

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

**Neptune Generics, LLC et al.,
Petitioners,**

v.

**Eli Lilly and Company,
Patent Owner
*IPR2016-00237, -00240***

**Sandoz Inc. et al.,
Petitioners,**

v.

**Eli Lilly and Company,
Patent Owner
*IPR2016-00318***

Patent Owner's Demonstratives

Vitamin B₁₂ Pretreatment Was Unprecedented

VIDEOTAPED DEPOSITION OF RON D. SCHIFF, M.D.

August 25, 2016

Chicago, Illinois

Q. My question was would the person of ordinary skill have been aware of anyone using vitamin B12 pretreatment with a folate analog or antifolate prior to 2000?

A. I would like to take a moment to consider my answer to that.

I don't believe that was the case at that time. The rationale was established and I don't know of any trials that were completed or even undertaken, correct?

Q. Or even undertaken, correct?

A. I don't know the answer to that. When you see a publication you don't necessarily know when the trial began.

Q. The person of ordinary skill would not have been aware of any ongoing clinical trials with a folate analog antifolate with B12 pretreatment.

A. I would say that's correct.

Vitamin B₁₂ Pretreatment Was Unprecedented

VIDEOTAPED DEPOSITION OF RON D. SCHIFF, M.D.

August 25, 2016

Chicago, Illinois

Q. Okay. And if there were other
prior to Niyikiza's publications to consider
vitamin B12 pretreatment with an antifolate
did it, correct?

A. I believe that's correct. Not
lometrexol.

Q. And not with pemetrexed either?

MS. LYDIGSEN: Object to the

BY THE WITNESS:

A. That's correct.

BY MR. PERLMAN:

Q. And not with any other folate
antifolate, right?

A. That's correct. Not in patient

experimental animals, yes. Not in patient

Vitamin B₁₂ Pretreatment Was Unprecedented

ORAL DEPOSITION OF
W. ARCHIE BLEYER, M.D.
Dallas, Texas
August 30, 2016

Q. Okay. And there's no
here of vitamin B12 being adminis
a patient prior to the administra
methotrexate for cancer chemother
any of the references you cited in

declaration?

A. No specific patient examp
exist in these references.

District Court: Vitamin B₁₂ Pretreatment Was Unprecedented

Case 1:10-cv-01376-TWP-DKL Document 336 Filed 03/31/14 Page 1 of 34 PageID #: 8232

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,)

Plaintiff,)

TEVA PARENTERAL
APP PHARMACEUTICALS
PLIVA HRVATSKA
TEVA PHARMACEUTICALS
BARR LABORATORIES

Despite Defendants' claim that the addition of vitamin B₁₂ would have been c
POSA, there are no examples in the prior art of cancer patients being pretreated with
before being given an antifolate or any suggestion that cancer patients receiving
chemotherapy should receive vitamin B₁₂ supplementation. The Niyikiza abstract

This matter is
19 and 21 (the "Asses
'209 Patent is a m

disodium ("pemetrexed") with two nutrients—folic acid and vitamin B₁₂—that protect against
the side effects of the drug ALIMTA®. The matter was before the Court for a bench trial
beginning on August 19, 2013 and concluding on August 29, 2013. This is a Hatch-Waxman
patent infringement action brought by Eli Lilly and Company ("Lilly"), the owner of the '209
Patent, against Defendants Teva Parenteral Medicines, Inc. ("Teva Parenteral"), Teva
Pharmaceuticals USA, Inc. ("Teva Pharmaceuticals") (collectively with Teva Parenteral,
"Teva"), APP Pharmaceuticals, LLC ("APP"), Barr Laboratories, Inc. ("Barr"), and Pliva
Hrvatska d.o.o. ("Pliva") (collectively, "Defendants") arising out of Defendants' filing of
Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration
("FDA") seeking approval to market the pemetrexed disodium products identified in Teva's

NEPTUNE GENERICS 1028 - 00001

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