

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ICEUTICA PTY LTD and IROKO)
PHARMACEUTICALS, LLC,)
Plaintiffs,)
VS.) Case No. 14-1515
LUPIN LIMITED and LUPIN) (SLR-SRF)
PHARMACEUTICALS, INC.,)
Defendants.)
-----)

VIDEOTAPED DEPOSITION OF
MANSOOR AMIJI, R.Ph., Ph.D.
Friday, December 18, 2015
Irvine, California

REPORTED BY:

GRACE CHUNG, CSR No. 6426, RMR, CRR, CLR

Page 2	Page 4
<p>1 2 3 4 5 Videotaped Deposition of MANSOOR AMIJI, 6 R.Ph., Ph.D., taken on behalf of Plaintiffs, at 2040 7 Main Street, 14th Floor, Irvine, California, 8 beginning at 9:04 a.m. and ending at 11:40 a.m., on 9 Friday, December 18, 2015, before GRACE CHUNG, CSR 10 No. 6246, RMR, CRR, CLR. 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p>1 I N D E X 2 3 WITNESS: 4 MANSOOR AMIJI, R.Ph., Ph.D. 5 6 EXAMINATION PAGE 7 BY MS. FLANAGAN 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>
Page 3	Page 5
<p>1 A P P E A R A N C E S 2 3 For the Plaintiffs: 4 FISH & RICHARDSON 5 BY: ELIZABETH FLANAGAN, ESQ. 6 222 Delaware Avenue 7 17th Floor 8 Wilmington, Delaware 19801 9 (302) 778-8472 10 eflanagan@fr.com 11 (Via Videoconference) 12 13 For the Defendants: 14 KNOBBE MARTENS 15 BY: CHRISTY LEA, ESQ. 16 BEN ANGER, ESQ. 17 2040 Main Street 18 14th Floor 19 Irvine, California 92614 20 (949) 760-0404 21 christy.lea@knobbe.com 22 ben.anger@knobbe.com 23 24 Also Present: KEITH FARRIS, Videographer 25</p>	<p>1 E X H I B I T S 2 3 NO. DESCRIPTION PAGE 4 Exhibit 1 Declaration of Dr. Mansoor M. Amiji 23 5 6 Exhibit 2 U.S. Patent 8,679,544 33 7 8 Exhibit 3 Document entitled "Mastersizer 3000 53 9 Smarter Particle Sizing" 10 11 Exhibit 4 Document entitled "Exhibit 12" 54 12 13 Exhibit 5 HPPS Operators Guide 68 14 15 16 Q U E S T I O N S I N S T R U C T E D N O T T O A N S W E R 17 PAGE LINE 18 20 16 19 21 7 20 22 7 21 22 17 22 23 24 25</p>

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1 Irvine, California
 2 Friday, December 18, 2015
 3 9:04 a.m.
 09:04 4 THE VIDEOGRAPHER: Good morning. Here
 09:04 5 begins video disc number 1, volume 1, in the
 09:04 6 deposition of iCeutica Limited versus Iroko
 09:04 7 Pharmaceuticals -- strike that, iCeutica TTY [sic]
 09:04 8 Limited and Iroko Pharmaceuticals versus Lupin
 09:04 9 Limited and Lupin Pharmaceuticals.
 09:04 10 Today's date is December 18, 2015. The
 09:04 11 time is 9:04 a.m. this deposition is being taken at
 09:04 12 the firm of Knobbe Martens located at 2040 Main
 09:04 13 Street in Irvine, California, and was made at the
 14 request of the plaintiffs.
 09:04 15 My name is Keith Farris, the legal
 09:04 16 videographer and notary. The court reporter today is
 09:04 17 Ms. Grace Chung from Gregory Edwards, LLC.
 09:05 18 Would all counsel now please introduce
 09:05 19 yourselves and state whom you represent.
 09:05 20 MS. FLANAGAN: Elizabeth Flanagan with
 09:05 21 Fish and Richardson, PC, on behalf of the
 09:05 22 plaintiffs.
 09:05 23 MS. LEA: This is Christy Lea and Ben
 09:05 24 Anger from Knobbe Martens on behalf of the
 09:05 25 defendants and the witness.

