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

TABLE OF CONTENTS

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

patients with folic acid and vitamin B_{12} according to a particular regimen. The '209 patent is directed to methods of administering pemetrexed comprising such pretreatment regimens.

II. The District Court Litigations

ALIMTA's success has led several companies to file Abbreviated New Drug Applications ("ANDAs") with the FDA seeking permission to sell generic versions of ALIMTA. Lilly is engaged in infringement litigation involving the '209 patent with several such ANDA filers, including Accord, in the United States District Court for the Southern District of Indiana.

A first action, which does not involve Accord, was tried to the Court in August 2013.[1] In December 2011, while that first action was ongoing, Accord sent Lilly a "notice letter" informing Lilly that it had filed ANDA No. 203485 to obtain approval from the FDA to market generic versions of ALIMTA. *See* 21 U.S.C. § 355(j)(2)(B). Under the Hatch-Waxman Act, a generic filer such as Accord who is seeking approval to sell a generic version of an approved drug prior to the

[1] Post-trial briefing in that action will occur through the end of this year, after which the parties will be awaiting the Court's decision. *See* Ex. 2002, Stipulation Regarding Post-Trial Briefing Schedule, *Eli Lilly & Co. v. Teva Parenteral Meds., Inc., APP Pharm., LLC, Teva Pharm. USA, Inc., Barr Labs, Inc., and Pliva Hrvatska d.o.o.*, No. 1:10-cv-01376 (S.D. Ind. Sept. 4, 2013), ECF No. 319.

expiration of a patent covering that drug or its use must send written notice to the patent owner that it has filed for approval to do so. The filing of an ANDA seeking approval to sell a generic drug prior to the expiration of a relevant patent is an act of patent infringement. 35 U.S.C. § 271(e).

In response to Accord's notice letter, on January 20, 2012, Lilly sued Accord in the United States District Court for the Southern District of Indiana, alleging that Accord's proposed generic pemetrexed products would infringe the '209 patent. *See* Ex. 2003, Compl., *Eli Lilly & Co. v. Accord Healthcare, Inc., USA*, No. 1:12-cv-00086 (S.D. Ind. Jan. 20, 2012), ECF No. 1. The action was assigned docket number 1:12-cv-00086 ("the '086 action"). Lilly served Accord with the summons and complaint on January 23, 2012. *See* Ex. 2004, Return of Service, *Eli Lilly & Co. v. Accord Healthcare, Inc., USA*, No. 1:12-cv-00086 (S.D. Ind. Feb. 6, 2012), ECF No. 7 (declaring that Accord was served on January 23, 2012). A subsequent action against Apotex Inc. and Apotex Corp.—two arms of yet another company seeking approval for a generic version of ALIMTA—was consolidated with the '086 action, and a bench trial is scheduled for July 2014.

In the one-year period from the date Lilly served Accord with a summons and complaint in the '086 action for infringement of the '209 patent—*i.e.*, by January 23, 2013—Accord did not file a petition for IPR of the '209 patent.

On January 14, 2013, Accord mailed Lilly a second notice letter stating that Accord had submitted an amendment to its ANDA. Accord's original ANDA sought permission to sell a generic pemetrexed product in two amounts—100 mg and 500 mg per vial—which match the two amounts in which ALIMTA is sold. The amendment added a third amount, 1000 mg per vial, to these two original amounts. Notably, pemetrexed is reconstituted into an intravenous solution and administered in a hospital or clinic setting at a dosage tailored to each individual patient. The dosage of pemetrexed administered to a patient thus does not depend on the amount of pemetrexed per vial. Ex. 2001, ALIMTA Prescribing Information, at 4. Because Accord sent Lilly a second notice letter, Lilly brought a second action against Accord under the Hatch-Waxman framework. Ex. 1000, Compl., *Eli Lilly & Co. v. Accord Healthcare, Inc. USA*, No. 1:13-cv-0335 (S.D. Ind. Feb. 28, 2013), ECF No. 1. That second action was filed on February 28, 2013, and the complaint was served on March 7, 2013; the new action was assigned docket number 1:13-cv-00335 ("the '335 action").

