UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACCORD HEALTHCARE, INC., USA,
Petitioner

v.

ELI LILLY & COMPANY,
Patent Owner.

Case IPR2013-00356
U.S. Patent No. 7,772,209

PATENT OWNER ELI LILLY AND COMPANY'S

PRELIMINARY RESPONSE TO PETITION FOR *INTER PARTES*

REVIEW OF U.S. PATENT NO. 7,772,209 UNDER 35 U.S.C. §§ 311-319

AND 37 C.F.R. §§ 42.1-.80, 42.100-.123

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Accord Healthcare, Inc., USA's ("Accord's") petition to institute *inter partes* review ("IPR") of U.S. Patent No. 7,772,209 ("the '209 patent") should be denied because it is untimely. Under 35 U.S.C. § 315(b), a defendant has one year after being served with a complaint for infringement of a patent to petition for an IPR of that patent, or else "[a]n inter partes review *may not be instituted*." § 315(b) (emphasis added). Patent Owner Eli Lilly and Company ("Lilly") sued Accord for infringement of the '209 patent well over one year before Accord filed its petition: Lilly served Accord with a complaint alleging infringement of the '209 patent on January 23, 2012, but Accord did not file its petition until June 14, 2013. That should end the matter; the plain language of the statute requires that Accord's petition be denied.

Accord asserts that it can nevertheless initiate an IPR because Lilly served it with a *second* complaint less than a year before the filing of Accord's IPR petition. *See* Corrected Petition for Inter Partes Review at 3 & n.1, *Accord Healthcare, Inc., USA v. Eli Lilly & Co.*, IPR2013-00356 (P.T.A.B. June 26, 2013) (hereinafter, "Pet."). Accord is wrong. The plain language of § 315(b) does not open a one-year window for requesting an IPR *each* time a party is served with a complaint. Rather, it imposes a one-year limit on when an accused infringer can petition for an IPR, starting from when that party is *first* served with a complaint alleging infringement of the patent. Because more than one year has elapsed since January

23, 2012—the date Lilly served Accord with a complaint for infringement of the '209 patent—Accord is barred from petitioning for an IPR of that patent, regardless of whether Lilly later filed and served an additional complaint for infringement of the same patent.

Indeed, the Board has squarely rejected Accord's reading of the statute. The Board recently held that "the filing of a later lawsuit [does not] render[] the service of a complaint in an earlier lawsuit to be a nullity" for purposes of determining whether the one-year window for filing an IPR petition has closed. *Universal Remote Control, Inc. v. Universal Elecs., Inc.*, IPR2013-00168, slip op. at 4 (P.T.A.B. Aug. 26, 2013). The Board concluded that regardless of whether a petitioner was later sued again for infringement of a patent, an IPR of that patent "may not be instituted" if the petitioner was *first* served with a complaint for infringement of the patent more than a year before the IPR petition was filed. *Id.* at 5. That is precisely the case here.

Because Accord was served with a complaint alleging infringement of the '209 patent more than a year before Accord filed its petition, the IPR it requests "may not be instituted," and its petition should be denied.

BACKGROUND

I. ALIMTA® and the '209 Patent

The '209 patent is owned by Lilly and protects Lilly's anti-cancer agent ALIMTA®. ALIMTA was the first drug ever approved by the Food and Drug Administration ("FDA") for the treatment of patients with mesothelioma (the primary cancer caused by exposure to asbestos), and is also indicated for treating the most common types of lung cancer. *See* Ex. 2001, ALIMTA Prescribing Information (May 2013), at 2.

The '209 patent is directed to methods of administering the active ingredient in ALIMTA, a compound called pemetrexed disodium, in a way that significantly improves patient safety. Pemetrexed belongs to a class of compounds known as "antifolates." Antifolates kill cancer cells by interfering with the use of certain nutrients ("folates") that cells need to grow and divide. Those same mechanisms, however, also kill rapidly dividing normal cells, which can lead to severe and life-threatening side effects. Surprisingly, administering folic acid—a folate—and vitamin B_{12} prior to the administration of pemetrexed reduces the incidence of severe side effects but does not reduce the efficacy of pemetrexed against cancer cells. Although considered to be counterintuitive when the method was first developed, such pretreatment is now required by the FDA for all pemetrexed patients. ALIMTA's product labeling includes mandatory instructions to pretreat

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