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09:06 1 today; correct?
 09:06 2 A. Yes.
 09:06 3 Q. I will do my best not to interrupt your
 09:06 4 answers. Will you please try to do the same and
 09:06 5 not interrupt my questions?
 09:06 6 A. Yes.
 09:06 7 Q. Will you please do your best to answer
 09:06 8 verbally and without nodding or shaking your head?
 09:06 9 A. Okay.
 09:06 10 Q. And if you answer my questions, can we
 09:06 11 assume that you understand them?
 09:06 12 A. Yes.
 09:06 13 Q. If you need to make any modifications or
 09:06 14 corrections to the testimony during the day, please
 09:06 15 let me know, and I will give you an opportunity to
 09:06 16 do that on the record. Okay?
 09:07 17 A. Okay.
 09:07 18 Q. And we can take a break about every hour
 09:07 19 or so. If you need to take a break sooner than
 09:07 20 that, let me know, and I will just ask that you
 09:07 21 finish answering any question that is pending.
 09:07 22 Okay?
 09:07 23 A. Okay.
 09:07 24 Q. Is there any reason that you cannot
 09:07 25 provide complete and accurate and truthful

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09:05 1 MANSOOR AMIJI, R. Ph., Ph. D.,
 2 having been first duly sworn, was examined
 3 and testified as follows:
 4
 5 EXAMINATION
 09:05 6 BY MS. FLANAGAN:
 09:05 7 Q. Good morning, Dr. Amiji.
 09:05 8 A. Good morning.
 09:05 9 Q. So we are taking this deposition with me
 09:05 10 via video and you there in person with a
 09:05 11 videographer. Please feel free to turn and look at
 09:05 12 me on the video screen if you would like.
 09:05 13 Otherwise, direct your attention at the video
 09:05 14 camera when you are answering your questions.
 09:05 15 Okay?
 09:05 16 A. Sure.
 09:05 17 Q. You understand that you are under oath
 09:05 18 today, sir?
 09:06 19 A. Yes, I do.
 09:06 20 Q. You understand that the testimony you are
 09:06 21 giving today is as if you are sitting in a
 09:06 22 courtroom; correct?
 09:06 23 A. Yes.
 09:06 24 Q. You understand that there is a court
 09:06 25 reporter taking down my questions and your answers

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09:07 1 testimony today?
 09:07 2 A. No, there isn't.
 09:07 3 Q. Sir, you have a Ph.D. in pharmaceutics; is
 09:07 4 that correct?
 09:07 5 A. Yes.
 09:07 6 Q. And you obtained that degree from Purdue
 09:07 7 University?
 09:07 8 A. Yes.
 09:07 9 Q. Can you describe for me your -- in a
 09:07 10 general sense, your employment history since
 09:07 11 receiving your Ph.D.?
 09:07 12 A. So I finished my graduate degree at Purdue
 09:07 13 in 1992, and then I was first employed at Columbia
 09:07 14 Research Lab in Madison, Wisconsin, from July of
 09:08 15 1992 to December of 1992. And then since January
 09:08 16 of '93, I came to Northeastern university in
 09:08 17 Boston, and I started as an assistant professor
 09:08 18 there, and I've been at Northeastern since.
 09:08 19 Q. What kind of work did you do at Columbia
 09:08 20 Research Labs in general?
 09:08 21 A. Columbia Research Lab was a company that
 09:08 22 started out by a faculty member at University of
 09:08 23 Wisconsin, Madison, and they were interested in
 09:08 24 hydrogel-based drug delivery.
 09:08 25 Q. And did you work in the lab during your

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09:08 1 time there?
 09:08 2 **A.** No. I worked with a company.
 09:08 3 **Q.** Generally, what kind of tasks were you
 09:08 4 responsible for, if you recall?
 09:08 5 **A.** There are several different kinds of tests
 09:08 6 that we did. We looked into hydrogel delivery
 09:08 7 systems for both oral administration as well as
 09:09 8 other routes of administration, and we looked at
 09:09 9 drug release. We looked at various absorption
 09:09 10 profiles, properties of the hydrogel, especially in
 09:09 11 relation to the adhesiveness to tissues.
 09:09 12 **Q.** Did you do any kind of postdoctorate work?
 09:09 13 **A.** No. I came straight from Purdue after
 09:09 14 receiving my Ph.D. into a career first in industry
 09:09 15 at Columbia Research Lab and then in academia.
 09:09 16 **Q.** At Northeastern, do you have a lab? Are
 09:09 17 you in charge of a research lab?
 09:09 18 **A.** Yes, I am.
 09:09 19 **Q.** And have you been in charge of a research
 09:09 20 lab since you joined the university in 1993?
 09:09 21 **A.** Yes.
 09:09 22 **Q.** In general terms, at this time, what is
 09:10 23 the focus of the research ongoing in your lab or
 09:10 24 under your direction in your lab?
 09:10 25 **A.** So we work on pharmaceutical formulations,

