UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

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

This Document Relates to ALL CASES

Report of Craig Ball, Special Master - Electronically Stored Information Regarding Preservation, Non-Retention and Restoration of GEL Intermediate Content
April 8, 2008

Summary of Report and Recommendations

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.

I respectfully recommend that the Court:

1. Defer ruling on or deny without prejudice Plaintiffs' request for an order directing me to undertake a more extensive inquiry into the status and disposition of GEL intermediate data. I believe that to the extent I have not already done so, I can meet the goals sought and sufficiently secure AstraZeneca's continued cooperation without such an order.

2. Defer ruling on or deny without prejudice Plaintiffs' request for an order directing AstraZeneca to restore selected backup tape intervals from 2005-07 and make de-duplicated production by May 30, 2008. In light of the deletions described, this may prove too *narrow* a restoration and production. Alternatively, reviewing a sample of the restored data sought may allow the scope to be narrowed or prove further restoration unnecessary. I believe the deadline sought will not allow sufficient time for completion of restoration and production. Assuming expedited production deadlines can be secured by agreement, I believe the order sought to be unnecessary at this time.

3. Grant in substance the relief sought by Plaintiffs seeking greater transparency in AstraZeneca's efforts to identify and recover data from outside GEL. *As narrowed in their Supplemental Statement in Support,* the relief sought is not unduly invasive and will likely aid both sides in securing a cost-efficient and credible outcome.

I. Scope of Report

On February 21, 2008, the court directed I determine whether, with respect to AstraZeneca's GEL database, "other accessible data that was non-retained following the onset of the company's preservation duties for this litigation" exists.

I've elected to tackle this question in two parts. The first, whether "other accessible data" was non-retained in GEL following the onset of the company's preservation duties" and, second, what material still exists, where it exists and in what forms it exists.

Additionally, the Court directed me to report on the matters raised by Plaintiffs' Motion to Compel Identification and Production of "Intermediate Data" from Astrazeneca's "Gel" Database and Defendant's responses thereto.

As the two assignments are closely related, this document seeks to fulfill both directives. I've also undertaken to make recommendations to the Court respecting the relief sought by the Plaintiffs in the instant motion.

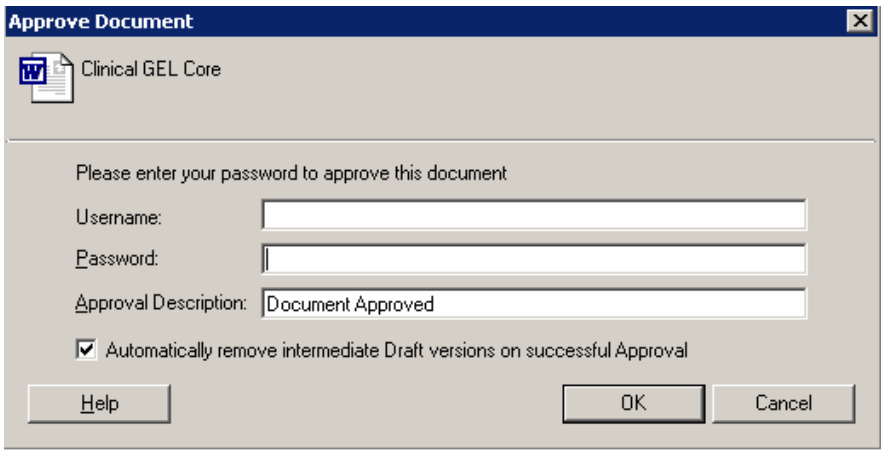
II. Factual Observations

After investigation and extensive discussions with AstraZeneca's counsel, consultants and in-house technical experts, I report to the court that:

1. GEL stands for Global Electronic Library. It 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.
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 (see check box in figure below).



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 intermediate content 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, Seroquel-related 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 GEL-originated 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.

III. Existing Sources of GEL Intermediate Content

A. <u>GEL intermediate content in reasonably accessible forms</u>:

1. **Material retained after March 2006 by U.S. Clinical Development.**
    a. **Nature**: This data should still exist with GEL in its native forms.
    b. **Volume**: Unknown; however, AstraZeneca has expressed the view that these documents constitute most of the responsive documents housed on GEL.
    c. **Status**: As relevant and non-privileged, this material should have been produced to plaintiffs on or before March 14, 2007.
    d. **Issues**: No information has been developed to indicate whether the retention of intermediate content by U.S. Clinical Development was uniform or complete. That is, as it appears to have been something of a maverick preservation effort

and at odds with the overall corporate practice of deleting Seroquel-related GEL intermediate content, I don't know the date in March 2006 when this retention effort began or if it was applied uniformly or selectively to GEL intermediate content thereafter.