On May 30, 2013, Lilly filed a motion to consolidate the '335 action with the '086 action because "the two cases present common questions of fact and law." Ex. 2005, Pl. Eli Lilly & Co.'s Mot. to Consolidate, *Eli Lilly & Co. v. Accord Healthcare, Inc., USA*, No. 1:12-cv-00086, at 3 (S.D. Ind. May 30, 2013), ECF No. 62. As Lilly explained to the District Court, Accord's 1000 mg/vial product was

simply "a generic version of ALIMTA® in a larger vial" than Accord's earlier 100 mg/vial and 500 mg/vial generic pemetrexed disodium products, and "[t]he only expected difference in subject matter between the two cases is the size of the vial in which the proposed ANDA product is to be sold." *Id.* at 2-3. Lilly's motion was granted on June 24, 2013, the '335 action was consolidated into the '086 action and administratively closed, and Lilly's infringement claims regarding all three of Accord's proposed vial sizes are being litigated together in the '086 action. *See* Ex. 2006, Order Granting Pl.'s Mot. to Consolidate, *Eli Lilly & Co. v. Accord Healthcare, Inc., USA*, No. 1:12-cv-00086 (S.D. Ind. June 24, 2013), ECF No. 65; *see also* Ex. 2007, Report on the Filing or Determination of an Action Regarding a Patent or Trademark, *Eli Lilly & Co. v. Accord Healthcare, Inc., USA*, No. 1:13-cv-00335 (S.D. Ind. July 1, 2013), ECF No. 29 (notice informing the Director of the PTO of the Court's decision to consolidate the two actions).[2]

Just prior to the Court's consolidation order, on June 14, 2013, Accord filed its IPR petition—over a year and four months after being served with a complaint for infringement of the '209 patent.[3]

---

[2] Consolidation did not alter the schedule for the '086 action, which is currently in fact discovery and remains set for trial in July 2014.

[3] On June 26, 2013, Accord filed its corrected petition for *inter partes* review to address defects in its application.

ARGUMENT

The plain language of 35 U.S.C. § 315(b) grants a defendant a single, one-year period following service of a complaint for patent infringement to file an IPR petition challenging the patent. As the Board has recently confirmed, the one-year time limit imposed by § 315(b) is unaffected by the filing of any later complaint. Moreover, that interpretation is consistent with the legislative history and is reinforced by important policy concerns. Because Accord missed its one-year statutory deadline, its IPR petition is untimely under § 315(b) and should be denied.

Lilly's arguments herein are limited to the untimeliness of Accord's petition, a threshold procedural defect that precludes the initiation of an IPR. However, Lilly also disagrees with Accord's allegations on the merits, contends that all claims of the '209 patent are valid and should be maintained, and reserves the right to present additional evidence and arguments should the Board grant Accord's petition and institute an IPR. *See generally Athena Automation Ltd. v. Husky Injection Molding Sys. Ltd.*, IPR2013-00290, slip op. (P.T.A.B. Sept. 3, 2013).[4]

[4] If an IPR is instituted, Lilly intends to demonstrate, among other things, that the art (including some of the very art Accord cites) taught away from pretreatment with folic acid and vitamin B_{12}, and indeed that vitamin B_{12} pretreatment (a

I. Accord's Petition Is Time-Barred Under 35 U.S.C. § 315(b).

A. Section 315(b) Unambiguously Forecloses Accord's Petition.

Inter partes review is a creation of the America Invents Act. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 6, 125 Stat. 284, 299-305 (2011). Among other limitations on the filing of an IPR petition, the law sets forth a one-year period during which a defendant in patent infringement litigation may file a petition to institute an IPR of the patent at issue. In relevant part, § 315(b) states that the period begins the date that the defendant is served with a complaint alleging infringement of the patent, and ends exactly one year later:

> (b) Patent Owner's Action.— An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner . . . is served with a complaint alleging infringement of the patent.

The Board has recognized that this plain language compels denial of an IPR petition whenever the one-year period beginning with service of a patent infringement complaint has elapsed. *Universal Remote*, slip op. at 5; *see also Motorola Mobility LLC v. Arnouse*, IPR2013-00010, 2013 WL 2023657, at *1 (P.T.A.B. Jan. 30, 2013) ("[U]nder 35 U.S.C. § 315(b), a party may not file a petition for *inter partes* review if the party had been served with a complaint

---

limitation of every claim) had never been used with any antifolate cancer treatment over the more than 50 years that such treatments have been in use.

alleging infringement more than one year previously."). *Cf. In re Swanson*, 540 F.3d 1368, 1376 (Fed. Cir. 2008) (explaining that statutory construction "'begin[s], as always, with the language of the statute'") (quoting *Duncan v. Walker*, 533 U.S. 167, 172 (2001)).

