UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: Seroquel Products Liability Litigation.

Case No. 6:06-md-1769-Orl-22DAB

_____/

ORDER

This cause came on for consideration with oral argument[1] on the issue of AstraZeneca's duty to preserve intermediate data from its Global Electronic Library. Plaintiffs previously sought an order compelling identification and production of data that AstraZeneca had deleted from its Global Electronic Library ("GEL") (Doc. No. 877), which was denied without prejudice and the parties were ordered to file memoranda in support of their arguments as to AstraZeneca's duties to preserve. Doc. No. 943. The Court also requested that the Special Master-Electronically Stored Information file a report on the issue. The Court rules that AstraZeneca's duty to preserve the intermediate data in its Global Electronic Library relating to Seroquel in 2003.

BACKGROUND

GEL is a web-enabled database application employed by AstraZeneca employees to collaborate in the creation, evaluation, modification and publication of regulatory information, including labeling, clinical study data and other regulatory submissions, including documents related to the regulation of Seroquel. Doc. No. 939 (SM-ESI Report). GEL also contains AstraZeneca's submissions to, and communications with, regulatory agencies, changes to warnings and other labeling information, Safety Evaluation and Review Meeting (SERM) minutes, SERM discussion documents, Periodic Safety Update Reports, and information related to clinical trials and studies.

[1]Oral argument was held on March 24, 2008, and there was further discussion of the issues at the April 10, 2008 status conference.

Doc. No. 949, 950. Plaintiffs allege that AstraZeneca removed from GEL many drafts, revisions, annotations and commentary ("Intermediate Data") related to the documents. Doc. Nos. 877, 949[2]. Following Plaintiffs' filing of their Motion to Compel (Doc. No. 877), and after discussion at status conferences, the Court ordered the parties to submit briefs (Doc. No. 941) on the issue of when AstraZeneca's duty arose to preserve the Intermediate Data documents in the GEL database. The Court referred the matter to the Special Master for Electronically Stored Information ("SM-ESI"), who determined:

> AstraZeneca manually deleted drafts, revisions, comments and annotations for GEL documents, including Seroquel-related documents, when it "approved" final versions. This occurred companywide until March 2006, when U.S. Clinical Development reportedly ceased the practice. Otherwise, it continued companywide until December 21, 2007. For data existing in GEL during and after November 2005, most of the deleted GEL intermediate content can likely be recovered from backup tapes. For documents approved as final before November 2005, the deleted data is likely not recoverable except as individual employees who exported and/or retained personal copies of intermediate content are identified and produce such items.

Doc. No. 939. AstraZeneca does not seriously dispute that the Intermediate Data was deleted or "not retained." Rather, the parties dispute the extent and the timing of when AstraZeneca's duty to preserve the Intermediate Data for Seroquel and arose. The parties were ordered to file memoranda in support of argument of when AstraZeneca's duty to preserve the intermediate GEL documents arose. Doc. Nos. 949, 950.

Timing of the Duty to Preserve

Plaintiffs contend that AstraZeneca's duty to preserve GEL Intermediate Data arose no later than September 4, 2003, when AstraZeneca was a party to litigation involving claims substantially identical to those of Plaintiffs in this MDL, and if not before then, the duty arose when other

[2]Plaintiffs did not submit certain "confidential" documents listed as Exhibits to its Memorandum until June 23, 2008. Doc. No. 1025; *see* Doc. No. 979 (granting leave to lodge documents).

litigation or governmental investigations took place. Doc. No. 949. Plaintiffs contend that AstraZeneca's duty to preserve GEL intermediate data arose in connection with the August 2003 filing of the class action complaint in *Zehel-Miller v. AstraZeneca Pharmaceuticals, LP*, Case No. 6:03-cv-1258-Orl-18, which they contend asserts claims nearly identical to those asserted by the many individual plaintiffs in the MDL. Plaintiffs also contend GEL intermediate data were evidence of central relevance to those claims, the data were accessible, and there was no cost or burden associated with preservation.

AstraZeneca acknowledges that a general duty to undertake reasonable efforts to preserve Seroquel-related materials relevant to the claims in this MDL arose in the Fall 2003 with the filing of the first Seroquel diabetes lawsuit. Doc. No. 950. However, AstraZeneca contends this was only a general duty to preserve and not a duty to preserve the GEL Intermediate Data in particular.

