UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: Seroquel Products Liability Litigation. **Case No. 6:06-md-1769-Orl-22DAB**

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ORDER

This cause came on for consideration with oral argument[1] on the following motions filed herein:

MOTION:	**PLAINTIFFS' MOTION TO COMPEL DEFENDANTS' RESPONSES TO REQUESTS FOR PRODUCTION OF DOCUMENTS (Doc. No. 629), as modified in the Parties' STATEMENT OF NARROWED ISSUES (Doc. No. 739)**
FILED:	**October 30, 2007**

THEREON it is **ORDERED** that the Motion is **GRANTED in part** and **DENIED in part.**

The parties have successfully reduced their issues with the help of the Special Master-PMO to nine issues. The Court rules as follows in the order listed on the parties' "narrowed list":

1. Request No. 14 - Drafts of package inserts, patient information sheets and Dear Doctor/Healthcare Provider letters relating to Seroquel that were prepared for five foreign countries and existing English translations.

As of October 23, 2007, AstraZeneca asserted objections and privileges, but identified bates number ranges for final patient information sheets and package inserts for the UK and Canada, stated that final patient information sheets, package inserts and Dear Doctor letters for Japan are being processed for production, that it is collecting and processing final patent information sheets, to the extent they exist, and package inserts from Australia and Sweden, that Dear Doctor Letters

[1]December 18, 2007.

for Canada and Sweden are being processed for production, and that AstraZeneca does not believe Dear Doctor Letters were sent in the UK and Sweden. Based on information from AstraZeneca, Plaintiffs' understanding that any drafts that did exist at one time in the GEL database no longer exist (they were "non-retained"), and final versions of the requested documents were being collected, but as of December 14, 2007, Plaintiffs had not received the documents.

AstraZeneca contends that responsive documents from the UK, Canada, and Sweden, and package inserts for Japan and Australia have been produced. Doc. No. 662 at 8. AstraZeneca planned to produce patient information sheets by February 14, 2008, but dispute whether Plaintiffs are entitled to, or whether AstraZeneca agreed to, production of drafts. According to counsel's representations at oral argument, if drafts of responsive documents were kept in the GEL database (for the UK, none were) they were deleted when the document was made final. As of January 22, 2008, the SM-ESI was "assured that the information" from GEL that he sought regarding whether the information created within GEL was truly gone, would be "forthcoming."

As to the final documents, the issue appears mooted by AstraZeneca's February 14, 2008 production. As to the drafts, it is **ORDERED** that the matter is referred to the SM-ESI for his determination as to whether "other accessible data that was non-retained following the onset of the company's preservation duties for this litigation" exists. Doc. No. 812.

2. Request No. 23 - Internal and external communications, including emails, regarding protocols for clinical study 125.

Plaintiffs request that the Court order AstraZeneca to search for and produce documents regarding protocols for clinical study 125. AstraZeneca contends that such communications are cumulative and duplicative of the communications already produced in custodian files and those produced as part of the IND/NDA. AstraZeneca primarily argues in its Response (Doc. No. 662)

that it has produced a significant number of documents and Plaintiffs have not identified any categories of materials that they believe to be missing from the productions; it is impossible to search every ostensible "location" in the company.

Even if some of the production is cumulative, some of it is not; therefore, it is **ORDERED** that AstraZeneca will produce the internal and external communications, including emails, regarding protocols for clinical study 125 within 11 days of the date of this Order.

3. Request No. 58 - Communications between members of the Benefit/Risk Team for Seroquel

Plaintiff reports that, as of October 2007, AstraZeneca had not produced any documents, although it agreed to run two keyword searches in the "appropriate custodial files" and produce Benefit/Risk Team meeting minutes. AstraZeneca contends some members of the Risk Benefit Team are included within the approximately 100 custodians whose files had been produces and communications among team members were not maintained in a central file; thus, it would be an undue burden for AstraZeneca to identify and search the files for each and every individual team member over the years for communications.

Given the scope of this litigation, requiring a limited number (even 100) of known individuals to search for significant information is not an undue burden. It is **ORDERED** that AstraZeneca will produce communications between members of the Benefit/Risk Team for Seroquel within 11 days of the date of this Order.

4. **Request No. 67** - Notes regarding contacts with any foreign regulatory authority in the UK, Australia, Canada, Japan, Sweden and the Netherlands relating to Seroquel

Plaintiffs seek to compel production of notes of contacts with the foreign regulatory authorities in six countries, over AstraZeneca's objections. AstraZeneca contends that any such

notes that exist in the 100 custodians' files have already been produced. Beyond that, the request is overly broad, unduly burdensome, harassing, because Seroquel is marketed in 80 countries, and the request is not reasonably calculated to lead to the discovery of admissible evidence. Doc. No. 662. With the limitation set forth below, the Court will order the notes of contacts produced.