Accord's IPR petition concedes that "[i]n January 2012, Patent Owner commenced a lawsuit for infringement of the '209 Patent." Pet. 3 n.1. As the proof of service in the '086 action indicates—and as Accord does not dispute—Accord was served with the complaint on January 23, 2012. Accord filed its IPR petition on June 14, 2013, well over a year after Accord was served. In such circumstances, where "the petition requesting the [IPR] proceeding is filed more than one year after the date on which the petitioner is served with a complaint alleging infringement of the patent," the Board has held that "*inter partes* review cannot be instituted." *Universal Remote*, slip op. at 5-6. Accord's petition should therefore be denied.

B. The Board Has Held That § 315(b) Does Not Allow for Successive One-Year Filing Periods.

Accord urges the Board to accept its untimely petition, asserting that it was "filed less than one year after the date on which Accord was served with 'a complaint.'" Pet. 3. Accord effectively asserts that "a complaint" in § 315(b) means "any complaint," thus permitting successive one-year periods for filing an IPR petition. By Accord's logic, the statutory one-year clock is reset each time a

defendant alters its infringing product in a way that results in the service of another complaint. The Board should reject this nonsensical interpretation.

This is not a matter of first impression. In *Universal Remote*, the Board held that the plain language of § 315(b) permits only a single one-year filing period. *Universal Remote*, slip op. at 5-6. That case, like this one, involved the timeliness of an IPR petition filed more than one year after a first complaint, but within one year of a second complaint. *Id.* at 2-3. There, as here, the first complaint, second complaint, and IPR petition all involved the same patent. *Id.* The petitioner, like Accord, argued that its IPR petition was timely notwithstanding the earlier-served complaint because it was filed within one year of the second-filed complaint. The Board rejected the petitioner's argument, holding that the petition was untimely under § 315(b) as it was not filed within the one-year period following the first complaint. *Id.* at 4-5 ("Service of a second complaint does not nullify the effect of a first served complaint for purposes of 35 U.S.C. 315(b)[.]") (emphasis omitted).

On the dispositive issue of timeliness under § 315(b), therefore, *Universal Remote* is indistinguishable from this case. Applying *Universal Remote*, the Board should hold that Accord's IPR petition is untimely in view of the complaint served in the earlier '086 action.[5]

[5] In *Universal Remote*, the petitioner's statutory filing period expired in 2002, such that the petitioner in effect had no opportunity to initiate an IPR. Here, the

The Board's decision in *Universal Remote* rested on sound principles of statutory interpretation. Section 315(b) sets a one-year limit on the period for filing an IPR petition. The statute is unambiguous and states that an IPR "may not" be instituted if a certain condition is met—namely, the service of "a complaint" more than a year before the filing of the IPR petition. It does not provide additional filing periods whenever the defendant provokes service of another complaint. *Universal Remote*, slip op. at 2; *see also Universal Elecs., Inc. v. Universal Remote Control, Inc.*, No. SACV 12-00329, 2013 WL 1876459, at *2 (C.D. Cal. May 2, 2013) ("This one year limit [under § 315(b)] sets a ceiling on the PTO's ability to commence *inter partes* review where there is ongoing litigation."); *Motorola Mobility*, 2013 WL 2023657, at *4; *Macauto U.S.A. v. Bos GmbH & KG*, IPR2012-0004, slip op. at 16 (P.T.A.B. Jan. 24, 2013).

The Board in *Universal Remote* also recognized that its interpretation of the statute is consistent with the legislative history underlying § 315(b). "It is well settled law that the plain and unambiguous meaning of the words used by Congress prevails in the absence of a clearly expressed legislative intent to the contrary."

---

argument for strictly enforcing the one-year time limit in § 315(b) is even stronger, as Accord had every opportunity to petition for an IPR after the Board began accepting IPR petitions on September 16, 2012, but before its statutory period ended on January 23, 2013.

