

Decker, Brian

From: Voshell, Colleen Casey
Sent: Friday, December 28, 2007 10:34 AM
To: Kerns, Kevin
Subject: FW: Database Discussion Document III
Attachments: Pre-mediation database discussion document III.pdf; Pre-mediation database discussion document III.doc

From: Kerns, Kevin
Sent: Sunday, December 02, 2007 12:16 AM
To: Voshell, Colleen Casey
Subject: FW: Database Discussion Document III

I made several changes and included the word doc as well. Have a good rest of the weekend, thanks for your help today.

KTK

From: Kerns, Kevin
Sent: Sunday, December 02, 2007 12:13 AM
To: lgornick@lskg-law.com; dcanty@lskg-law.com; MPederson@weitzlux.com; jjaffe@weitzlux.com
Cc: McConnell, Stephen; rpass@carltonfields.com; 'Craig Ball'
Subject: Database Discussion Document III

Enclosed please find a document setting forth AZ's positions with respect to the remaining databases at issue. AZ endeavored in the attached to provide sufficient detail to facilitate a productive mediation next week. AZ's discussion of objections in the attached is without waiver of its right to assert any objection to Plaintiffs' RFP's. Moreover, that AZ did not choose to specifically discuss an objection in the attached shall not be a waiver of any of its objections.

We look forward to seeing you in New York on Tuesday.

Sincerely,

Kevin T. Kerns

12/28/2007

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**ASTRAZENECA'S PRE-MEDIATION POSITION PAPER
ON REMAINING REQUESTS FOR PRODUCTION OF DATABASES**

1. **AZER (Expense Report)**

(a) **AstraZeneca's Intended Production**

- All PSS expense reimbursement should be subject to production, if at all, only through the case specific discovery program.

(b) **Overview of AstraZeneca's Objections**

- AstraZeneca objects to the production of expense information for PSS activities unrelated to the issues in this litigation.
- Moreover, the images of the underlying documents that are the source of the data (receipts, etc.) in the AZER Oracle database and that are housed in KWIKTAG are not discoverable. These images are cumulative of the information in the Oracle database. The burden of extracting, processing, redacting and producing these documents far outweighs their marginal relevance.

2. **AZU**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce the Seroquel related courses from AZU, including the courses that are in SCORM format, and the tables and fields specified in Request 6.

(b) **Overview of AstraZeneca's Objections**

- AstraZeneca is producing the substantive Seroquel related information and data from AZU, and AstraZeneca objects to Plaintiffs' Request for Production to the extent it seeks tangential, irrelevant information like "internal course announcements from the training department that *might* have been sent to the sales department personnel."
- AstraZeneca objects to providing audit trails to the extent that courses are not created, reviewed or revised in AZU. The courses are created by third parties and loaded into AZU. If a course is updated, the old and new course are both stored in AZU.

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- AstraZeneca objects to producing AZU Bulletin Board, AZ Merchandize, Peer Net, Internal Newsletters, and AZU Hot Topics because the burden of generating queries to attempt to locate responsive materials far outweighs the marginal benefit.

3. CLINTRACE

(a) AstraZeneca's Intended Production

- AstraZeneca states that the detailed case reports already produced to Plaintiffs contain the majority of the requested data.
- In addition to the detailed case reports already produced, AstraZeneca will provide a count of Clintrace IDs

(b) Overview of AstraZeneca's Objections

- AstraZeneca objects to the Request for all audit trails from the database. AstraZeneca has never run an audit trail of the scope and magnitude requested. The burden of creating a query and running the report would outweigh the marginal relevance of the information of the audit.
- AstraZeneca objects to providing system diagrams, as such a request seeks discovery about the database and not about Seroquel.
- AstraZeneca is required to redact patient, drug and certain voluntary reporter information from adverse event reports; therefore, AstraZeneca cannot produce the requested information in any format other than .tif.
- AstraZeneca objects to the extent that some of the information sought by plaintiffs is cumulative and duplicative insofar as the detailed case reports produced by AstraZeneca contain a "medications as reported" section that requires redaction for other AZ drugs.
- AstraZeneca objects to producing a listing of fields to the extent that such a request seeks discovery about discovery and, moreover, responsive information is contained in "Chapter 5 – Panel and Item Definitions" in the Clintrace 2.10 Reference Guide, which was provided to Plaintiffs on or about October 17, 2007.

4. CFR/DEN

(a) AstraZeneca's Intended Production

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- CRF/DEN houses the Case Report Forms that need to be redacted because they contain patient identifying information as well as other AZ concomitant medications. AstraZeneca will extract, redact and produce the all documents relating to case report forms housed in the CFR/DEN database.

(b) Overview of AstraZeneca's Objections

- AstraZeneca objects to producing information regarding products other than Seroquel
- AstraZeneca objects to plaintiffs' request to query *every* table in the database. Given that AstraZeneca is producing the underlying information from the database, this request is overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence.
- AstraZeneca objects to producing tables and fields from the database. This request is unduly burdensome and that burden far outweighs the marginal probative value in that a custom program needs to be written to extract these tables and fields. The information, if any, in look up tables is not relevant and is not reasonable calculated to lead to the discovery of admissible evidence.