2. **Intermediate content associated with GEL documents not yet finalized at the time GEL contents were collected for processing and production in December of 2007.**
    a. **Nature:** This data should still exist in native forms though separated from the native GEL database. It should exist as accessible data within collections maintained by FTI, AstraZeneca's principal e-discovery service provider.
    b. **Volume:** Unknown to me, but known to the parties.
    c. **Status:** This material is believed to have been produced on or before March 14, 2008;
    d. **Issues:** Plaintiffs report that some of this production yet lacks associated searchable text. Other issues as may exist with this material (if any) must await completion of this data being loaded on Plaintiff's ESI review platform.

3. **Intermediate GEL content exported daily from the GEL Seroquel "cabinet" beginning December 21, 2007 and continuing to date.**
    a. **Nature**: This data exists outside GEL in its native document form, but possibly lacking associated utility objects and certain metadata. It's expected that these materials have been grouped and ordered to preserve their relationship to the approved final document.
    b. **Volume**: Unknown.
    c. **Status**: AstraZeneca has not shared its plans for supplementary production from this collection. Further, AstraZeneca's March 14, 2008 production of GEL content reflects items in GEL at a point some days or weeks before the 12/21/07 preservation date. We must yet determine if potentially relevant documents were finalized in the interval between the collection of GEL and the beginning of preservation on 12/2107, addressing any relevant omissions.
    d. **Issues**: AstraZeneca has recently discovered that some Seroquel-related intermediate content is housed *outside* the Seroquel cabinet; consequently, the preservation effort must be tweaked to address that absence. Materials not preserved as a consequence of focusing too narrowly on the Seroquel cabinet may need to be retrieved or restored from other sources.

4. **Intermediate GEL-originated content that may have been retained by GEL users on local, network or portable storage areas and devices or as paper printouts.**
    a. **Nature:** Until deleted in the document approval process, GEL offered users the ability to print or save document drafts. Such items could be stored on local hard drives of machines still in service, on machines retired or re-tasked, on shared network areas assigned to current or former employees, on external hard drives, floppy disks, recordable CDs or thumb drives. These items could also have been e-mailed to others or to the users' personal accounts. They may also exist as paper printouts in the desk drawers or file cabinets of any of

more than 1,600 users. By GEL-*originated* intermediate content, I refer to drafts, revisions, comments and annotations authored within GEL, using the database's collaboration and editing features. These items only exist outside of GEL on the off-chance that someone undertook to save a personal copy. Such content should be distinguished from GEL-*contributed* content, where users modified documents *outside* of the GEL database and then added these to GEL. The latter is addressed in the next numbered section.

b. **Volume**: Unknown. AstraZeneca did not require users to save or print GEL intermediate content and asserts it has no records memorializing whether or how often users undertook to print or save GEL intermediate content.
c. **Status**: To the extent that items of this nature exist within the collections of the 103 persons identified as key custodians, these items should have heretofore been collected and produced as part of the custodial production. For others in possession of local, network and paper drafts, AstraZeneca proposed that it conduct targeted interviews of high level employees to identify individuals ("non-custodians") likely to have offered substantive drafting input into seven categories of documents of the sort likely to be relevant in this cause.
d. **Issues**: AstraZeneca couches its optimism that items deleted in GEL may survive as follows: "If drafts of key documents were saved to a non-custodian's email folder or hard drive, the expectation is that they should have been retained in accordance with the document retention notices distributed by the AstraZeneca Legal Department." This is a peculiar calculus considering that these document retention notices were presumably distributed to the GEL Document Management Specialists, yet most of these Specialists routinely deleted drafts. If the notice failed to motivate a single mouse click in persons specially tasked to manage documents, it's unclear why such notice would have succeeded in persuading non-custodians to find and sequester machines, media and e-mail.