Universal Remote, slip op. at 5 (quoting *Hoechst Aktiengesellschaft v. Quigg*, 917 F.2d 522, 526 (Fed. Cir. 1990)). Accord, like the petitioner in *Universal Remote*, "has not pointed to any particular legislative history associated with 35 U.S.C. § 315(b) which clearly expresses that the filing of a later lawsuit renders the service of a complaint in an earlier lawsuit to be a nullity." *Id.* at 5. That is not surprising, for the legislative history demonstrates that lawmakers uniformly understood the IPR provision as containing "procedural safeguards to prevent a challenger from using the process to harass patent owners" and to help avoid "abusive serial challenges to patents"—both of which would be dangers if an accused infringer could reopen the window for filing an IPR by triggering the filing of a second infringement complaint. Ex. 2008, 157 Cong. Rec. S936, S952 (daily ed. Feb. 28, 2011) (Statement of Sen. Grassley); *see also* Ex. 2009, Meeting of H. Comm. on the Judiciary, Tr. of Markup of H.R. 1249, at 72 (Apr. 14, 2011) (statement of Judiciary Committee Chairman Lamar Smith) ("The *inter partes* proceeding in H.R. 1249 has been carefully written to balance the need to encourage its use while at the same time preventing the serial harassment of patent holders."); Ex. 2010, 157 Cong. Rec. S1360, S1374 (daily ed. Mar. 8, 2011) (Statement of Sen. Kyl) (recognizing "procedural limits on post-grant administrative proceedings that will prevent abuse of these proceedings for purposes of harassment or delay").

For these reasons, § 315(b) precludes an IPR if more than one year has elapsed from when an accused infringer was served with a complaint for infringement, without regard to whether a second complaint has also been served. Even Accord concedes that Lilly served it with a complaint more than a year before Accord's petition. Pet. 3 n.1. Only by advancing an interpretation antithetical to the plain language of § 315(b) and its legislative history can Accord assert that its petition is not time-barred.[6]

C. Accord's Assertion That the Two Civil Actions Involve "entirely different products" Does Not Excuse Accord from Missing Its One-Year Filing Deadline.

Accord further asserts that although it failed to file an IPR petition within the statutory one-year period running from service of process in the '086 action, its untimeliness should somehow be excused because the '086 and '335 actions "involve entirely different products and are based on different set[s] of facts." Pet. 3 n.1. Accord's argument is wrong both as a matter of law and on the facts of this case.

---

[6] Accord's petition is also untimely under 37 C.F.R. § 42.101(b), the PTO's regulation implementing § 315(b), which contains language that tracks the language of § 315(b) and forbids IPRs requested more than a year after the party is served with a complaint.

As a threshold matter, it makes no difference under § 315(b) whether a second complaint for patent infringement concerns the same product or a different product as an earlier complaint for infringement of the same patent. Either way, the one-year period under § 315(b) is not restarted upon service of the second complaint. The statute focuses on "the patent" asserted, not on what products are at issue—it unambiguously applies to any petitioner who has been "served with a complaint alleging infringement of *the patent*." § 315(b) (emphasis added). And based on this language, the Board found in *Universal Remote* that the IPR petition was untimely even though the patentee had served a second complaint involving products "different from those" in an earlier-served complaint. *See* Ex. 2011, Preliminary Response of Patent Owner, *Universal Remote Control, Inc. v. Universal Elecs., Inc.*, IPR2013-00168, at 3 n.1 (P.T.A.B. May 28, 2013); *see also Universal Remote*, slip op. at 4. Accord is simply wrong to assert that whether the earlier and later complaints concern "different products" is relevant.

Even if it mattered under § 315(b) whether the second-filed infringement suit concerned a "different product," however, Accord's argument still fails on the facts of this case. The products at issue in the '086 and '335 actions are virtually identical. Each of Accord's three accused products (100 mg/vial, 500 mg/vial, and 1000 mg/vial) contain the same active ingredient, pemetrexed disodium, and have the same physical, chemical, and biological properties—the *only* difference is the

quantity of pemetrexed in each container. Even if Accord chooses to refer to them as separate "products," or the FDA treats them as different "products" for purposes of regulatory approval, they are not different in any way that is meaningful to the '209 patent claims. The quantity of pemetrexed in each vial is not a limitation of any claim of the '209 patent and does not affect any issue of infringement or validity.

Indeed, Accord has conceded that the factual and legal questions regarding infringement and validity are identical for each ANDA product. Although Accord now states in its petition that the complaint involving its 100 mg/vial and 500 mg/vial products and the complaint involving its 1000 mg/vial product "are based on different set[s] of facts," Accord previously represented just the opposite in its correspondence with Lilly. As Accord stated in its January 14, 2013 notice letter—in which it was required to disclose the bases for its theories of invalidity and/or noninfringement of the '209 patent, *see* 21 U.S.C. § 355(j)(2)(B)(iv)(II)—the 1000 mg/vial product rested on "the same" factual and legal bases as its 100 mg/vial and 500 mg/vial products:

> Accord notes that the *factual and legal bases* for this paragraph IV certification and the statement that the U.S. Patent No. 7,772,209 is invalid and/or the valid claims will not be infringed by Accord's Pemetrexed Disodium for Injection, 1000 mg/vial *are the same* as those forth in the Notice Letter sent by Accord to Lilly on December

8, 2011 [*i.e.*, the notice letter involving Accord's 100 mg/vial and 500 mg/vial products].