Scope of the Duty to Preserve

Plaintiffs contend that GEL Intermediate Data were put squarely at issue by the 2003 *Zehel-Miller* complaint (if not before then, by other litigation or governmental investigation) because the complaint's allegations raised allegations similar to those in this case. AstraZeneca contends that the general duty to preserve that arose in Fall 2003 did not require it "to undertake efforts to determine how drafts and other intermediate data were treated on its many databases, and to rewrite its databases and alter its routine business practices to store information differently. More specifically, this general duty did not require AstraZeneca to take company-wide steps to identify and preserve Seroquel-related intermediate data stored on GEL." Doc. No. 950. Plaintiffs argue that AstraZeneca's inadequate "cascading" of a legal hold to certain key custodians who presumably would have retained intermediate data outside of GEL, was unreasonable in light of the facts – that

there were thousands of GEL contributors, for whom there existed no policy or protocol for saving content to local drives.

AstraZeneca argues that it was not obligated to "undertake a detailed and specific investigation and to implement special preservation efforts" for Intermediate Data stored on GEL until 2007, because it was only then that the "MDL Plaintiffs first specifically identified and articulated a demand for all GEL Intermediate Data." Only at that point in 2007, did "AstraZeneca anticipate that such data was viewed by Plaintiffs as relevant and discoverable." Doc. No. 950. AstraZeneca contends that, at the earliest, the duty to preserve GEL Intermediate Data would not have attached prior to the entry of CMO #2 – January 2007 – however even in CMO #2 the preservation provision was a general one and "GEL was preserved in this regard because it was not decommissioned or destroyed, and no final documents were deleted. Doc. No. 950. AstraZeneca contends that CMO #2 did not give rise to a specific duty to it they characterizes as "'drill[ing] down' into the specifics of each of AstraZeneca's many databases to determine the specific content and potential relevance, if any, of each category or item of information that may be contained in them, and to institute specific alterations in normal operations to maintain all forms of such material." Doc. No. 950. AstraZeneca argues that it was not required to preserve the Intermediate Data on GEL because "the business premise on which GEL operates is that such intermediate data is not important or relevant once the final, approved document . . . is submitted to the regulators." Doc. No. 950.

The Sedona Conference recommends in Principle 5:

> The obligation to preserve electronically stored information requires reasonable and good faith efforts to retain information that may be relevant to pending or threatened litigation. However, it is unreasonable to expect parties to take every conceivable step to preserve all potentially relevant electronically stored information.

Sedona Principles, Second Edition: Best Practices, Recommendations & Principles for Addressing Electronic Dcoument Production (The Sedona Conference Working Group Series, 2007). The duty to preserve evidence "arises not only during litigation but also extends to the period before the litigation when a party reasonably should know that the evidence may be relevant to anticipated litigation." *Silvestri v. Gen. Motors Corp.*, 271 F.3d 583, 591 (4th Cir. 2001); *Rambus, Inc. v. Infineon Techs. AG*, 220 F.R.D. 264 (E.D. Va. 2004). Once a party reasonably anticipates litigation, "it has a duty to suspend any routine document purging system that might be in effect and to put in place a litigation hold to ensure the preservation of relevant documents." *Id*.

The Special Master-ESI made a number of important factual findings relevant here in his April 8, 2008 Report:

> 2. GEL stores information relating to Seroquel as well as other AstraZeneca products. It is used internationally. GEL reportedly holds approximately 1.75 million documents, regularly accessed by thousands of AstraZeneca employees.
> 3. The GEL database was widely used as the primary or sole repository of intermediate content (e.g., drafts, revisions, comments and annotations) that drove the evolution of and maturation into final relevant documents for, inter alia, product labeling and regulatory submissions.
> 4. The GEL database is a key information asset, described by AstraZeneca as "mission-critical" and clearly central to the company's collaborative processes for creation, evaluation and modification of business documents, including documents relevant to the issues in this cause. GEL is not of a minor or peripheral character in AstraZeneca's operations such that it might reasonably be overlooked in or deemed inconsequential to meeting AstraZeneca's obligations to preserve ESI.
> 5. AstraZeneca acknowledges that, at least since September of 2003 when it started "cascading" legal hold notices to personnel, the company was obligated to instruct its employees with documents relevant to the litigation to preserve such documents, including documents in their draft forms.
> 6. The GEL database does not automatically delete or purge intermediate content. Absent specific, intentional human intervention, the GEL database will retain intermediate content so long as there is sufficient storage space to do so. A lack of storage capacity has never been raised by AstraZeneca as a justification for its disposition of intermediate content.
> 7. Though GEL is used by thousands of AstraZeneca employees, only a select group of Document Management Specialists (previously called GEL Local Administrators)

have the authority to carry out procedures that delete intermediate content as part of a document finalization and approval process.

