UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF VIRGINIA

ALEXANDRIA DIVISION

GILDA HAGAN-BROWN,	)	
Plaintiff,	)	
vs.	)	1:14-CV-01614-AJT-JFA
ELI LILLY AND COMPANY,	)	Hon. Anthony J.
an Indiana corporation,	)	Trenga
Defendant.	)	

The videotaped deposition of MATT KUNTZ, taken in the above-entitled cause, before Paula Ann Erickson, Certified Shorthand Reporter, Registered Professional Reporter and Notary Public, on May 6, 2015, at the Double Tree Hotel, 510 East Illinois Route 83, Mundelein, Illinois, at the approximate hour of 1:36 p.m.

Reported by: Paula A. Erickson, CSR, RPR, CLR

APPEARANCES:

MR. R. BRENT WISNER
BAUM, HEDLUND, ARISTEI & GOLDMAN, PC
12100 Wilshire Boulevard
Suite 950
Los Angeles, California 90025
(310) 707-3233
rbwisner@baumhedlundlaw.com

Appeared on behalf of the Plaintiff.

MR. MICHAEL F. LYNCH
LYNCH LAW OFFICE
3613 South Eastern Avenue
Las Vegas, Nevada 89169
(702) 684-6000

Via telephone on behalf of the Plaintiff, Robert Gentry, in Nevada action.

MR. KEITH A. TEEL and MR. BRETT C. REYNOLDS
COVINGTON & BURLING, LLP
One City Center
850 Tenth Street, NW
Washington, D.C. 20001
(202) 662-5501
kteel@cov.com
breynolds@cov.com

Appeared on behalf of the Defendant and the Deponent, Matt Kuntz.

ALSO PRESENT:
Stephan Hoog - Videographer

* * * *

I N D E X

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Note: Deposition Exhibit Nos. 1 - 15 were marked and attached to the transcript.

prescribing Cymbalta?

A. Well, that would be how it would start; and then that would be submitted and discussed with FDA and ultimately approved by FDA.

Q. Okay. So the original drafting of these sections, the content of those sections, that was done by Lilly, correct?

A. Correct.

Q. And then that was submitted for the FDA to get approval from the FDA?

A. That's right.

Q. All right. Would it be fair to say that that was the same process that occurred for all of the labeling content and all of the labeling?

A. No. It wouldn't.

Q. Okay. Are there certain sections that the FDA specifically writes?

A. They may at times write certain language prior to, say, a sponsor admitting it and that often is the case with what's called Class Labeling where there may be -- FDA may be aware of an issue because they are reviewing across a whole class of drugs, and they would identify potentially some sort of labeling

revision that would be needed and they would notify the sponsors.

Q. Is an example of Class Labeling is that the boxed warning?

A. Correct. Yep.

Q. Okay. So the boxed warning wasn't specifically written by Lilly, correct?

A. I don't know if it was initially written by Lilly for Cymbalta, but I know this is for the antidepressant class a class warning.

Q. Okay. Are you familiar with any other sections that were Class Labeling in this label?

A. I do believe there were some drug interactions that were potentially added, but I am not sure about anything specifically.

Q. Does anything prevent Lilly from requesting a change or exclusion to Class Labeling to the FDA?

A. No. Nothing would prevent us from attempting to propose a change or a modification.

Q. So, for example, if some specific Class Labeling didn't really apply to Cymbalta, Lilly could submit an application to the FDA saying this didn't apply?

A. Yes. You could.
Q. And presumably that would have to be supported by some sort of data?
A. Right.
Q. Okay. The sections under Section 17 for patient counseling information, do you know when that was included in the Cymbalta label?
A. No, I don't. It would have been at the time the label was revised to comply with this PLR format, I don't believe -- I don't believe, and I am not sure about the timing about when this specific format was adopted, but I believe it was after the initial approval of Cymbalta.
Q. Cymbalta was approved in 2004, right?
A. Right.
Q. Is it your understanding that the PLR, or the Position Labeling Rule, was implemented around 2006, 2007?
MR. TEEL: Objection. Lack of foundation.
THE WITNESS: That sounds right but, again, I don't remember --
BY MR. WISNER:
Q. Okay.
A. -- the timing for the PLR.

what that means?

