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February 13, 2018

VIA ECF AND FEDERAL EXPRESS

Honorable Judge Claire C. Cecchi
United States District Court
District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, NJ 07101

In Re: Proton-Pump Inhibitor Products Liability Litigation
2:17-md-2789 (CCC)(MF) (MDL 2789)

Dear Judge Cecchi,

On behalf of the Plaintiffs' Steering Committee, we are writing to advise the Court of ongoing issues and delays related to the AstraZeneca Defendants' document productions. Additionally, to avoid such continued problems in the future and to more efficiently address discovery disputes, we respectfully request that the Court consider scheduling bi-weekly teleconferences to address matters related to discovery. With such a schedule in place, the parties can avoid the delays and issues described herein.

A. Search Terms

As Your Honor may recall, at the January 12, 2018 status conference, the Court heard the parties' respective positions concerning the use of Plaintiffs' proposed search terms, which included several "stand alone terms." Following argument on the issue, the Court ordered the AstraZeneca Defendants to run Plaintiffs' proposed terms and to "provide Plaintiffs with sufficient information to evaluate the volume generated by specific terms and by custodian." Case Management Order No. 8, ¶ 4 (Dckt. No. 115). Based on our discussions at the status conference and the Court's Order, Plaintiffs anticipated that we would be receiving analytics relating to the search terms within two weeks of the conference. *See* Jan. 12, 2018 Status Conf. Tr. at 32:12-16.

On January 17, 2018, Plaintiffs inquired as to the status of such analytics in an email to Ms. Windfelder. At that time, we were told that Defendants hoped "to have a couple Custodians complete next week." On January 24, 2018, Plaintiffs and the AstraZeneca Defendants had a conference call, during which we were told that AstraZeneca was still collecting the custodians' files and that more time was needed.[1] On February 2, 2018, Plaintiffs again wrote to inquire about the status of the analytics. Ms. Windfelder responded that:

[1] Plaintiffs understanding is that AstraZeneca has an internal team responsible for document collection for litigation and compliance issues, and that this group was collecting the full custodial

> Due to technical issues, AZ was not able to start transferring Custodial Files until this week; the remainder will be sent early next week. I am told by the vendor the Files for the initial delivered Custodians will be available late next week. We're continuing to assess the handful of files we do have and will run the revised terms you provided so we can discuss on Thursday.

On Thursday, February 8, 2018, we were informed by counsel that they still had not received the balance of the files from AstraZeneca and thus, were unable to confer on the search term results. Further, they stated that they did not view the Court's order as requiring them to provide the PSC with any analytics. Rather, they believed they were only obligated to discuss their results with us in the event a single term resulted in an unreasonable volume of documents. Thus, nearly one month after Your Honor ordered the AstraZeneca Defendants to run Plaintiffs' proposed search terms and to provide us with data on the results, we have nothing.

Plaintiffs are troubled by the AstraZeneca Defendants' response, which in our view reflects a pattern of delay. Notably, the list of custodians at issue was produced by the AstraZeneca Defendants on November 6, 2017, and many of them had been previously identified by counsel months earlier. There is no excuse for AstraZeneca's failure to provide these files to defense counsel. Indeed, such a transfer should have occurred months ago. Plaintiffs are also concerned by AstraZeneca's refusal to provide data on the search terms. During our February 8, 2018 telephone call, Plaintiffs were told that defense counsel would "raise the issue with their client." This request is not new. Indeed, it was discussed at the January 2018 status conference. Yet, nearly a month later, defense counsel has not even discussed the issue with their client. The information sought is simply data about the volume of documents responsive to the search terms proposed by the PSC. It should be disclosed so that the parties can work together to narrow searches, if necessary.

Given the delay, Plaintiffs are now requesting that the Court order the AstraZeneca Defendants to review and produce the custodial files at issue without the use of search terms or alternatively, to simply run the search terms proposed by the PSC. Plaintiffs should not be required to wait yet another month to resolve these issues. Further, AstraZeneca should be required to clarify whether they are providing the full custodial files for search term filtering and who is running the search terms--AstraZeneca or their third-party vendor.

