

## COVINGTON

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### BY ELECTRONIC MAIL

March 19, 2015

R. Brent Wisner, Esq.  
Baum Hedlund Aristei & Goldman, P.C.  
12100 Wilshire Blvd., Suite 950  
Los Angeles, CA 90025

**Re: *Hagan-Brown v. Eli Lilly & Co.*, 14-CV-1614 (E.D. Va.)  
*Ali v. Eli Lilly & Co.*, 14-CV-1615 (E.D. Va.)**

Dear Mr. Wisner:

I write in response to your letters dated March 13, 2015 and to follow up after the parties' telephonic meet-and-confer on March 17, 2015 concerning Lilly's responses to Plaintiffs' First Set of Requests for Production ("RFPs"), First Set of Interrogatories, and Amended First Set of Requests for Admission ("RFAs"). Lilly stands by its objections to many of Plaintiffs' discovery requests and maintains that much of the information Plaintiffs seek is contained in Lilly's existing substantial production. However, in order to facilitate discovery on the expedited schedule in this Court and minimize motions practice, Lilly provides the following information regarding certain responses per the parties' discussion during the meet-and-confer. Lilly hopes that the parties will be able to reach a compromise on other outstanding issues. This letter addresses the RFPs first, followed by the Interrogatories and the RFAs.

As a preliminary matter, with the exception of requests for which Lilly stands on its objections, Lilly will produce all remaining responsive documents and provide any outstanding responses by April 3, 2015. Although Lilly will provide the majority of these documents and responses to Plaintiffs next week, if Lilly collects and produces the emails of two additional custodians and/or additional documents related to Plaintiffs' design defect claim, as suggested during the meet-and-confer, that process may take longer, hence the April 3, 2015 deadline.

### **I. Requests for Production**

#### Custodian Issues (RFP Nos. 13, 24, 25, 26, 35, 36, 39, 41)

Lilly understands that the parties have a tentative agreement that Lilly will collect documents from two additional Lilly employees named by Plaintiffs that are responsive to certain search terms. Lilly notes that Plaintiffs have not yet confirmed the two additional custodians for collection. Beyond this agreement, the parties have a continued dispute concerning other custodians, which relates to these Requests.

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### RFP No. 2

Lilly has confirmed that documents representing the Summary Basis of Approval (“SBA”) are publicly available on Drugs@FDA for most Cymbalta indications. As you may know, FDA is no longer required to write a SBA and often satisfies its requirement to publicly disclose its approval basis not with a single SBA document but by posting key documents from the NDA approval package on its website. These approval package documents are publicly available for the Cymbalta indications listed below. As for the GAD indications, they are not on the FDA website, and Lilly is investigating whether it has copies of the approval package documents and if so, whether they have been previously produced. Contrary to your representation, the document you cite shows that in 2008 Lilly did *not* have these documents related to the GAD approval readily available and had reached out to FDA for help due to the difficulty in obtaining these documents. See CYM-01510972; CYM-01510975.

#### MDD (NDA 21-427):

[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2004/021427\\_s000\\_Cymbalta.cfm](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021427_s000_Cymbalta.cfm)

#### DPNP (NDA 21-733):

[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2004/021733s000\\_CymbaltaTOC.cfm](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021733s000_CymbaltaTOC.cfm)

#### MDD Maintenance Therapy (sNDA 21-427, S-015):

[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2007/021427Orig1s015\\_s017.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2007/021427Orig1s015_s017.pdf)

#### Fibromyalgia (NDA 22-148):

[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2008/022148\\_cymbalta\\_toc.cfm](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2008/022148_cymbalta_toc.cfm)

#### Chronic Musculoskeletal Pain (NDA 22-516):

[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2010/022516\\_cymbalta\\_tocEDT.cfm](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022516_cymbalta_tocEDT.cfm)

### RFP Nos. 23, 43, 64

Plaintiffs have asked for Excel file versions of certain documents responsive to these requests. The document of LSS data responsive to RFP No. 23 is not a native Excel file and was provided to us in PDF format, which we have sent to you. Otherwise, we have provided the other requested files in Excel format.