A. Yes. Spontaneous is a term that is used to indicate that the terms were not solicited. For example, like in a clinical trial setting, the clinical trial investigators ask have you had any adverse events, what were those, et cetera, so you are actually soliciting that information; whereas, in the postmarketing setting, these would be terms, events, cases that would be reported to Lilly unprompted without any sort of solicitation through the call center or maybe through a sales rep or other mechanism.

Q. Okay. Is it your under -- Okay. Now just take a second and just finish reading through the rest of the section just so you have a sense of what's in it.

A. Okay.

Q. Let me know when you are done.

A. Okay. I am finished.

Q. Keep that Exhibit 1 open to that section because we are going to be referencing it.

A. Okay.

(Whereupon, Deposition Exhibit No. 2 was marked and dated.)

BY MR. WISNER:

Q. I am handing you what I have marked as Exhibit 2. Do you recognize this document?

A. Well, I am looking at the title. It's the Summary of Product Characteristics so it would be the European label.

Q. And that would be if you turn the page, this is referring to Cymbalta?

A. For Cymbalta, yes.

Q. Okay. Now, if you turn to Page 6, do you see the section that's titled Discontinuation of Treatment?

A. I do.

Q. Okay. Now, would it be fair to say that this is sort of the European counterpart to the US label?

MR. TEEL: Objection. Lack of foundation.

THE WITNESS: Yeah. It looks to be, yeah, the same kind of information.

BY MR. WISNER:

Q. In the US label, the section is titled Discontinuation of Treatment with Cymbalta,

right?

A. Yes.

Q. And in this label it's titled Discontinuation of Treatment. Do you see that?

A. Right.

Q. Okay. Now in the European label -- Have you seen this label before?

A. Yeah. I am sure I have seen it before, yes.

Q. And during the time that you were a US Regulatory Associate?

A. Yes.

Q. Okay. If you read right here it says, "Withdrawal symptoms when treatment is discontinued are common, particularly if discontinuation is abrupt" and then it references the section see 4 -- see Section 4.8, right?

A. Uh-huh.

Q. Now, it says right here in the European label withdrawal symptoms. Do you see that?

A. I do.

Q. And you would agree with me that nowhere in the US label does it say withdrawal symptoms, and let me specify that question.

Nowhere in this Section 5.7 does it say withdrawal symptoms?

A. No. I don't see it here.

Q. Okay. Under European label it says, "Withdrawal symptoms when treatment is discontinued are common." Nowhere in Section 5.7 in the US label does it say that discontinuation symptoms are common?

MR. TEEL: Object to the form.

THE WITNESS: No. It doesn't say that in the label.

BY MR. WISNER:

Q. Okay.

A. Although I would note that as a pharmacist and I am assuming most healthcare professionals would be aware that any antidepressant has the potential for withdrawal symptoms for discontinuation.

Q. I understand that but my question was that the US label specifically doesn't say that discontinuation symptoms are common, right?

A. No.

Q. Okay. In the European label it goes on to read, "In clinical trials, adverse events seen on abrupt treatment discontinuation

occurred in approximately 45 percent of patients treated with Cymbalta and 23 percent of patients taking placebo." Do you see that?

A. I do.

Q. And previously you mentioned that you had seen that 45 percent language before.

A. I don't know if we saw it or we just discussed it, but yes.

Q. Okay.

A. Yeah.

Q. And in the US label under Section 5.7, it doesn't make any mention of any 45 percent?

A. No.

Q. Okay. During your time at Lilly, were you ever aware of whether or not Lilly ever attempted to change the Section 5.7 in the US label to include any 45 percent?

A. I'm not aware.

Q. And that didn't occur while you were a US Regulatory Associate, correct?

A. As far as I know, we didn't -- I don't recall any revisions to this particular section of the USPI.

Q. Okay. The next sentence in the European label says, "The risk of withdrawal

symptoms seen with SSRIs and SNRIs may be dependent on several factors including the duration and dose of therapy and the rate of dose reduction." Do you see that?

A. Yes.

Q. The US label doesn't state that the severity -- Strike that.

The US label doesn't state that the risk of withdrawal symptoms may be dependent on the dose or duration of therapy, does it?

MR. TEEL: Objection. Lack of foundation.

THE WITNESS: No. It doesn't.