B. <u>Document Production Schedule</u>

The search term issue above, with a few exceptions, applies only to the custodial files of potential witnesses. Search terms are generally not required for the identification and production of non-custodial sources of information relating to the PPI products at issue in this litigation. These

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files for those potential witnesses identified to date (46, thus far) and providing them to the third-party vendor that manages AstraZeneca's document production for this MDL. We further understood that this vendor would be running the search terms provided by Plaintiffs and providing the analytics. Plaintiffs seek clarity on this point, as we are now concerned that AstraZeneca is not providing the full custodial file (as defined in the ESI Order) or that they are running the search terms rather than a third-party vendor.

non-custodial sources include but are not limited to: regulatory file databases, clinical trial information, marketing and promotional materials. Although a few disputes remain, the parties have largely agreed on the scope of the production for non-custodial sources. Yet, to date, these productions have not been completed and appear to have been done in a piecemeal manner. Indeed, the AstraZeneca Defendants have made only 5 substantive document productions. The first three were produced in June and July of 2017 and consisted largely of material previously produced in the prior California litigation. The other two large productions were not made until January 2018. While there have been several other productions, most included only a handful of documents each, with none exceeding 75 documents.

Plaintiffs are concerned that AstraZeneca's document production is moving too slowly. We have made numerous requests concerning the status of the non-custodial productions, the most recent on February 6, 2018. On February 9, 2018, Defense counsel responded, providing vague target dates (e.g., "AZ will effort to produce by licensing agreements by next month" or "AZ anticipates commencing production of this information in March"). Plaintiffs request that the AstraZeneca Defendants be required to confer with us on a written production schedule for non-custodial productions and, once the search term issues are resolved, custodial productions as well.

C. The Manner in Which Documents Are Produced

Plaintiffs are also concerned that certain document collections are being produced by AstraZeneca out of order. For example, as part of their regulatory production, the AstraZeneca Defendants have produced copies of their New Drug Applications (NDA) for Prilosec and Nexium. Typically, such applications include a cover letter, table of contents, executive summary, and various sections detailing the clinical experience for the drug in development. Further, there are lists of Appendices. They often exceed hundreds of thousands of pages. As early as 1997, the FDA was accepting submissions, at least in part, in electronic format and by 2005, required such all such submissions to be in an electronic format. Defendants' regulatory productions have been deficient for the following reasons:

- Some documents that were provided to the FDA in electronic format were only provided to Plaintiffs as scanned PDFs. As a result, the corresponding hyperlinks within the documents don't work. This is not compliant with the requirements of the Court's ESI Order;
- NDA sections have been produced out of sequence; and
- NDA sections appear to have been broken up in an arbitrary manner that does not correspond with the Table of Contents. For example, in many instances a single page or a handful of pages from an NDA has been produced as a stand-alone document. This has also greatly exaggerated the number of documents produced, as a single NDA has been produced as thousands of individual documents.

To identify and reorder all the components of an NDA is a herculean task. It is impossible to imagine that AstraZeneca made its regulatory submissions to the FDA in such a fashion. Nor is it plausible that it stores its regulatory submissions in this way for their own reference and use. When informed of this problem, defense counsel did not deny that the regulatory documents were produced this way. Rather, during a conference call on February 8, 2018, they represented that

this is how the documents were received from the client. At that time, Plaintiffs informed defense counsel of our intent to raise this issue with the Court. On February 9, 2018, Plaintiffs were advised that AstraZeneca's vendor was working on a "metadata file overlay" that would place the regulatory production in its proper order. No date for this fix has been provided. This current status of this production impedes Plaintiffs' ability to review such documents. Discovery should be a cooperative process. It should not be a game of "52-Card Pickup," designed to create obstacles for Plaintiffs.

D. Plaintiffs Request Bi-Weekly Telephonic Discovery Conferences

To avoid the discovery issues and delays described herein, Plaintiffs believe it is prudent to have bi-weekly, telephonic discovery conferences. This will permit the parties to address disputes as they arise. Additionally, it should make the monthly in-person status conferences more efficient, as the parties will require less of the Court's time to address discovery issues. We anticipate that these teleconferences will not be needed on a long-term basis. Further, Plaintiffs are sensitive to Your Honor's busy schedule, and propose that such teleconferences be limited to 30 minutes.

We look forward to discussing these issues in more detail with the Court at Your Honor's earliest convenience or at the February 22, 2018 status conference.

Respectfully submitted,

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cc: All Counsel of Record (via ECF)