UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,	)	
	)	Cause No.
Plaintiff,	)	1:10-CV-01376-TWP-DKL
	)	Indianapolis, Indiana
vs.	)	**August 22, 2013**
	)	9:04 a.m.
TEVA PARENTERAL MEDICINES, INC., APP PHARMACEUTICALS, LLC, PLIVA HRVATSKA D.O.O., TEVA PHARMACEUTICALS USA, INC., BARR LABORATORIES, INC.,	)	
	)	
Defendants.	)	
	)	

V O L U M E IV

Before the Honorable
TANYA WALTON PRATT

OFFICIAL REPORTER'S TRANSCRIPT OF
BENCH TRIAL

Court Reporter: David W. Moxley, RMR, CRR, CMRS
United States District Court
46 East Ohio Street, Room 340
Indianapolis, Indiana 46204

PROCEEDINGS TAKEN BY MACHINE SHORTHAND
TRANSCRIPT CREATED BY COMPUTER-AIDED TRANSCRIPTION

approving the drug, was saying no. So, it was a tough situation, yeah. We had to act quickly.

Q. And during the call, was there a discussion about what the response should be?

A. Yes, there was.

Q. Can we take a look at Exhibit 2262, please? And let's pull up 1-1. Thank you.

Is this the letter that Lilly sent back to the FDA the next day, on December 22nd, Doctor?

A. Yes, it is.

Q. And in the beginning, does the letter just recast what the response was -- what the FDA's fax said?

A. Yes, in the fax of December 21st, late afternoon.

Q. And that's -- the FDA said that the information in the annual report about the toxicities in the trial does not appear to support the addition of vitamins?

A. That's correct.

Q. What is the annual report referring to?

A. The annual report is now still referring to that September 10th cutoff; and actually, in a sense, it's probably comprehensible at this time if the FDA reviewer is still referring to this document, because that document didn't include the deaths -- the sudden deaths we saw post that annual report.

Q. Did Lilly in this letter describe those -- that additional

information?
A. Yeah, we had to right away.
Q. Okay. Let's look at 1-4, still on the first page.
Can you describe what Lilly is telling the FDA here?
A. Yeah. Lilly is telling the FDA that we have actually additional information on the safety profile that we have seen in addition to what we had as of September 10th.
Q. Okay. And then 1-3, please.
And then, in the bottom of that page, and onto the next page, can you explain what Lilly is stating here?
A. Yeah. Here, Lilly is actually updating the FDA that within the time that we're going back and forth on the reaction, especially from that report, we have seen actually patients dying from drug-related deaths; and that was extremely concerning to us.
Q. Can we take a look at 2-3? This is on the second page of the letter. There's a paragraph.
And the paragraph says, "Lilly has consulted a number of oncology experts regarding patients' safety"; and then it says, "These consultants were in unanimous agreement that intervention was necessary to promote patients' safety in the pemetrexed trials."
Does that accurately reflect what the experts told you on that conference call you had?
A. Yes.

Q. The next sentence, Doctor, says, "They all further suggested that supplementation with folic acid would offer the best chance of reducing serious toxicity to the broadest patient population."

Does that accurately reflect what you were told or what Lilly was told by the experts on that call?

A. Yes.

Q. Then the next sentence says, "These experts felt that supplementation with low levels of folic acid would not adversely affect efficacy of pemetrexed."

Does that statement accurately reflect what the experts were saying on the call?

A. No, actually not.

Q. What were the experts saying about efficacy on the call, Doctor?

A. What I understood on the call was that the risk/benefit had shifted towards intervening to protect the patients from the toxicities, and this was warranted by these drug-related deaths now being observed, and that we had --

MR. WIESEN: Your Honor, now we've gone into hearsay that's contradicting documents they submitted to the FDA.

MR. GENDERSON: Your Honor, this is not hearsay now. It's not for the truth. It's for what was stated. And we're going to explain that the person who wrote this letter wasn't on the call. All of this happened over a -- literally an

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	)	Indianapolis, Indiana
vs.	)	**August 23, 2013**
	)	9:06 a.m.
TEVA PARENTERAL MEDICINES, INC., APP PHARMACEUTICALS, LLC, PLIVA HRVATSKA D.O.O., TEVA PHARMACEUTICALS USA, INC., BARR LABORATORIES, INC.,	)	
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