BY MR. WISNER:

Q. Okay. In the European label, jump down a few sentences here, it says, "They" and it's referring to withdrawal symptoms, right, they usually occur -- Sorry. Let me say that -- Do you see the sentence that starts with, "They usually occur"?

A. Uh-huh.

Q. "They" that's referring to withdrawal symptoms, right?

A. Yes.

Q. Okay. And it reads, "They usually

occur within the first few days of discontinuing treatment but there have been very rare reports of such symptoms in patients who have inadvertently missed a dose." Do you see that?

A. I do.

Q. Now, in the US product insert under the section Discontinuation of Treatment with Cymbalta, it does not state that discontinuation symptoms will occur or likely occur within the first few days of treatment -- discontinuing treatment?

A. No. I don't see that.

Q. And in the US label, there is no mention that inadvertently missing a dose could potentially lead to discontinuation symptoms?

A. No.

Q. And, again, I take it because you don't recall any efforts being done by Lilly to change this section while you were at Lilly, are you aware of whether or not Lilly ever attempted to include a statement about missing doses in the US product insert?

A. No. I don't recall of anything like that.

Q. And if there was, in fact, evidence to

support that particular risk, based upon your experience as a US Regulatory Associate, Lilly could have taken actions to try to include that information in the US label, correct?

A. If it would -- I think it would depend on the data and the reliability of the data itself. What you are saying, yes, is theoretically possible.

Q. And it's possible that Lilly could have changed the US label to include the 45 percent risk, right?

MR. TEEL: Objection. Lack of foundation.

THE WITNESS: Well, Lilly could have potentially. Again, with all the, you know, caveats around the sources of data for this, but could have proposed it to FDA.

BY MR. WISNER:

Q. Okay.

A. It's, you know, FDA ultimately approves the label and it would appear to me that without looking at across other SSRIs, that this is fairly standardized language.

Q. But you haven't looked at other SSRIs, correct?

A. No. I haven't. I don't remember anything from when I was in this role.

Q. So you're just saying that based -- What do you base that opinion that it's standardized language?

A. Based on the last two paragraphs and often FDA would, again, in my experience, allow a sponsor to provide some product -- their product specific information and then follow it with more class labeling.

Q. Okay. So the first paragraph then in the US label, that appears to be a product specific section?

A. That's -- that's right.

Q. Okay. In the European label, the next sentence says, "Generally, these symptoms are self-limiting and usually resolve within two weeks, though, in some individuals they may be prolonged two to three months or more." Do you see that?

A. Yes.

Q. Now, if you look at the US section on Discontinuation of Treatment with Cymbalta, there is no indication -- well, first of all, there is no statement that discontinuation

symptoms could last two to three months or more?

A. There is the statement that the events are self-limited -- generally self-limiting and some have been reported to be severe but there is nothing that would say prolonged for two to three months.

Q. And, in fact, there is no indication in the US label about how long discontinuation symptoms may last?

A. Well, I mean, the self-limiting language, but it doesn't, again, reflect that kind of potential for a prolonged experience.

Q. And what is your understanding of the phrase "self-limiting"?

A. That they resolve without further intervention.

Q. Okay. Does it suggest that it's a short period of time or does it have no -- Does it suggest that it's a short period of time?

MR. TEEL: Objection. Lack of foundation.

THE WITNESS: I wouldn't necessarily think of it that way, no. It's just it's self-limiting. It's it will resolve without intervention.

BY MR. WISNER:

Q. Now, based on your understanding of that, is two to three months is that -- if someone were to experience symptoms for two to three months, is that -- could that still be self-limiting?

MR. TEEL: Objection. Lack of foundation.

THE WITNESS: Yeah. I guess it could with that sort of definition, yeah.

BY MR. WISNER:

Q. Because eventually after two to three months, it would have gone away on its own?

A. Yeah. That's it resolves on its own. That's a good way of saying it.

Q. Okay. All right. The last sentence here in the European label says, "It is, therefore, advised that the duloxetine should be gradually tapered when discontinuing treatment over a period of no less than two weeks according to the patient's needs." Do you see that?

A. I do.

Q. And it references a section see

Section 4.2. Do you see that?

