

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
APOTEX INC., and APOTEX CORP.,
EMCURE PHARMACEUTICALS LTD.,
HERITAGE PHARMA LABS INC.,
HERITAGE PHARMACEUTICALS INC.,
GLENMARK PHARMACEUTICALS, INC., USA,
GLENMARK HOLDING SA,
GLENMARK PHARMACEUTICALS, LTD., MYLAN LABORATORIES
LIMITED, TEVA PHARMACEUTICALS,
FRESENIUS KABI USA, LLC, and WOCKHARDT BIO AG
Petitioners,

v.

ELI LILLY & COMPANY,
Patent Owner.

Case No: IPR2016-00318¹
Patent No. 7,772,209

**PATENT OWNER'S MOTION FOR OBSERVATIONS ON THE
DEPOSITION OF PETITIONER SANDOZ'S EXPERT
PATRICK J. STOVER, PH.D.**

¹ Cases IPR2016-01429, IPR2016-01393, and IPR2016-01340 have been joined
with the instant proceeding.

Pursuant to 77 Fed. Reg. 48756, Patent Owner Eli Lilly & Company

(“Lilly”) submits this motion for observations regarding cross-examination of Petitioner Sandoz’s reply declarant Patrick J. Stover, Ph.D.

Observation 1. Dr. Stover agreed that he does not “have any particular experience in the area of oncology”; he has not “done work directly on human cancer treatment”; and he does not treat patients. Ex. 2137 at 10:8-10, 10:25-11:5, 24:15-16. Dr. Stover further agreed that he is “not providing opinions in this case from the perspective of the person of ordinary skill in the art” to the extent that the POSA “is a person who is a clinician who treats patients” and that he cannot “opine about the knowledge of an oncologist.” *Id.* at 23:14-19, 26:4-8. This testimony is relevant in assessing Dr. Stover’s expertise and ability to opine on nutritional issues involving the administration of pemetrexed, a chemotherapy drug for treating cancer.

Observation 2. Dr. Stover testified:

Q. Are you familiar with a particular toxicity called neutropenia?

A. I am not an expert in neutropenia, no.

Q. Okay. So do you know how pemetrexed causes neutropenia?

A. I -- I am not an expert in how pemetrexed causes neutropenia, no.

Q. Okay. So to the extent other experts in this case have opined that pemetrexed can cause neutropenia by inhibiting DNA synthesis, you don't agree with that opinion?

A. I have –

* * *

A. I have no opinion on that.

Ex. 2137 at 15:21-16:11 (objection omitted). This testimony is relevant because it undermines Dr. Stover's opinion that folic acid will act differently to counteract pemetrexed's toxicity than to counteract its efficacy against cancer cells, Ex. 1091 ¶¶ 19-23, because Dr. Stover has no understanding of the mechanisms by which pemetrexed causes the toxicities that had been observed in the prior art and that, according to Petitioner, would have motivated the POSA to administer folic acid. Likewise undermining his opinion that folic acid will act differently to counteract pemetrexed's toxicity than its efficacy, Dr. Stover testified that "one would infer that pemetrexed would have an effect [on cancer] both through its effect on TYMS [TS] as well as through DHFR" and agreed that "pemetrexed may have an effect on rapidly dividing healthy cells through the inhibition of one or both of those enzymes." Ex. 2137 at 19:25-20:9.

Observation 3. Dr. Stover testified:

Q. And I understand there is a debate among the experts about the incidence of these toxicities, but there

had been toxicities reported to rapidly dividing cells as of 1999?

A. Correct.

Q. That would have been understood by the person of ordinary skill to be arising from the inhibition of some combination of these same enzymes?

A. I'm not a clinician, so I can't speak to what a POSA would -- would infer.

Q. But it was -- it was -- from your standpoint as a biochemist and based on what was known in the art as of 1999, it was -- it was understood that pemetrexed had an impact on rapidly dividing healthy cells, at least in part by inhibiting these same enzymes that contribute to its anticancer effects?

A. I -- that would be an accurate statement, yes. One has to be concerned.

Ex. 2137 20:10-21:5. This testimony is relevant because it supports Patent Owner's point that pemetrexed's inhibition of certain enzymes both allows it to effectively treat cancer and impacts rapidly-dividing healthy cells, causing toxicity. Paper 36 at 5.

Observation 4. Dr. Stover testified:

Q. You're not speaking to what would have been typical practice by the oncologists?

A. I'm not speaking, again, to what an oncologist would or would not do. I'm speaking to the information

that was available to a clinical team giving care to a patient.

Ex. 2137 at 109:20-25. This testimony is relevant in assessing the weight to accord Dr. Stover's opinions involving the administration of pemetrexed, a chemotherapy drug for treating cancer; Dr. Stover has not expressed opinions regarding what the person of ordinary skill in the art would have thought or been motivated to do.

Observation 5. Dr. Stover testified:

Q. I think you referred at another point in today's testimony to oncologists who you run across at folate meetings?

A. That's correct.

Q. Would David Goldman be an example of such an oncologist?

A. David Goldman is one. Joe Mason is one. So oncologists do attend these -- the various meetings that I attend, yes.

Q. Yeah, I was just wondering about David Goldman specifically. He -- he -- is he an example of an oncologist who has what you'd consider to be a fulsome understanding of one-carbon metabolism?

A. David is someone who -- who certainly works in the area of one-carbon metabolism. He is not a metabolic biochemist. He is more on the clinical side. I

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