

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

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

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.