IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC.,)
Petitioner,) IPR 2020-00040
)
v.) U.S. Patent No.
) 7,326,708
MERCK SHARP & DOHME CORP,)
Patent Owner.)
_____)

DEPOSITION OF MUKUND CHORGHADE, PH.D.
APPEARING REMOTELY

August 6, 2020
9:32 a.m.

Reported by: Lori J. Goodin, RPR, CLR, CRR,
RSA, California CSR #13959

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WITNESS: MUKUND CHORGHADE, PH.D.

* * *

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RSA, California CSR #13959

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Lori J. Goodin, RPR, CLR, CRR,
RSA, California CSR #13959

(Exhibits provided electronically to the court reporter.)

Thursday, August 6, 2020, 9:32 a.m.

PROCEEDINGS

THE VIDEOGRAPHER: We are now on the record. This is Video Number 1 in the video recorded deposition of Dr. Mukund Chorghade, taken in the matter of Mylan Pharmaceuticals, Inc., Petitioner, v. Merck Sharp & Dohme Corp., Patent Owner.

Pending before the United States Patent and Trademark Office before the Patent and Trial Appeal Board, IPR 2020-00040 for patent Number 7,326,708.

This deposition is being held by Zoom video remote conferencing and the physical recording is taking place in Culpeper, Virginia.

Today's date is August 6, 2020, and the time on the video screen is 9:32 a.m.

My name is Daniel Holmstock. I am the legal videographer, from Digital Evidence Group. The court reporter today is Lori

Goodin, also in association with Digital Evidence Group.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely. And due to the nature of remote reporting, please pause briefly before speaking to ensure all parties are heard completely.

Counsel your appearances will be noted on the stenographic record.

At this point now, our court reporter will now administer the oath.

* * *

Whereupon,

MUKUND CHORGHADE, PH.D.,

a witness called for examination, having been first duly sworn, was examined and testified as follows:

* * *

EXAMINATION

BY MR. FISHER:

Q. Good morning, Dr. Chorghade. Did I

pronounce that correctly?
A. Yes, you did. Thank you.
Q. Okay, good morning.
Could you state your full name and address for the record, sir.
A. Full name, Mukund Shanker Chorghade. Address, 7 Jones Court, Hillsboro, New Jersey 08844.
Q. Is there any reason that you cannot testify truthfully and accurately today?
A. There is no reason.
Q. Okay. Before today's deposition, I corresponded with Merck -- Mylan's counsel, Mr. -- or Dr. Malik, about shipping a box of materials related to the deposition to you.
Do you have that box in your office?
A. Yes, I do.
Q. Okay. My understanding is that it is not yet opened or has it been opened?
A. That is correct, yes.
Q. It has not yet been opened?
A. It has not been opened.

Q. Okay.
A. No.
Q. If you have something to open it with, would you go ahead and open the box?
DR. MALIK: Stan, may I do so, too?
MR. FISHER: Absolutely.
BY MR. FISHER:
Q. And so when you have it open, you can take the binder that is in the box out but leave the other tabbed folders in there.
A. Are you requesting that I pull out this black binder?
Q. Yes, sir.
A. I have just done that.
Q. Excellent. So, what I have tried to do and hopefully the shipping has worked out, is put in a binder your declaration, in other words your testimony that you have already submitted in the matter, along with the exhibits that you attached to your declaration.
So, that should be in the binder. And you want to just flip through it and see if

you see your declaration and your CV and some of the other exhibits that you have submitted.
There should be about 16 tabs.
A. Yes. So, there is a United States patent '708. There is my declaration. There is a patent '498. There are some research papers.
Q. Okay. You don't -- so, what I have done and I will represent to you and hopefully the copying job made it there -- I haven't had the opportunity to flip through that binder myself given the COVID issues.
A. There are 16 tabs over here, yes.
Q. Right. And so, you can keep that out in front of you. We may be discussing some of the exhibits in that binder today.
I will tell you that what remains in the box are a number of documents that we may or may not discuss today.
And, what I have done is numbered the documents in the box. They should be in Redwelds, something like 1 to 30, or 1 to 32.
If we happen to discuss one of those

documents, I will ask you at that time to pull out, you know, Redweld Number 3 or whatever it may be, and we can discuss the document at that point.
We will also have the documents up on the screen. I do know -- I'm, I'm old school. I like to see the documents in paper. They will be on the screen for you. It will be up to you what you use. Okay?
A. Thank you. So, bear with me for five seconds while I pull up a chair to rest this on by my side.
MR. FISHER: I had to do the same thing myself. No problem.
THE WITNESS: So, I have just pulled up a chair to rest this binder and I can pull out anything I want.
(Exhibit Number 1002 marked for identification.)
BY MR. FISHER:
Q. Okay. So, your declaration is entered as Exhibit 1002. That should be in the

binder you pulled out.
A. Yes, it is here.
Q. Okay, all right. So, that is there for your reference to the extent you need it.
Sir, you provide background on yourself in your declaration, right?
A. Correct.
Q. You are an expert in medicinal chemistry; is that right?
A. Yes, I am.
Q. What is medicinal chemistry?
A. Medicinal chemistry is basically the science of discovering new drugs through studying their structure activity relationships.
And then developing the drug.
Q. And, structure activity relationships, is that SAR?
A. Correct.
Q. Okay. You provide in your declaration a fairly extensive background on various medicinal chemistry related issues, right?

