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January 14, 2013

**VIA FACSIMILE, USPS EXPRESS MAIL and CONFIRMATION BY USPS CERTIFIED MAIL WITH RETURN RECEIPT**

Legal Department
Eli Lilly and Co. Inc.
Lilly Corporate Center
Indianapolis, IA 46285

Phone: 1 (317) 276-2000
Facsimile: 1 (775) 832-8501

**Re: Notice of Paragraph IV Certification of Non-infringement and/or Invalidity of the claims of U.S. Patent No. 7,772,209 Pursuant to 21 C.F.R. § 314.95 Concerning Amendment to ANDA No. 203485 for Pemetrexed Disodium for Injection, 1000 mg/vial**

To Whom It May Concern::

Pursuant to 21 C.F.R. § 314.95 and 21 U.S.C. § 355(j)(2)(B)(ii)(I) (i.e., section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act ("Act")), Accord Healthcare Inc., USA ( "Accord") hereby provides notice to Eli Lilly & Co. that it has submitted to the U.S. Food and Drug Administration ("FDA"), and the FDA has received, an amendment to Accord's Abbreviated New Drug Application ("ANDA")No. 203485.

Specifically, Accord has submitted an amendment to ANDA No. 203485 under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) seeking approval to engage in the commercial manufacture, use, and/or sale of Pemetrexed Disodium for Injection, **1000 mg/vial,** on the basis that the claims of U.S. Patent No. 7,772,209 are invalid. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. §§ 314.95(c)(6)(i)-(ii), 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.

Since the 1000 mg/vial dosage is not a dosage listed in the Orange Book, we provide this notice as a matter of courtesy only. Accord reserves the right to allege the same, similar, different or new theories of non-infringement and/or invalidity and nothing in this or its

December 8, 2011 Notice Letters shall be construed as to limit Accord's rights to make any allegation in this or any subsequent litigation regarding any issue.

Pursuant to 21 C.F.R. § 314.95(c)(7), Accord identifies the following name and address of an agent in the United States authorized to accept service of process in connection with ANDA no. **203485** and any amendment thereto for the applicant:

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Furthermore, in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(III), as amended by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003), this notice letter also includes, and Accord hereby extends, an "Offer of Confidential Access to Application" to Lilly under the specific restrictions set forth below in this letter.

**OFFER OF CONFIDENTIAL ACCESS TO APPLICATION**

Pursuant to 21 U.S.C. § 355(j)(5)(C), as amended by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003), this notice letter includes an Offer of Confidential Access to Application. As required by § 355(j)(5)(C)(i)(III), and pursuant to certain restrictions described below, Accord offers to provide Lilly with confidential access to certain information from its amendment to ANDA No. **203485** for the sole and exclusive purpose of determining whether an infringement action referred to in § 355(j)(5)(B)(iii) can be brought.

Section 355(j)(5)(C)(i)(III) allows Accord to impose restrictions "as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information". That provision also grants Accord the right to redact its ANDA in response to a request for Confidential Access under this offer.

As permitted by statute, Accord imposes the following terms and restrictions on its Offer of Confidential Access:

(1) Accord will permit confidential access to certain information from its proprietary ANDA No. **203485** and any amendment thereto to attorneys from one (1) outside law firm representing Lilly provided, however, that such attorneys do not engage, formally or informally, in

prosecution of patent applications related to Pemetrexed Disodium. Such information (hereinafter, "Confidential Accord Information") shall be marked with the legend "CONFIDENTIAL".

(2) The attorneys representing Lilly who have been permitted access under paragraph (1) shall not disclose any Confidential Accord Information to any other person or entity, including Lilly employees, outside scientific consultants, and/or other outside counsel retained by Lilly, without the prior written consent of Accord's counsel, SUGHRUE MION, PLLC.