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09:11 1 **A.** So there are approaches where you design
 09:11 2 nanoparticles or nanodelivery systems using the
 09:11 3 same technologies of fabrication that's used for
 09:11 4 making computer chips.
 09:11 5 **Q.** What did you mean by "milling processes"?
 09:11 6 **A.** So milling is a process where you reduce
 09:11 7 particle size. You start out with either
 09:12 8 large-sized crystal of a drug and then you reduce
 09:12 9 it down to a smaller size.
 09:12 10 In our case, this would be nanoparticles
 09:12 11 that are made using those crystals of drugs, larger
 09:12 12 crystals.
 09:12 13 **Q.** What do you mean by "nanoparticle"?
 09:12 14 **A.** So nanoparticle is basically defined as an
 09:12 15 entity that has a dimension of 1 to 1,000
 09:12 16 nanometer.
 09:12 17 **Q.** How long has your research lab been
 09:12 18 working on ways to make nanoparticles?
 09:12 19 **A.** So I started even when I was at Purdue, so
 09:12 20 I would say even before I came to Northeastern in
 09:12 21 '93. But since '93, as I've been at Northeast,
 09:13 22 I've been working on nanoformulations now. So it
 09:13 23 would be, I would say, close to about 23 — yeah,
 09:13 24 23 years.
 09:13 25 **Q.** Okay. So nanoparticle has always been

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09:10 1 specifically looking at various ways to enhance the
 09:10 2 delivery of drugs to target sites in the body. We
 09:10 3 work with various formulations that are intended
 09:10 4 for oral, intranasal and systemic therapies, and we
 09:10 5 are specifically focused on nanoparticle-based drug
 09:10 6 delivery systems.
 09:10 7 **Q.** Did your lab focus on ways to make
 09:10 8 nanoparticles?
 09:10 9 **A.** Yes.
 09:10 10 **Q.** The research lab?
 09:10 11 THE REPORTER: I'm sorry. I could not
 09:10 12 hear you. Research?
 09:10 13 BY MS. FLANAGAN:
 09:10 14 **Q.** Your research lab.
 09:10 15 **A.** Yes.
 09:10 16 **Q.** And — thank you. What ways is your lab
 09:11 17 currently researching for how to make
 09:11 18 nanoparticles?
 09:11 19 **A.** So we have used a number of methods. We
 09:11 20 have worked with nanoprecipitation methods. We
 09:11 21 have also used nanofabrication. We have used
 09:11 22 approaches such as the milling processes. We have
 09:11 23 used a number of different strategies to make
 09:11 24 nanoparticles.
 09:11 25 **Q.** What do you mean by nanofabrication?

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09:13 1 part of the research that your lab has been focused
 09:13 2 on?
 09:13 3 **A.** Yes. In — you know, we have used a
 09:13 4 number of different formulation, again, designing
 09:13 5 for oral or systemic administration.
 09:13 6 **Q.** You're not a medical doctor; correct?
 09:13 7 **A.** No. I am a pharmacist.
 09:13 8 **Q.** But you're not — you don't have an MD
 09:13 9 degree?
 09:13 10 **A.** No. I have a Ph.D., and I'm also an R.Ph.
 09:13 11 I am a pharmacist.
 09:13 12 **Q.** But you're not a medical doctor?
 09:13 13 **A.** No, I'm not a medical —
 09:13 14 **Q.** You don't have an MD degree?
 09:13 15 **A.** No.
 09:13 16 **Q.** And as a registered pharmacist, have you
 09:14 17 ever prescribed a medication?
 09:14 18 **A.** No. I — certainly, you know, I have
 09:14 19 worked on various types of medications from my
 09:14 20 research perspective, as well as I'm familiar with,
 09:14 21 you know, medication-dispensing function, and
 09:14 22 I've — previously I worked as a pharmacist in
 09:14 23 dispensing, but these days I don't work as a
 09:14 24 pharmacist, but I still maintain my license.
 09:14 25 **Q.** But the answer to my question in terms of