5. CORPORATE INTRANET & PUBLIC INTERNET WEBSITES

(a) AstraZeneca's Intended Production

- AstraZeneca will produce the Seroquel related information from the SourceSafe database which stores Internet content.
- AstraZeneca is assessing plaintiffs' request for information from the corporate intranet.

(b) Overview of AstraZeneca's Objections

- AstraZeneca objects to producing anything other than the Seroquel related content from SafeSource.

6. DIRM

(a) AstraZeneca's Intended Production

- See below.

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(b) **Overview of AstraZeneca's Objections**

- DIRM contains the study master file for AZ sponsored studies. DIRM itself is an "index" of Study Master files, Investigator CVs, Clinical Study Agreements, Clinical Research Organization Agreements, SAEs/MedWatch/3500As. Much of the information is submitted to FDA, and, as such, has been produced to plaintiffs.
- Plaintiffs' request for the study master file and imaged documents therein for every Seroquel related clinical trial is vastly overbroad and the information therein is cumulative.

7. **eCTD**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce non-duplicative Seroquel submissions, if any, that were sent to FDA using eCTD electronic submission protocol.

(b) **Overview of AstraZeneca's Objections**

- AstraZeneca objects to producing anything other than the Seroquel submissions.

8. **eROOM**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce relevant, non-privileged information from eRooms with "Seroquel" or "quetiapine" in the title, purpose, description or key word.
- AstraZeneca will produce database objects that have an association with the eRooms described above.

(b) **Overview of AstraZeneca's Objections**

- AstraZeneca objects to producing other eRooms except as described above. The burden of searching and producing documents from other eRooms outweighs the marginal relevance of such additional information.
- AstraZeneca objects to the extent that Plaintiffs' Request purports to specify the resources that AstraZeneca should use to respond to this Request.

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- AstraZeneca objects to Plaintiffs' Request for a report on eRooms. The reports requested by plaintiffs are cumulative of the information that AstraZeneca is producing.
 - AstraZeneca objects to providing databases diagrams, counts of eRooms across the system, lists of eRoom users, etc. Such information is discovery about the system and not about Seroquel.
 - AstraZeneca objects to the request to provide "a list of all users associated with Seroquel that have eRoom accounts." This request is unintelligible and vague.
 - AstraZeneca objects to providing the queries that it runs to produce the requested information. AstraZeneca will maintain records of these queries.
 - AstraZeneca objects to the extent that Plaintiffs' Requests for Production seeks database documentation regarding other systems.
 - AstraZeneca objects to the extent that the Request seeks production of association lists.
9. **GEL** – As stated on the call with Special Master Ball on Thursday, November 29, 2007, Bill Adams from FTI is meeting with AZ IT resources on Monday to discuss the GEL production. AstraZeneca will be prepared to discuss the GEL production at the mediation.
10. **IMPACT**
- (a) **AstraZeneca's Intended Production**
 - AstraZeneca will produce a list of Seroquel studies from IMPACT.
 - (b) **Overview of AstraZeneca's Objections**
 - AstraZeneca objects to producing information regarding the progress of clinical trials contained in IMPACT. Such information is not reasonably calculated to lead to the discovery of admissible evidence. Moreover, once the trials themselves are complete, clinical trial reports are generated and those reports will be produced to plaintiffs.
 - AstraZeneca objects to the extent that this request is overly broad in that it seeks information about all Seroquel studies in the Impact database.

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- AstraZeneca objects to Plaintiffs' references to IMPACT as a Documentum system. IMPACT is not a such a system.

11. **IIRIS**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce Seroquel data and reports that contain Seroquel relevant information from IIRIS.

(b) **Overview of AstraZeneca's Objections**

- AstraZeneca objects to producing copies of the queries it runs.

12. **KNOWBOL**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce Seroquel related information from KNOWBOL.

(b) **Overview of AstraZeneca's Objections**

- AstraZeneca objects to producing non-Seroquel related information, for instance, logs.

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13. **LBX**

(a) **AstraZeneca's Intended Production**

- AstraZeneca is processing speaker evaluation forms from LBX and those forms will be produced shortly in response to an RFP.
- AstraZeneca is in discussion with Novis about other Seroquel related data.

(b) **Overview of AstraZeneca's Objections**

- LBX is proprietary technology owned by Novis, a third party over whom AstraZeneca has no control.
- AstraZeneca objects to producing information regarding products other than Seroquel.
- LBX stores data regarding speakers. It does not contain transcripts of speaker programs.

14. **LIFECYCLE SCIENTIFIC**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce the Excel spreadsheet that is the Lifecycle Scientific Database, the documents linked to that spreadsheet, and metadata related to those documents. The spreadsheet contains links to PowerPoint presentations prepared by a third party regarding published Seroquel literature from the public domain.

(b) **Overview of AstraZeneca's Objections**

- Plaintiffs' request for the tables and fields is overbroad and not reasonably calculated to lead to the discovery of admissible evidence. AstraZeneca is producing the Excel spreadsheet, underlying documents and metadata associated with those materials.