(3) As provided by § 355(j)(5)(C)(i)(III), attorneys permitted access under paragraph (1) shall make use of the Confidential Accord Information for the sole and exclusive purpose of determining whether an action referred to in § 355(j)(5)(B)(iii) can be brought and for no other purpose. In this regard, the attorneys permitted access under paragraph (1) shall be permitted to advise whether or not to bring suit alleging infringement of U.S. Patent No. 7,772,209. Moreover, the Confidential Accord Information shall not be used to prepare or prosecute any future or pending patent applications by Lilly, or in connection with any filing to, or communication with, the FDA relating to Accord's ANDA No. **203485** and any amendment thereto. The attorneys permitted access under paragraph (1) agree to take all measures necessary to prevent unauthorized disclosure or use of the Confidential Accord Information, and that all Confidential Accord Information shall be kept confidential and not disclosed in any manner inconsistent with this Offer of Confidential Access. Attorneys permitted access under paragraph (1) further agree never to use Confidential Accord Information, directly or indirectly, in competition with Accord, nor will it allow any other person or entity to do so.

(4) The Confidential Accord Information disclosed is, and remains, the property of Accord. By providing the Confidential Accord Information, Accord does not grant, implicitly, explicitly, or otherwise, to Lilly and/or attorneys permitted access under paragraph (1) any interest in or license for or to the Confidential Accord Information.

(5) Lilly and / or attorneys permitted access under paragraph (1) shall, within forty-five (45) days from the date that it first receives the Confidential Accord Information, return to Accord's counsel, SUGHRUE MION, PLLC, all Confidential Accord Information and any copies thereof. Lilly's law firm shall return to SUGHRUE MION, PLLC, all Confidential Accord Information before any infringement suit is filed by Lilly, if suit is commenced before this 45-day period expires. Lilly and / or attorneys permitted access under paragraph (1) shall return to Accord's counsel, SUGHRUE MION, PLLC, all Confidential Accord Information and any copies thereof, even if Lilly does not file suit against Accord within forty-five (45) days from the date that it first receives the Confidential Accord Information. In the event that Lilly opt to file suit, none of the information contained in or obtained from any Confidential Accord Information that Accord provides will be included in any publicly-available complaint or other pleading.

(6) Nothing in this Offer of Confidential Access shall be construed as an admission by Accord regarding the validity, enforceability, and/or infringement of any U.S. Patent. Further, nothing herein shall be construed as an agreement or admission by Accord with respect to the competency, relevance, or materiality of any such Confidential Accord Information, document, or thing. The fact that Accord provides Confidential Accord Information upon request of Lilly shall not be construed as an admission by Accord that such Confidential Accord Information is relevant to the disposition of any issue relating to any alleged infringement of the Lilly patent, or to the validity or enforceability of any such patent.

(7) The attorneys from Lilly and / or attorneys permitted access under paragraph (1) will acknowledge in writing their receipt of a copy of these terms and restrictions prior to production of any Confidential Accord Information. Such written acknowledgement shall be provided to Accord's counsel SUGHRUE MION, PLLC.

(8) This Offer of Confidential Access shall be governed by the laws of the State of Maryland.

Section 355(j)(5)(C)(i)(III) of the Act provides that any request for access that Lilly make under this Offer of Confidential Access "shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in [this] offer of confidential access" and that the "restrictions and other terms of [this] offer of confidential access shall be considered terms of an enforceable contract." Thus, to the extent that Lilly request access to Confidential Accord Information, it necessarily accepts the terms and restrictions outlined above. Written notice requesting access under this Offer of Confidential Access should be made to:

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By providing this Offer of Confidential Access to Application, Accord has satisfied the condition set forth in 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc) to bring a Declaratory Judgment action under 28 U.S.C. § 2201 *et seq.*, pursuant to 21 U.S.C. § 355(j)(5)(C). As Lilly is no doubt aware, under controlling Federal Circuit precedent, a patent holder is required to conduct a reasonable pre-suit investigation before filing pleadings accusing a third party of patent infringement. If Lilly desires to conduct a pre-suit investigation to determine whether it would have a good faith factual and legal basis to ever bring a suit alleging infringement of any of the valid claims of U.S. Patent No. 7,772,209 against Accord, Lilly should accept Accord's Offer of Confidential Access to its ANDA and review it at this time.

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Receipt of this notice begins the 45-day period provided in Section 505(j)(5)(B)(iii) of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act. The ANDA will be amended with a copy of the return receipt for this notice, as required by 21 C.F.R. § 314.95(e).

Very truly yours,

Chidambaram Iyer

Chid S. Iyer

cc: Ellen E. Oberwetter, Esq. (via Email)