

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES S.A., and
DR. REDDY'S LABORATORIES, INC.,
Petitioner,

v.

INDIVIOR, U.K., LIMITED,
Patent Owner.

Case IPR2019-00329
Patent 9,687,454 B2

Record of Oral Hearing
Held: March 3, 2020

Before SUSAN L. C. MITCHELL, ZHENYU YANG, and
RICHARD J. SMITH, *Administrative Patent Judges*.

Case IPR2019-00329
Patent 9,687,454 B2

APPEARANCES:

ON BEHALF OF THE PETITIONER:

IRA J. LEVY, ESQUIRE
ROBERT FREDERICKSON, III, ESQUIRE
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ON BEHALF OF THE PATENT OWNER:

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The above-entitled matter came on for hearing on Tuesday, March 3, 2020, commencing at 12:59 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Donna Jenkins, Notary Public.

P R O C E E D I N G S

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JUDGE MITCHELL: Good afternoon everyone. We have a final hearing this afternoon in IPR 2019-00329. I am Judge Mitchell and seated to my right is Judge Yang and appearing remotely is Judge Smith. I would like to get appearances for the parties on the record if we could. Who do I have for Petitioner?

MR. LEVY: May it please the Court, my name is Ira Levy. I am lead counsel for Petitioner's Dr. Reddy's Laboratories S.A., and Dr. Reddy's Laboratory, Inc. With me is back-up counsel Mr. Robert Frederickson who will be arguing today. Also with me is Ms. Alexandra Valenti, back-up counsel and we're also pleased Your Honor to be joined today by Mr. Andrew Allen, Director of IP at Dr. Reddy's and Deepti Jain, Associate Director of Intellectual Property at Dr. Reddy's.

JUDGE MITCHELL: Great. Thank you and welcome, and who do I have for Patent Owner.

MR. CHEN: Yes. Thank you, Your Honor, and good afternoon. My name is Peter Chen, I'm with Covington & Burling. I'm lead counsel today for the Patent Owner, Indivior UK, Ltd. With me is my colleague, Isaac Belfer, at counsel table and in addition we have from Indivior the General Counsel of Intellectual Property for the corporation, Ms. Kathryn Jones and seated next to her is Ms. Lisa Stahl who is patent counsel at Indivior. Thank you very much.

1 JUDGE MITCHELL: Great. Thank you and welcome. I
2 know that we set forth our procedure for how we're going to
3 handle the oral argument in our Hearing Order and we're going to
4 follow that, but I just wanted to emphasize a couple of things
5 before we get started as a reminder. So each party has 45
6 minutes total time to present arguments and certainly to assist
7 Judge Smith who is following along with your argument and also
8 just for the clarity of the record when we go back and look at the
9 transcript, if you refer to an exhibit that you certainly state the
10 exhibit number and the page to which you are referring, and
11 when you're referring to a demonstrative that you state the slide
12 number.

13 Also please make sure that you stay at the podium so that
14 the mike can pick up everything that you say so that Judge Smith
15 can hear everything and not miss any of your statements. Also
16 please be aware that Judge Smith cannot see what's projected on
17 the screen. He certainly has the demonstratives and can follow
18 along but if you pull up an exhibit, if you please just give him a
19 minute to pull it up so that he can continue to follow along with
20 your argument. The Petitioner has the burden of showing
21 unpatentability of the challenged claims, so the Petitioner goes
22 first. The Patent Owner will then have an opportunity to present
23 a response and in addition to the Petitioner being able to reserve
24 rebuttal, Patent Owner may reserve a little bit of time for
25 rebuttal. So Petitioner, would you like to reserve any time?

1 MR. FREDERICKSON: Yes, Your Honor, ten minutes
2 please.

3 JUDGE MITCHELL: Great. Thank you. So whenever
4 you're ready.

5 MR. FREDERICKSON: May it please the Board. Good
6 afternoon, my name is Robert Frederickson on behalf of
7 Petitioner. We are here today because the challenged claims of
8 the 454 patent are not entitled to the priority date of the 571
9 application which was filed on August 7, 2009. That is the only
10 issue for the Board to decide in today's proceeding. If the 454
11 claims cannot claim priority to the filing date of the 571
12 application, Patent Owner does not contest that Myers anticipates
13 all challenged claims.

14 Slide 1, please. Seven years after the 571 patent was filed
15 application was filed in the summer of 2016, the United States
16 District Court for the District of Delaware held that the invention
17 as it was described and claimed in the 571 application was
18 invalid as obvious. In direct response to that ruling in
19 September of 2016, the Applicants abruptly amended all claims
20 in the then pending 454, the application that led to the 454
21 patent. That amendment included limitations claiming that the
22 specific amounts of polymers and pharmaceutical films were an
23 aspect of the invention. The limitations at issue are directed
24 towards specific values and bounded ranges of the amount of
25 polymers and films and they are expressed in two forms. The

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