   I did not direct AstraZeneca to implement its plan to find non-custodial drafts because I was not persuaded that the likelihood of success justified the effort and cost. My sense was that, to the extent that such intermediate content exists at all in personal collections, I'd expect most such items to surface within the collections of the 103 key custodians. Going beyond primary custodians in hopes of finding items no one knows exist failed my cost-benefit assessment.

   However, despite my misgivings, AstraZeneca believed it a good plan and has undertaken to move forward. I don't criticize AstraZeneca for diligently pursuing a plan it expects will succeed. They are bearing the cost of same and, so far, it has not diverted resources from more promising endeavors.

   Moreover, the plaintiffs have embraced AstraZeneca's plan to the extent AstraZeneca agrees to make the process and results more transparent in several reasonable ways and commit to production of material collected in the effort by May 30, 2008.

I still regard the proposed plan as more hat than cattle, but if the parties agree on it and believe it can work with improved transparency, I demur.

5. **Intermediate GEL-contributed content that may have been retained by GEL users on local, network or portable storage areas and devices or as paper printouts.**
    a. **Nature:** GEL users could author documents outside of GEL and contribute (i.e., upload) them to GEL, where they could be reviewed, edited and annotated by other users. Originating outside of GEL, these documents may exist on users' local hard drives or network shared areas, in e-mail, on external media or paper. Because users would have to affirmatively act to discard these items from such local storage locations, they're more likely to have been retained by their authors, if still employed by AstraZeneca.
    b. **Volume**: Unknown. AstraZeneca's routine deletion of intermediate GEL content and activity logs prevents easy determination of the volume and origins of contributed content.
    c. **Status**: Here again, to the extent these items were contributed by one of the 103 key custodians or circulated to them outside of GEL (e.g., via e-mail or otherwise), these items should already have been collected and produced. The reservations expressed about AstraZeneca's targeted plan described above are less-compelling here, where the documents are at least known to have existed outside of GEL at some time in their history; but, it still seems to dally at the periphery at considerable cost.
    d. **Issues**: AstraZeneca is going forward with its plan, and plaintiffs seek certain reasonable modifications to assure greater transparency and integrity of process.

B. <u>GEL intermediate content in forms generally deemed not reasonably accessible</u>:

1. GEL backup tapes in the United Kingdom and Sweden, November 2005 to date

    e. **Nature:** AstraZeneca runs GEL from servers situated in the United Kingdom. It periodically backs up the contents of these servers to tape. AstraZeneca also maintains a disaster recovery site in Sweden that houses a second set of servers that frequently duplicate or "mirror" the GEL database. This is not a "backup," in the traditional sense, but a fully-functional, alternative database facility. Thus, either system can fail catastrophically but GEL data would remain available with minimal disruption. The Swedish GEL servers are periodically backed up to tape.
    f. **Volume**: On 2/29/08, AstraZeneca reported that it held 499 backup tapes in the U.K. comprising 13 backup sets and representing periodic snapshots of GEL data from February 2007. Another 1,055 backup tapes are in Sweden and comprise 21 backup sets, representing GEL data at intervals from November 2005 to date. Portions of earlier backup sets also survive, but as these are incomplete and thus of little use.

Though there is considerable duplication in content between the UK and Swedish tape sets because of their overlapping intervals, it can't be assumed that all of the information available from the UK set will exist on the Swedish set, or vice-versa. Differences will exist as a consequence of each system being backed up on different dates and at different times. Because each backup set is a snapshot of a complex and rapidly-changing environment, a relevant Seroquel document may be finalized and its intermediate content altered or deleted in a manner that would be, e.g., evident on a UK set but not seen on a Swedish set. Accordingly, the data volume is greater than just the de-duplicated contents of the Swedish tape sets.

g. **Status**: I saw these tapes as a reliable means to gain insight into the nature (materiality and relevance) and volume of deleted Seroquel-related intermediate GEL content. Even if AstraZeneca's is extraordinarily successful in its targeted collection from "non-custodians," it will not succeed in recovering all deleted intermediate GEL content. Even to measure such success or failure requires an understanding what was deleted, and deletion makes that impossible unless new data sources emerge. The best we can do is look to periods when we do have information and extrapolate into the past.