A. Yes, I do.
Q. Now, I didn't see in the background section on your experience a reference to salt formation in your background.
Did I miss that?
A. That is not expertise that is typically communicated. That comes under the whole development experience scenario.
Q. Okay. So, you don't specifically reference in your declaration salt formation, is that right, as part of your background?
A. This is correct.
Q. Have you ever performed a salt screen?
A. Many times.
Q. Okay. When was the last time you performed a salt screen?
A. The last time would have been around 2014 or 2015.
Q. And was it you personally doing the salt screen, or were you supervising others in 2014?

A. At that point I was a supervisor.
Q. Okay. And what is a salt screen?
A. A salt screen is basically something that is done when you screen a particular salt and make -- screen a particular amino acid, and test it against various salts.
And particular aspect of the testing is whether these materials are going to be crystalline, or whether they are going to be easily hygroscopic or not.
So, you determine the most optimum favorable salt for your applications.
Q. So, in the first instance, you are checking to see whether, if it is a basic drug, the acid counterion forms a salt, right?
A. This is correct.
Q. And then if it forms a salt, you are evaluating the properties of the salt. Right?
A. This is correct.
Q. And so you indicated that you performed many salt screens.
How frequently prior to 2014, the

last time that you have done it, were you performing salt screens?
A. There were always at least one per drug that we worked on all through my career.
Q. Uh-huh. And so, would you be the one performing the salt screens if you were involved in the project in developing a drug?
Or would it be somebody else that you worked with?
A. In the early part of my career, it would have been me. In the later part when I rose through the ranks in the company I was more directional. I was more of a director than handling it myself.
Q. Okay. When you or your colleagues were performing the salt screens that you had personal involvement in, what did you do if a particular drug didn't form a salt with a counterion?
A. Our basic job was to explore through the screens the most optimal counterion.
And, there have been -- there is

knowledge of several bases which can form a counterion with an acid. And several acids which form a counterion with the base.

Q. Okay. So, if you were running a screen and the drug in question didn't form a salt with a counterion, would you move on to the next counterion that -- to form a salt? Is that the way it progressed?

DR. MALIK: Objection, foundation.

THE WITNESS: The way we progressed is to look at the salt formation and see what the nature of that salt is. And then move on if necessary.

BY MR. FISHER:

Q. Okay. Now when you perform salt screens, and I'm talking about you, being you, your team on the various projects you worked on, how many counterions did you typically evaluate with a particular drug in question? Was it two, three, a dozen?

Just give me some sense of how big the screens were.

A. In the early part of my career, we used to typically screen five inorganic acids. We would screen typically about eight to 10 inorganic bases.

And that was always our first, first shot at the problem.

Q. And, so just to make sure I have that right, roughly five inorganic acids, and eight to ten inorganic bases, on the one hand, against whatever drug in question you were looking to develop, on the other?

A. Yes, based on the structure.

Q. And, why would you screen both inorganic acids and inorganic bases at the same time?

A. It was not at the same time.

You would typically look at the structure. If it is an organic amine, you would look at the inorganic acids for forming a counterion.

If it was an organic acid, then you would look at the inorganic bases.

Q. I see.

A. But, not at the same time.

Q. I see, okay.

So, if the drug was a basic drug, you would look at the inorganic acids as the potential counterion?

A. This is correct.

Q. And did you have situations in your experience where you screened the eight to ten inorganic acids and you didn't get salt formation or one or more of the acids?

A. The typical five inorganic acids would always give a salt formation.

And, we have never encountered a case where there was no salt formation.

Q. Okay. And what were the --

Do you remember offhand what the five inorganic acids that you would typically screen were?

A. Yes, I do. It was hydrochloric acid, sulfuric acid. Phosphoric acid was a obvious one. At times it was nitric acid. And

then finally we always used to use something typically like benzene sulfonic acid.

Q. Okay. Do you consider yourself an expert in salt selection?

A. It is part of my general expertise as in drug discovery and development, yes.

Q. So, that is a yes, you do consider yourself an expert in salt selection?

A. Yes, I do.

Q. Now, when I reviewed the background in your declaration, I noticed that you don't reference polymorph characterization as part of your background.

Did I miss that?

A. I have not referenced polymorph formation.

Q. Do you consider yourself an expert in polymorph characterization?

A. Yes.

Q. Have you run polymorph screens previously?

A. Again, when I was a director, people

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