A. I do.

Q. Now, in the US label under Section 5.7 or Section 2.4 which we looked at previously, it does not state that discontinuation of Cymbalta should be tapered over a period of no less than two weeks, does it?

A. No. It doesn't say two to four weeks.

Q. In fact, nowhere in the US label in either Section 5.7 or 2.4 does it tell you a time period for which tapering should be done?

A. Gradual is the only language that I have seen.

Q. But you would agree with me that gradual over three days is different than gradual over three months, right?

A. Yeah.

Q. So this doesn't give you a timeframe specifically in the US label?

A. No.

Q. All right. Do you recall whether Eli Lilly ever attempted to include a statement of discontinuing over a period of no less than two weeks into the US product insert?

A. Not that I recall.

(Whereupon, Deposition Exhibit No. 3 was marked and dated.)

BY MR. WISNER:

Q. Okay. Doctor, I am handing you what I have marked as Exhibit 3. Actually, though, before we talk about that exhibit, you'd agree that the information contained on the European label is different than -- with regards to discontinuation is different than the information contained on the US label?

MR. TEEL: Object to the form.

THE WITNESS: I think that the way the information is conveyed is different. It's -- it's more focused on the likelihood of a discontinuation event occurring versus the kinds of events that occur.

BY MR. WISNER:

Q. And when you are referring when you say "it," you're referring to the European label?

A. Yes. In the first instance it was the European label versus the kinds of events, the observed events, being represented in the USPI.

Q. I'm happy you raised that. If you actually could turn to Page 8 of the European label. Sorry. Before you do that. On Page 6,

you see it says in the first sentence it says see Section 4.8?

A. Yes.

Q. And that's in reference to withdrawal symptoms when treatment is discontinued are common. Do you see that?

A. I do.

Q. Okay. So let's turn to Section 4.8. I believe it starts on Page 4.8 -- starts on Page 8. Do you see that?

A. At the bottom, yes.

Q. Yeah. If you turn the page -- Well, it starts off it says Undesirable Effects, right? Do you see that?

A. I do.

Q. And it says the Summary of the Safety Profile and it reads, The most commonly reported adverse reactions. Do you see that?

A. Yes.

Q. And if you turn the page, under Section B it says Tabulated summary of adverse reactions. Do you see that?

A. Yes.

Q. And it says Table 1 and it's labeled Adverse Reactions, right?

A. Right.
Q. And Table 1, that spans three pages; is that true?
A. Yes.
Q. And then if you look at Section C, it says Description of selected adverse reactions. Do you see that?
A. I do.
Q. And then under there it says, "Discontinuation of duloxetine, particularly when abrupt, commonly leads to withdrawal symptoms."
A. Okay.
Q. And then it says, "dizziness, sensory disturbances, including paresthesia or electric like -- shock-like sensations, particularly in the head, sleep disturbances, including insomnia and intense dreams, fatigue, somnolence, agitation or anxiety nausea and/or vomiting," and it keeps going on with a bunch of different potential reactions, right?
A. Right.
Q. Take a second look at the US label. All of the reactions listed in first paragraph of 5.8, those reactions are contained

in that paragraph, right?

MR. TEEL: Object to the form.

THE WITNESS: I can do a check real quick.

BY MR. WISNER:

Q. Yeah. Please do.

A. I don't see -- Maybe I just missed it. Myalgia is that there? I'm not sure.

Q. That is. It's right after headache in the European label. Between headache and irritability.

A. No -- Yeah. Okay. I am looking at the USPI.

Q. Oh. Okay.

A. You're asking me if all of the USPI terms are in here?

Q. Yes.

A. Yes.

Q. In here, you're referring to the European label?

A. Yes. In the SPC, European label.

Q. Okay. And, in fact, the SPC, or the European label, that has actually more reactions than the US label, right?

A. Yeah. I think it looks like it does.

Q. Okay. So a second ago I said that the information contained in the European label that contains different information than the US label. Would it be fair to say actually that it contains more information about the risks of discontinuation than the US label?

MR. TEEL: Object to the form.

THE WITNESS: I think it contains more text and additional details, yes.

BY MR. WISNER:

Q. And by additional details, for example, the European label says that these symptoms occurred in 45 percent of patients; whereas, the US label doesn't mention 45 percent, right?

A. That would be an example.

Q. And the European label says that symptoms can last two to three months or more and the US label doesn't specify a timeframe, right?