Ex. 2012, Letter from Chid S. Iyer to Eli Lilly & Co., at 1 (Jan. 14, 2013) (emphases added).[7] Even Accord has therefore admitted that with respect to the '209 patent, its three accused products rest on the same factual and legal footing. Thus, not only is Accord legally incorrect that service of a second complaint involving a different product matters to the § 315(b) analysis, but by Accord's own admission its argument lacks a factual basis as well.

II. Accord's Interpretation Would Have Far-Reaching Consequences in Hatch-Waxman Litigation.

Adopting Accord's interpretation of § 315(b) would lead to particularly pernicious consequences in the context of Hatch-Waxman litigation. In an ordinary patent infringement action, the patent owner generally controls when suit is filed, and a defendant typically lacks control over when it is sued. Thus, if a defendant has already been sued and then alters its infringing product or releases a trivially different one, this may or may not cause the patentee to file a new complaint.

Hatch-Waxman litigation works differently. The statutory scheme is designed so that infringement and validity disputes are generally litigated before

[7] Accord's petition does not mention its previous directly contradictory representation, despite Accord's obligations under 37 C.F.R. § 42.11.

the generic company has approval from the FDA and before it is selling its product. And the statutory scheme effectively allows the *defendant* to control when it is sued for infringement. That is because Hatch-Waxman infringement suits are generally triggered by the defendant sending the patent owner a notice letter. Once a defendant does so, the statute requires the patentee to "br[ing]" an "action . . . for infringement of the patent" within 45 days after receipt of a notice letter or else the ANDA may be immediately approved. 21 U.S.C. § 355(j)(5)(B)(iii). The same is true when a Hatch-Waxman defendant amends its ANDA and sends an additional notice letter to the patent holder—under the statutory scheme, the patent owner is all but compelled to sue again.

Under Accord's reading of § 315(b), not only can a Hatch-Waxman defendant effectively control the filing of a second complaint, but in doing so, it can *re-open at will* the window for requesting an IPR of the very patent on which it has already been sued more than a year earlier. And it can do so simply by making a trivial change to its product, amending its ANDA, and serving a new notice letter. That is precisely the case here, where the difference between the old and new products is merely the amount of drug product per vial, which has no bearing on any issue in the infringement cases. Accord's interpretation would thus create a loophole in the IPR statute for ANDA filers, who would have both an incentive and an ability to stagger their ANDA filings or subsequently amend their ANDAs

to exploit successive one-year periods for filing an IPR petition. The Board should not permit such opportunistic gaming of the IPR process.

CONCLUSION

Accord missed its statutory one-year period for filing an IPR petition under 35 U.S.C. § 315(b). The Board should deny Accord's petition as untimely and decline to institute an IPR of the '209 patent.

The Board is hereby authorized to charge any fees or costs associated with this submission and to credit any excess payments to Deposit Account No. 05-0840.

Dated: September 19, 2013

Respectfully submitted,

/Andrew V. Trask/

Andrew V. Trask
Reg. No. 59,239
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, DC 20005
202-434-5098 (Telephone)
202-824-4223 (Facsimile)
atrask@wc.com

Attorney for Patent Owner
Eli Lilly and Company

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing 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 was served on September 19, 2013, by filing this document through the Patent Review Processing System as well as delivering a copy via electronic mail upon the following attorneys of record for the Petitioner:

Chidambaram S. Iyer
ciyer@sughrue.com
accordipr@sughrue.com
Sughrue Mion PLLC
2100 Pennsylvania Ave, N.W.
Washington, DC 20037

Chandran B. Iyer
cbiyer@sughrue.com
accordipr@sughrue.com
Sughrue Mion PLLC
2100 Pennsylvania Ave, N.W.
Washington, DC 20037

Dated: September 19, 2013

Respectfully submitted,

/Andrew V. Trask/

Andrew V. Trask
Reg. No. 59,239