol or a mixture of a phospholipid and a cholesterol.

18 And so, here we have each of the 4-lipid components described in the
19 069 patent claims and ranges for each of those 4-lipid components all in the
20 same lipid nucleic acid particle. Laid out in one part of the specification,
21 these are all intended to be combined together and these four components,
22 the cationic lipid, the phospholipid, the cholesterol and the conjugated lipid
23 are intended to equal 100 percent of the lipid component in the particle. You
24 could, in theory, have additional components but when we're talking about a
25 four component system, these should total 100 percent. So, if you increase
26 one of them, you have to correspondingly increase another one.

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