A. It only says gradual.

Q. Yeah. And in the US -- and the European label says you should discontinue over a period no less than two weeks and the US label doesn't make a mention of how long tapering should occur for.

A. Right.
Q. So, Doctor, again my question, you can disagree with me if you want, would it be fair to say that the European label contains more information about the risks of discontinuation than the US label?
MR. TEEL: Object to the form. Use specifically of the term "doctor".
THE WITNESS: It would appear based on the comparison across these two regional labels that there is different information and a more descriptive -- more description of the overall incidence of discontinuation events and more details around what gradual discontinuation means in the European label.
BY MR. WISNER:
Q. Now, the US label, did you ever discuss with ever anyone at Eli Lilly in the Medical or in the Regulatory Group that physicians might get confused about the 1 percent threshold in that label?
A. No. I don't recall ever having a discussion about that.
Q. If a physician were to read that and think that the risks of discontinuation are

2009, right?

A. That's right.

Q. And this memo is dated 2007?

A. Right.

Q. Okay. Do you know whether or not in 2007 this memo was shared with Lilly?

A. I don't.

Q. Okay. All right. Well, this is -- and in the Executive Summary it says, "During routine postmarketing surveillance of medication errors, DMETS identified a signal involving the opening of Cymbalta capsules prior to administration to achieve a lower dose of the drug."

What is DMETS?

A. It's the FDA Division of Medication Errors and Technical Support.

Q. Okay. And it says identified a signal. What is your understanding of that word "signal"?

A. Yeah. That's a -- that's a term that would signify that in the review of aggregated safety data from the errors database, this issue came up somehow in their analysis. There is lots of probably different algorithms that they

would have applied but --

Q. And you have familiarity with such things as signals based on your work in the Pharmacovigilance Group, right?

A. Yeah. That's right.

Q. Okay. It says here that there has been a signal that opening of Cymbalta capsules prior to administration to achieve a lower dose of the drug.

Do you ever recall discussing this issue at Eli Lilly in your regulatory capacity?

A. I don't.

Q. Okay. If you turn the page, on Page 2, under Section 3, it says, "During routine monitoring of medication errors, DMETS received a case where a patient intentionally opened a Cymbalta capsule to achieve a lower dose."

During your time at Eli Lilly, do you recall ever having any discussions with anyone at Eli Lilly about people opening up the capsules to create smaller dosages for Cymbalta?

A. I don't.

Q. Do you recall whether or not anyone at Eli Lilly took actions to update the label or make changes to the US label in response to the

potential of patients opening up Cymbalta capsules?

A. I don't recall that.

Q. Okay. If you turn to Page 3, under Section C, Wrong Technique, go down midway through the paragraph. It says, "One (n=1) case involved opening 20 milligram capsules while tapering off Cymbalta to avoid withdrawal effects."

Do you see that?

A. I do.

Q. In this document, the FDA has identified a signal and supporting that identification of that signal is discussing at least one incident where a patient has opened the 20 milligram capsule so as to avoid withdrawal effects, correct?

A. That's what this report is stating.

Q. Do you know whether or not Lilly took any actions to update the label to warn patients not to open up the 20 milligram capsules to avoid withdrawal effects?

A. I don't recall.

Q. Do you know if Lilly, at any time, considered submitting a prior approval

supplement to obtain smaller doses of Cymbalta for the purposes of tapering?

A. No. I'm trying to recall if there was a lower dose for the pediatric studies but I just don't recall.

Q. Okay. So do you recall -- Well, do you recall whether or not Lilly ever did try to obtain a smaller than 20 milligram dose of Cymbalta -- Sorry. Let me rephrase that.

Do you recall whether or not -- Do you know whether or not Lilly ever tried to obtain approval for a dosage of Cymbalta less than 20 milligrams?

A. I don't know.

Q. Okay. Turn to Page 6, it says, Upon -- under Section 3, the paragraph under Section 3 -- Well, the section reads Institute of Safe Medicine Practices Outpatient Medication Errors. And then underneath that it says, "Upon DMETS request, the Institute for Safe Medication Practices (ISMP) searched their database for outpatient medication errors involving Cymbalta."

Do you -- The ISMP, that's the organization that published that QuarterWatch

report we mentioned earlier, right?

