UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEPTUNE GENERICS, LLC,
Petitioner,

v.

ELI LILLY AND COMPANY,
Patent Owner.

Case No. IPR2016-00240
Patent No. 7,772,209

PATENT OWNER'S PRELIMINARY RESPONSE UNDER 35 U.S.C. § 313 AND 37 C.F.R. § 42.107

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Neptune's Petition should be denied. Taken on its own terms, the Petition fails to establish a reasonable likelihood that Neptune would prevail as to at least one claim of U.S. Patent No. 7,772,209 (the "'209 patent"). That alone is reason enough not to institute trial.[1]

The Board should also decline to institute trial for an independent reason: essentially the same arguments—if not the identical arguments—that Neptune raises concerning the validity of the '209 patent have already been litigated in—and rejected by—a federal district court. That decision is currently before the Federal Circuit, and the appellate court will in all likelihood issue an opinion many months before any decision on the merits here, should trial be instituted. Accordingly, allowing Neptune to challenge the obviousness of the '209 patent—a challenge filed well after the appeal proceedings were underway—is not only inconsistent with the principles of judicial economy that underlie the America Invents Act, but is the type of repeated attack on patent validity that Congress

[1] Patent Owner Lilly does not in this Preliminary Response seek to address the merits of Neptune's Petition, nor, necessarily, does it provide the evidence that it will rely on that shows that Neptune's contentions are without merit. Should trial be instituted, Lilly will address the merits and the nonobviousness of the '209 patent in its Patent Owner Response.

cautioned against in creating the new post-issuance proceedings.

As noted above, the alleged obviousness of claims of the '209 patent has been litigated by Lilly and various generic companies (the "ANDA filers") in the Southern District of Indiana, *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc., et al.*, Case No. 1:10-cv-1376. Following trial, the District Court upheld the validity of the asserted claims of the '209 patent. In reaching its decision, the District Court considered—and rejected—the very line of argument Neptune raises here. And it was not a close case. The finding of nonobviousness did not turn on the clear-and-convincing evidence burden of proof applicable in district court litigation. Rather, the District Court held that none of the disputed claim elements, let alone any asserted claim as a whole, was obvious over the prior art. In so holding, the District Court decided as a factual matter what the prior art would have taught the person of ordinary skill in the art ("POSA"), and concluded that the POSA would have been motivated not to do what Neptune posits.

The decision of the District Court is currently on appeal to the Federal Circuit. *See Eli Lilly & Co. v. Teva Parenteral Medicines, Inc., et al.*, No. 2015-2067 (Fed. Cir.). Briefing should be completed in two weeks. Thus, the Federal Circuit appeal is well ahead of this proceeding, and the appeals court will in all likelihood issue its opinion many months in advance of any decision on the merits here.

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