8. When a Document Management Specialist seeks to approve a GEL document as the final version, they are automatically reminded that doing so will remove (*i.e.*, delete) the intermediate draft versions, and the Specialist is presented with the option to preserve such intermediate draft content.

9. The deletion of intermediate GEL content will not occur accidentally, automatically, spontaneously or by default. Deletion requires the Document Management Specialist manually enter a password after receiving the deletion reminder just described and being afforded the option to preserve intermediate content.

10. The effort required of Document Management Specialists to retain intermediate GEL content is trivial. If a Document Management Specialist wishes to preserve intermediate content, he or she need simply undertake a single mouse click to reverse the default setting displayed within the "Approve Document" dialogue box . . .

[graphic omitted]

11. From a programming standpoint, it would have been a simple matter for AstraZeneca to have made preservation of drafts upon document approval the system's default action. Then, instead of requiring Document Management Specialists to click their mouse when they sought to preserve intermediate content, they'd click to delete it. However, the ease with which Document Management Specialists could retain intermediate content notwithstanding default settings suggests that programmatic changes were not essential and may, in fact, have been undesirable considering overall business needs.

12. Although the steps required to preserve GEL intermediate content are trivial, the total cost and burden of preservation doesn't end with the deactivation of automatic removal. There necessarily would be burdens and costs flowing from the need to store and manage the additional volume of intermediate content for Seroquel-related matters, and AstraZeneca points to a potential for confusion should one of its employees mistakenly submit a retained draft instead of a finalized document. However, despite being invited to do so, AstraZeneca has not produced evidence to support an assertion of added burden, cost or confusion and so I cannot weigh those factors or report on them.

13. With one notable exception, throughout the course of this litigation until December 21, 2007, AstraZeneca's Document Management Specialists routinely deleted GEL intermediate content by entering their passwords to approve documents without clicking the mouse button to uncheck the option to remove intermediate draft versions. This should not have occurred as an oversight or by inadvertence because Document Management Specialists are instructed to ensure the check box for the automatic removal of draft versions is set correctly before initiating approval and, of course, they cannot initiate document approval without first being presented with the option to preserve intermediate content.

14. Beginning in March 2006, the U.S. Clinical Development group began removing the check mark at approval and preserving GEL intermediate content for documents under their auspices.

15. Despite inquiry, it's unclear why certain Document Management Specialists within the U.S. Clinical Development group saw and acted upon an obligation to preserve GEL intermediate content while other GEL Document Management Specialists continued to delete such content until I required its preservation for potentially relevant Seroquel-related content after my appointment as Special Master late in 2007. It appears, however, that the limited preservation by U.S. Clinical Development was undertaken as a response to this litigation and not for other business purposes; yet, AstraZeneca denies that it had any obligation to preserve Seroquel-related intermediate GEL content in March 2006, or thereafter (until late in 2007).

16. GEL itself is not a Seroquel-specific database; however, numerous areas within GEL called cabinets or folders are Seroquel- and quetiapine-specific. Apart from the actions of the U.S. Clinical Development group just described, AstraZeneca's Document Management Specialists did not cease the practice of deleting intermediate content in GEL, even for Seroquel- and quetiapine-specific areas and documents.

17. Insofar as I can tell, AstraZeneca's Document Management Specialists (excluding those in U.S. Clinical Development) continue the practice of deleting intermediatecontent in GEL, even for Seroquel- and quetiapine-specific areas and documents. Instead, to facilitate continued deletion in this manner, this material is now preserved by periodic export to another system—a mechanism proposed by AstraZeneca and launched on December 21, 2007, in response to my request that the company preserve potentially-relevant, Seroquel-related intermediate GEL content.

18. AstraZeneca contends that at no time prior to the end of 2007, did it have a legal duty to preserve potentially-relevant, Seroquel-related intermediate GEL content.

19. Plaintiffs contend that AstraZeneca's duty to preserve potentially-relevant, Seroquelrelated intermediate GEL content arose no later than September 4, 2003 and posit that the duty may have arisen much earlier.

20. Except for the above-described GEL Intermediate content preserved by the U.S. Clinical Development group after March 2006, all potentially-relevant, Seroquel-related intermediate GEL content was routinely deleted by AstraZeneca when documents were finalized until December 21, 2007.

21. Assuming it's not been discarded or altered, and assuming that the custodians have sufficient recollection or records to identify them, some unknown volume of GELoriginated intermediate content might have been copied or printed out of GEL and retained by persons participating in the document creation collaboration and still employed by AstraZeneca. This also assumes that AstraZeneca can identify these collaborators.