A. Right.

Q. And it appears here that the FDA's DMETS has requested data from that organization?

A. Yes. That's what it looks like.

Q. Okay. If you turn to Page 7 under Section A, Patients Attempting to Reduce or Avoid Adverse Effects of Cymbalta, do you see that section?

A. Yes.

Q. All right. Second to the last sentence in that paragraph, the first paragraph it reads, "Three cases (n=3) reported patients opening the capsules to create a dose of Cymbalta less than 20 milligrams in an attempt to reduce the adverse events associated with the discontinuation of Cymbalta."

Would it have been possible for Lilly to have submitted an SNDA -- or sorry -- a preapproved -- Would it have been possible for Lilly to have submitted a Prior Approval Supplement to obtain smaller doses -- approval -- to obtain approval of smaller doses of Cymbalta below 20 milligrams?

MR. TEEL: Objection. Calls for

speculation. Lack of foundation.

THE WITNESS: I mean, it's not as simple as just submitting that, you know, request to FDA. They would expect to have data to support the use of that and you would have to do quite a bit, I would think, of clinical evaluation of that lower dosage form.

BY MR. WISNER:

Q. Do you know if Lilly ever did conduct clinical trials to evaluate the discontinuation effects of a subtherapeutic dose below 20 milligrams?

A. I'm not aware.

Q. Okay. Based on your understanding of the CBE regulation, would Lilly have been able to make changes to the Cymbalta label advising patients that there was no way to taper below 20 milligrams?

MR. TEEL: Objection. Again, lack of foundation.

THE WITNESS: I'm not sure I quite understand what you are asking. Can you rephrase it?

BY MR. WISNER:

Q. Using the CBE regulation, would Lilly

have been able to make changes to the discontinuation warning in the Cymbalta label for the US advising patients that there was no way to taper below 20 milligrams?

A. Well, again, I think it could have been possible is the best way to answer that question.

Q. Thank you. You can't say for sure right now that it would have been impossible?

A. Yeah. That's right.

Q. Okay. Do you recall ever being consulted about potential changes to the Japanese label for Cymbalta?

A. I believe this was something we may have discussed in preparation for today. I am not a hundred percent sure.

Q. Okay. Well, independent of what any lawyer may have said to you --

A. Right.

Q. -- do you recall that your approach to make changes -- your approach about the Japanese label?

A. I honestly, at the moment, I don't remember that. For some reason, though, there is something in that -- anyways, I'm sorry. I

deposition of Matthew Kuntz.

THE REPORTER: Mr. Wisner, how do you prefer your production?

MR. WISNER: Electronic. Can we get it in about a week?

THE REPORTER: Absolutely. Sir, copy?

MR. REYNOLDS: Just electronic. About a week also.

(Deposition concluded at 6:06 p.m.)

(FURTHER DEPONENT SAITH NOT.)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

GILDA HAGAN-BROWN,)
Plaintiff,)
vs.) 1:14-CV-01614-AJT-JFA
ELI LILLY AND COMPANY,) Hon. Anthony J. Trenga
an Indiana corporation,)
Defendant.)

I, MATT KUNTZ, being first duly sworn, on oath say that I am the deponent in the aforesaid deposition taken on May 6, 2015; and that said transcript consisting of Pages 1 to 222 is a true and correct record of the testimony given by me at said deposition except as I have so indicated on the errata sheets provided herein.

_____
MATT KUNTZ

Subscribed and sworn to
before me this day
of , 2015

Notary Public

C E R T I F I C A T E

I, Paula Ann Erickson, Certified Professional Reporter, Registered Professional Reporter and Notary Public, do hereby certify:

That the witness in the foregoing deposition named was present at the time and place therein specified;

That the said proceeding was taken before me as a Notary Public at the same time and place and was taken down in shorthand writing by me;

That this transcript is a true and accurate transcript of my shorthand notes so taken, to the best of my ability.

I further certify that I am neither counsel for nor related to or employed by any of the parties to this action and that I am not a relative or employee of any counsel employed by the parties hereto or financially interested in the action.

Paula Ann Erickson
Certified Shorthand Reporter
Registered Professional Reporter
License No. 084-003899
Notary Public

Dated this 15th day

of May, 2015.