15. **MACS**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce all Seroquel related information, fields and tables from MACS.

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16. **MARKETPRO**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce .jpgs of Seroquel related materials from MARKETPRO.

(b) **Overview of AstraZeneca's Objections**

- Data regarding the materials ordered by particular pharmaceutical sales specialists is provided in case specific discovery. Materials ordered by other sales representatives are not reasonably calculated to lead to the discovery of admissible evidence.

17. **OUTLOOK PUBLIC FOLDERS**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce relevant, non-privileged Seroquel information, if any from U.S. public folders.
- AstraZeneca will produce Seroquel related forms that are in Outlook public folders.

(b) **Overview of AstraZeneca's Objections**

- AstraZeneca objects to searching multiple servers because public folders are replicated to global servers.

18. **PLANET**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce the Seroquel related summaries and the information from the table fields (which are the metadata fields about the literature articles) requested by plaintiffs if applicable.

(b) **Overview of AstraZeneca's Objections**

- Plaintiffs' requests for "140 attributes" and the "questions the user gets asked for each attribute" are vague and not reasonably calculated to lead to the discovery of admissible evidence.

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19. **SALES INSITE**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce Seroquel related information, tables and fields from Sales InSite.
- AstraZeneca will produce an Excel extract of tables and fields necessary to decipher codes relating to Seroquel.

(b) **Overview of AstraZeneca's Objections**

- AstraZeneca objects to providing a screen shot of the SALES INSITE user interface.

20. **SAMPLING**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce an Access database containing the Seroquel related information from SAMPLING. The Access database will contain tables and the relationships between those tables as they exist in SAMPLING.

(b) **Overview of AstraZeneca's Objections**

- AstraZeneca objects to plaintiffs' request for a "list of fields" to the extent that it purports to require AstraZeneca to create documents. AstraZeneca is producing the relevant fields from the database.
- AstraZeneca objects to providing the queries that it runs to produce the requested information. AstraZeneca will maintain records of these queries.

21. **SAMSON**

(a) **AstraZeneca's Intended Production**

- See below.

(b) **Overview of AstraZeneca's Objections**

- SAMSON contains form letters sent to investigators enclosing adverse event information generated from Clintrace. The packet in SAMSON is the "enclosed please find" form letter, the adverse

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event report and the Excel spreadsheet derived from IMPACT showing to whom the letter was sent.

- In addition to the fact that the adverse reports are in Clintrace, this information is ultimately incorporated into the Investigator's Brochure. AstraZeneca has produced the Seroquel Investigator's Brochures and identified the bates numbers for those documents. The information in SAMSON is not discoverable in light of AstraZeneca's production of adverse event information from Clintrace and of the Investigator's Brochures. The burden to produce this marginally relevant data outweighs its potential probative value.

22. SAP

(a) Overview of AstraZeneca's Objections

- SAP is an enterprise resource planning application that contains four modules.
- There are 2 components of Purchase to Pay: requisitions and payables. Requisitions are ultimately turned into payables. Requisitions are redundant to what is being produced in case specific discovery. AstraZeneca already produces information from the Purchase to Pay module reflecting payments from AstraZeneca to certain doctors in Case Specific Discovery.
- The other modules in SAP are either redundant of information that is being produced elsewhere or are not relevant to a Seroquel products liability, failure to warn case. For example, plaintiffs' seek supply chain information from the "Order to Cash" module. This module contains information regarding direct purchasers of Seroquel, for example – who actually bought Seroquel (AZ selling to wholesalers; delivery notes; invoicing to customer). AZ objects to Plaintiffs' request for Supply Chain module (purchasing components of Seroquel).
- Plaintiffs' request for the "finance module" is not reasonably calculated to lead to the discovery of admissible evidence. The "finance module" is similar to a balance sheet.
- AZ objects to producing SAP exports to other applications.

23. STEP 2000

(a) AstraZeneca's Intended Production

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- AstraZeneca will produce the Seroquel specific product codes and the table dumps that Plaintiffs request.

(b) **Overview of AstraZeneca's Objections**

- AstraZeneca is providing plaintiffs the information requested from the database. AstraZeneca objects to creating "a list of the different categories of items that were entered into the database."

24. **TOUCHSTONE INTERACTIVE**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce flash presentations (either on a locked laptop or via a secure web site) and a sequel server database containing Seroquel related content from Touchstone Interactive in a usable format.

(b) **Overview of AstraZeneca's Objections**

- AstraZeneca objects to producing logs, synchronization information, reports, including administrative reports.
- AstraZeneca objects to Plaintiffs request for "request knowledge of where the FUSION TEAM within AstraZeneca retrieves the content merged into Touchstone Interactive." Such information is not reasonably calculated to lead to the discovery of admissible evidence. AstraZeneca is producing the Seroquel related content from Touchstone Interactive. Plaintiffs are aware that AstraZeneca receives this content from an outside source and loads the information into the Touchstone Interactive system.

25. **VIEWPOINT**

(a) **AstraZeneca's Intended Production**

- AstraZeneca will produce Seroquel related information from ViewPoint.