It is **ORDERED** that, within 11 days of the date of this Order, AstraZeneca will produce notes regarding contacts with any foreign regulatory authority in the UK, Australia, Canada, Japan, Sweden and the Netherlands relating to Seroquel to the extent the information is located in the United States and kept in electronic form.

5. Request No. 75 - UK Marketing Authorization Applications relating to Seroquel

Plaintiffs seek to compel production of a specific category of documents, *i.e.*, UK Marketing Authorization Applications relating to Seroquel. AstraZeneca objects to the request, arguing that it is for material which is the equivalent of the IND/NDA and consists of tens of thousands of pages, and is not relevant to products liability suits brought in the United States.

Based on AstraZeneca's representations, the UK Marketing Authorization Application is a well-defined document and not burdensome to produce. Much of the information sought in these requests relates to regulation within and by foreign countries and is "reasonably calculated to lead to the discovery of admissible evidence." FED. R. CIV. P. 26(b). It is **ORDERED** that, within 11 days of the date of this Order, AstraZeneca will produce the UK Marketing Authorization Applications relating to Seroquel to the extent the information is located in the United States and kept in electronic form.

6. Marketing Request No. 2 - Notes relating to Seroquel taken by members of the teams identified in Request No. 1.

Plaintiffs seek to compel the notes relating to Seroquel taken by members of 41 teams during team meetings. AstraZeneca objected to the burden of identifying and locating notes of 41 teams which equaled "potentially hundreds of team members." Doc. No. 662 at 13. AstraZeneca also contends that Plaintiffs cannot raise this issue because they had not met and conferred on it.

Because it is not clear whether further meet and confer on this issue has occurred, and the issues are not precisely drawn as to the scope and significance of the requested information and the actual burden associated with producing it, the motion is **DENIED** as to this request, without prejudice.

7. Marketing Request No. 3 - Communications relating to Seroquel between members of ten specific teams.

AstraZeneca initially argued that production of these communications would be an undue burden for AstraZeneca because these communications were not maintained in a central file and to identify and search the files of individual team members from the teams would be burdensome. Plaintiffs have since limited their requests to ten teams. AstraZeneca previously offered, after Plaintiffs received and reviewed the team minutes, to consider reasonable requests to search additional custodial files for communications among team members; but Plaintiffs have made no such requests. Doc. No. 662 at 14.

Because it is not clear whether further meet and confer on this issue has occurred, and the issues are not precisely drawn as to the scope and significance of the requested information and the actual burden associated with producing it, the motion is **DENIED** as to this request, without prejudice.

8. PRA Requests - Principles of Prescription Drug Promotion.

Plaintiffs seek compel *in camera* review of AstraZeneca's guide that purportedly governs its promotion of its products, arguing it is relevant to their claims of AstraZeneca's aggressive promotion of Seroquel for approved and off-label uses. Doc. No. 629 at 25. AstraZeneca asserts the guide is protected from disclosure by the attorney-client privilege.

When queried by the Court at oral argument, AstraZeneca's counsel admitted that the guide had been broadly circulated within the company, from which, the Court concludes, the guide has lost its attorney-client privilege, if it ever had any.

It is **ORDERED** that, within 11 days of the date of this Order, AstraZeneca will produce the Principles of Prescription Drug Promotion, which shall be treated as confidential in accordance with the Court's prior orders.

9. Bates numbering - The identification of bates numbers for documents contained in AstraZeneca's Marketing, Sales, and PRA production

Plaintiffs seek to compel responses from AstraZeneca that identify bates numbers for documents contained in AstraZeneca's PRA production (62,000 pages) responsive to various Marketing, Sales, and PRA Requests relating to Seroquel, listed in Doc. No. 739 at 3-4. *See also* Doc. No. 629 at 20-21, 23-25. Although AstraZeneca has offered Plaintiffs searchable indices to the production, the index also does not contain bates numbers. Doc. No. 629 at 23.

In its Response, AstraZeneca argues that it is not required to provide bates numbers in response to a request for documents, and it has already provided Plaintiffs with searchable indices and Microsoft Access database. Doc. No. 662 at 4-5. AstraZeneca contended at oral argument that the searching is not easy because the materials are not text searchable; thus, it is no easier for AstraZeneca to identify the bates numbers than it is for Plaintiffs, although AstraZeneca would be willing to assist Plaintiffs.

If the documents are in a searchable format, then the parties have a duty to cooperate to minimize difficulties in document authentication. It is **ORDERED** that the matter is referred to the SM-ESI to assist the parties in establishing a methodology to resolve disputes concerning the authenticity of the documents (but not to decide the authenticity itself).

DONE and **ORDERED** in Orlando, Florida on February 21, 2008.

David A. Baker

DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE

Copies furnished to:

Counsel of Record