22. Conversely, GEL allowed users to contribute drafts created using other applications (e.g., Word, PowerPoint, Excel or Adobe Acrobat). These also comprised a component of intermediate content and were deleted from GEL upon document finalization, except as described above. The contributors may have retained copies of their contributions on local machines, removable media, and network shared areas or in paper printouts.

23. The volume and nature of the intermediate content pertaining to Seroquel-related GEL documents is unknown. This uncertainty remains the principal impediment to fashioning an appropriate response. The plaintiffs are convinced that the deleted data

> is relevant and material to issues in the case. AstraZeneca counters that the deleted material would be, "at best, of de minimis probative value."
> 24. Reasoning that the best way to assess the relevance and materiality of missing evidence is to examine the evidence--or as close to it as you can get--I directed the parties to propose a narrow sampling methodology for GEL intermediate content on back up tapes (please see Addendum at conclusion of this report). I further suggested that plaintiffs should plumb the GEL intermediate content retained by U.S. Clinical Development from March 2006 forward. My purpose wasn't to facilitate production of Post-11/2005 data as much as to help the parties gauge the amount and probative value of deleted and unrecoverable GEL intermediate content. Instead, the sampling effort spontaneously gave way to a broad backup tape restoration and production effort backed by AstraZeneca. Though broader and costlier than what I sought; it serves the same ends as my requested sampling and puts more relevant information in the plaintiffs' hands at an earlier time. Unfortunately, the proposed restoration, review and production isn't a speedy undertaking, and won't conclude for months.

Doc. No. 939 (SM-ESI Report).

It is undisputed that, from a programming standpoint, it would have been easy or "a simple matter" for AstraZeneca to have made preservation of drafts upon document approval the system's default action. AstraZeneca has not produced evidence to support an assertion of added burden, cost or confusion which would have been caused (or was caused in the U.S. Clinical Development) by the change. AstraZeneca also offers no explanation as to why beginning in March 2006, Document Management Specialists in one particular group, the U.S. Clinical Development group, began the easy step of "removing the check mark at approval" and preserving GEL Intermediate Data for documents, even though other GEL Document Management Specialists kept deleting the Intermediate Data for Seroquel- and quetiapine-specific areas until late in 2007. Even now, the Intermediate Data in GEL is preserved by periodic export to another system, begun on December 21, 2007, in response to the SM-ESI's request. Despite the SM-ESI's efforts, the volume and nature of the Intermediate Data pertaining to Seroquel-related GEL documents is still unknown.

The Court finds that AstraZeneca had a duty to preserve the Seroquel- and quetiapine-specific Intermediate Data in Gel at the time the *Zehel-Miller* was filed. "The obligation

to preserve evidence arises when the party has notice that the evidence is relevant to litigation or when a party should have known that the evidence may be relevant to future litigation." *Zubulake v. UBS Warburg LLC*, 220 F.R.D. 212, 216 (S.D.N.Y. 2003) (citing *Fujitsu, Ltd. v. Federal Express Corp*., 247 F.3d 423, 436 (2d Cir. 2001)).

The *Zehel-Miller* complaint filed in 2003 contained allegations that AstraZeneca's marketing and promotion efforts were made "while fraudulently withholding important safety information from physicians, the FDA, and the public, specifically that AstraZeneca was aware of numerous reports of diabetes associated with the use of Seroquel." Doc. No. 949-2 ¶¶ 25, 38f ("whether Defendants knowingly omitted, suppressed or concealed material facts about the unsafe and defective nature of Seroquel from governmental regulators, the medical community and/or the consuming public"); ¶ 48 (failure to perform adequate testing concerning the safety of the drug); ¶ 51 (negligent design, manufacturing, testing, advertising, marketing, promotion, labeling, warnings, and sale). AstraZeneca's answer also contained affirmative defenses which included a preemption defense and raise issues of safety information and testing of the drug. Doc. No. 949-6, affirm. def. 6, 10. AstraZeneca knew or should have known at that point that draft documents in GEL were relevant or could be relevant to future litigation over Seroquel. *See Zubulake*, 220 F.R.D. at 216.

Determination of an appropriate remedy for this failure to preserve evidence will await further indications of the results of what the Court understands to be on-going efforts to recover, restore or otherwise obtain as much of the potentially relevant information as reasonably possible. The Court will need a better understanding of the scope and potential significance of any information no longer available, despite these efforts. At an appropriate time, the parties may bring the matter back before the Court for assessment of these issues.

DONE and **ORDERED** in Orlando, Florida on June 24, 2008.

David A. Baker

DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE

Copies furnished to:

Counsel of Record