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09:14 1 do you prescribe medications, the answer is no?
 09:14 2 **A.** Yes. No, I don't prescribe medications.
 09:14 3 **Q.** And you never have?
 09:14 4 **A.** That's correct; yes, I've never prescribed
 09:14 5 medications.
 09:14 6 **Q.** When did you work as a registered
 09:14 7 pharmacist?
 09:14 8 **A.** It was quite a while ago. I would say
 09:14 9 sometime in the early 2000.
 09:15 10 **Q.** And you were actually dispensing
 09:15 11 medications in that role?
 09:15 12 **A.** Yes.
 09:15 13 **Q.** Have you ever been involved in writing
 09:15 14 clinical study protocols for investigating a drug?
 09:15 15 **A.** I have reviewed a number of different
 09:15 16 clinical protocols for various type of new drug
 09:15 17 applications, as well as abbreviated new drug
 09:15 18 applications.
 09:15 19 **Q.** So you've never been involved in writing
 09:15 20 those clinical study protocols, though?
 09:15 21 **A.** Not writing, but I have been -- I have
 09:15 22 certainly reviewed as part of the NDA or ANDA
 09:15 23 submissions.
 09:15 24 **Q.** And in what context have you been
 09:15 25 reviewing clinical study protocols?

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09:15 1 **A.** In term -- when I consult for companies
 09:15 2 that are interested in developing formulations that
 09:16 3 are going through clinical trials, as well as a
 09:16 4 number of different cases that I've been involved
 09:16 5 as an expert witness.
 09:16 6 **Q.** Have you been involved in writing clinical
 09:16 7 study reports for drugs?
 09:16 8 **A.** No. Again, I have reviewed reports as
 09:16 9 well. I have reviewed various reports that have
 09:16 10 come from clinical trials.
 09:16 11 **Q.** Have you ever served as a clinical study
 09:16 12 investigator?
 09:16 13 **A.** No, I have not.
 09:16 14 **Q.** The protocols and clinical study reports
 09:16 15 that you mentioned you reviewed, have any of them
 09:16 16 related to NSAIDs?
 09:17 17 **A.** I'm sorry. I didn't get the last part of
 09:17 18 your question.
 09:17 19 **Q.** N-S-A-I-D-S, NSAID drugs?
 09:17 20 **A.** Yes. You mean the nonsteroidal
 09:17 21 anti-inflammatory drugs. I believe there may be
 09:17 22 some. I don't recall exactly, but I have worked on
 09:17 23 NSAIDs for, you know, both in my research, as well
 09:17 24 as I've also reviewed a number of clinical
 09:17 25 protocols based on some of the work that I have

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09:17 1 done.
 09:17 2 **Q.** Your consulting work?
 09:17 3 **A.** Correct.
 09:17 4 **Q.** Approximately how many times have you been
 09:17 5 deposed, Dr. Amiji?
 09:17 6 **A.** I would say about six or seven times.
 09:17 7 **Q.** Have you testified at trial before?
 09:17 8 **A.** Yes, I have.
 09:17 9 **Q.** About how many times?
 09:17 10 **A.** Three times.
 09:17 11 **Q.** Have you testified at any hearings in
 09:18 12 court outside the context of a trial?
 09:18 13 **A.** Yes, I have.
 09:18 14 **Q.** About how many times?
 09:18 15 **A.** One.
 09:18 16 **Q.** Do you recall the context for that
 09:18 17 hearing?
 09:18 18 **A.** Yes.
 09:18 19 **Q.** And what was that hearing for?
 09:18 20 **A.** It was an arbitration panel. I was an
 09:18 21 expert witness serving on an arbitration panel.
 09:18 22 **MS. LEA:** And sometimes arbitrations are
 09:18 23 confidential, so I would caution the witness not to
 09:18 24 reveal any confidential information about other
 09:18 25 parties.

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09:18 1 **BY MS. FLANAGAN:**
 09:18 2 **Q.** When was the last time that you gave
 09:18 3 testimony under oath, either at a deposition,
 09:18 4 trial, or arbitration?
 09:18 5 **A.** In the latter part of November this year.
 09:19 6 **Q.** Doctor, did you do anything to prepare for
 09:19 7 your deposition today?
 09:19 8 **A.** Yes. I reviewed my report, my
 09:19 9 declaration. I reviewed the patents. I reviewed
 09:19 10 the various exhibits.
 09:19 11 **Q.** When patents did you review?
 09:19 12 **A.** The patents-in-suit.
 09:19 13 **Q.** And what do you mean, "the various
 09:19 14 exhibits"? What -- what does that mean?
 09:19 15 **A.** The exhibits that are part of the
 09:19 16 declaration that I provided.
 09:19 17 **Q.** So your CV and the materials considered
 09:19 18 list?
 09:19 19 **A.** That's correct.
 09:19 20 **Q.** Anything else that you reviewed to prepare
 09:19 21 for your deposition?
 09:20 22 **A.** No. It's -- yeah, those are the documents
 09:20 23 that I -- you know, that have been involved. In
 09:20 24 preparing the declaration, I basically reviewed all
 09:20 25 of those documents.

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