### RFP Nos. 30, 31, 32, 33

Lilly is investigating doing targeted searches of collections of documents or emails from the Global Patient Safety division or another relevant department to produce documents related to the development of a 20 mg dose of Cymbalta, and the consideration, if any, of lower doses.

### RFP No. 38

Lilly previously searched for the minutes of various committees related to Cymbalta, including the Periodic Safety Review Committee, the Safety Surveillance Team, and the G10 Team, and produced the fruits of this search along with other committee related materials in

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December 2014. The Excel attachment to this letter lists the Bates numbers corresponding to these documents (714 documents total).

### RFP No. 42

Plaintiffs have asked for a PDF version of the document responsive to this request to replace a corrupted file. This has been sent to you.

### RFP No. 46

Lilly objected to this request because the names of medical providers not involved in this litigation are not relevant. Furthermore, if any medical information letters relating to Cymbalta and discontinuation symptoms were sent by Lilly to the doctors involved in this litigation, or other similar pending actions, they will be captured by Plaintiffs' other documents requests. As a compromise, Plaintiffs agreed to accept information about the number of doctors who were sent Lilly's medical information letter about Cymbalta and discontinuation symptoms. Lilly responds that from September 2006 to September 2013, Lilly sent its medical information letter on Cymbalta discontinuation symptoms to 1,072 health care professionals.

### RFP No. 73

Lilly confirms that the brand plans produced to Plaintiffs are all the Cymbalta brand plans that Lilly was able to locate through multiple diligent searches. Nevertheless, in response to your inquiry, we are investigating whether we can identify earlier plans.

## **II. Interrogatories**

### Interrogatory No. 2

Although Lilly maintains its objection that identifying every current and former employee who worked on Cymbalta in the ten listed departments is unreasonably burdensome and nearly impossible, Lilly is in the process of gathering additional names in each department to provide to Plaintiffs. Lilly notes that many of these individuals can be identified from the correspondence contained in Lilly's existing production and from its three 30(b)(6) depositions. Lilly notes that Exhibit 2 to the 30(b)(6) deposition of Elyas Musleh and Exhibit 2 to the 30(b)(6) deposition of Stephen Knowles collectively list 43 current and former Lilly employees whose names are responsive to this Interrogatory.

### Interrogatories Nos. 4, 5

The documents cited in Lilly's responses are the complete records responsive to these Interrogatories (and RFP No. 64) from the beginning of the Cymbalta product line to 2013. The charts at CYM-02777128 - CYM-02777355 present information about non-employee doctors associated with Lilly relating to Cymbalta from 2004 to 2005, and those at CYM-02739356 - CYM-02743863 present the information in a slightly different format from 2006 to 2013. The other documents, CYM-02743864 - CYM-02777127, contain information about the activities of these individuals between 2004 and 2013.

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Interrogatories Nos. 6, 8, 9

Lilly is investigating which vendors, if any, were involved in the activities described in these Interrogatories, to the extent it is feasible to determine.

Interrogatories Nos. 18-20

Lilly's production of publication plans is forthcoming, which we believe satisfies these Interrogatories as to journal publications relating to Cymbalta. As for articles relating to other products, Lilly stands on its objections.

**III. Requests for Admission**

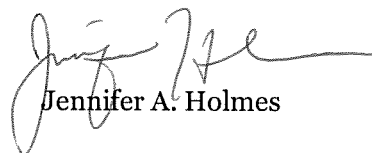
RFA No. 29

Lilly is continuing to investigate the extent to which the Perahia article or the information contained therein was provided to sales representatives for distribution to medical professionals and will provide Plaintiffs with a response next week.

\* \* \*

It is Lilly's understanding that for the remaining requests discussed in Plaintiffs' letters, either the parties came to an agreement during the call or the parties have reached an impasse at this time. There are also some requests that may be on hold for further consideration by Plaintiffs.

Sincerely,



Jennifer A. Holmes