   To that end, I directed the parties to propose a sampling protocol meeting criteria set out in the Addenda to this Report. Without my seeking broader restoration, AstraZeneca anticipated that outcome and is working with me and negotiating with the Plaintiffs to make production of deleted GEL intermediate content from it backup tapes.

h. **Issues**: Backup tape restoration will resurrect some deleted GEL intermediate content unavailable from any other source, but it cannot restore all such information. Obviously, backup tapes hold only the data present on the system being backed up at the time of its backup. Any intermediate content deleted prior to the earliest backup is extinguished, except in the event a user happened to keep a personal copy of the draft, still holds it and is one of those persons contacted by AstraZeneca in its targeted search for such material. Failing that, intermediate GEL content for documents finalized between the onset of the preservation duty and November of 2005 is gone forever. It is beyond even the reach of a forensic examination of the magnetic media. Tapes will also not contain intermediate data for any document begun and finalized between backups or drafts created between the last back up and finalization of a document.

IV. Pending Motion and Proposed Relief

Plaintiffs note that last October, I inquired of AstraZeneca's counsel whether GEL logged, recorded or otherwise tracked the non-retention of intermediate data when documents were finalized. Early in November, I was told in a very direct and unequivocal way that no such logging existed. I've lately learned that, in fact, the GEL system *does* log data concerning deletion of GEL intermediate content but that these logs are overwritten on a monthly basis.

Apparently, such overwriting has continued throughout the ensuing five months while I labored under the impression that no such logs could exist.

Plaintiffs characterize this as AstraZeneca "covering the covering of its tracks." Plaintiffs are understandably frustrated, but I don't see guile behind the act. I think it more likely that either someone failed to ask questions with sufficient particularity to gather accurate information last fall or the person supplying the information simply stated their understanding or expectation without establishing the facts. Considering that GEL intermediate content for November and December of 2007 still exists on back up tape and GEL intermediate content since December 21, 2007 has been fully preserved at my direction, the lack of logging in that interval is without adverse consequence. Though I would have preferred to have had my inquiry met with accurate information, the fact that it was not seems to me less a cover up than a mess up.

We have made great strides since last fall, and I've seen marked improvement in terms of the care and specificity with which AstraZeneca shares information. In some ways this event exemplifies that improvement. Five months ago, a question about database logging produced a categorically wrong answer from AstraZeneca. Lately, the same inquiry elicits a detailed, specific and accurate reply. The work of the last five months has been an education for us all, and I prefer to think that counsel in particular have gotten better at asking the right questions and recognizing when they must challenge and probe to secure the right answers.

Plaintiffs ask the court to direct me to delve much deeper into GEL database matters, specifically:

> The SM-ESI (with such technical assistance he may deem appropriate) shall conduct an inspection of the GEL database. The SM-ESI shall:
>
> (a) assess the operation and capability of GEL and related backup systems to capture and retain information associated with deletion of Seroquel-related intermediate data, including (without limitation), logs or audit trails;
>
> (b) ascertain the extent to which such records exist;
>
> (c) investigate the facts and circumstances surrounding any failure to retain such data; and
>
> (d) identify any GEL functionality or content which may otherwise assist in identification or recovery of Seroquel-related intermediate data deleted from GEL.
>
> Within seven days, AstraZeneca will provide SM-ESI with unfettered access to all systems, documentation, and technically sophisticated representatives necessary to perform the inspection.

I feel I have been closely scrutinizing the technical issues involving GEL; however, to exercise the level of firsthand scrutiny plaintiffs seek would entail my traveling to Sweden and the United Kingdom, the principal locations of the GEL servers and back up systems. Such an effort would be both time-consuming and costly. More, I don't see much benefit to the parties or the court.

Though it might assuage some of plaintiffs' concerns and independently bolster AstraZeneca's representations concerning its systems and back up practices, I don't expect it's likely to put the parties in much different positions than they now occupy in terms of intermediate GEL content. Unless I were to turn up backup tapes or data stores that haven't been discovered or disclosed to date—and I have no magic lamp to facilitate same—I expect that much Seroquel-related GEL intermediate content existing prior to November of 2005 will not again see the light of day.

Further, while I'm capable of conducting an investigation into the facts and circumstances surrounding the failure to retain intermediate data, I'm not more capable than the many excellent lawyers on both sides. Such an investigation probably won't require an expert in computer forensics and electronic discovery to garner the information sought.

In a similar vein, ordering me to take possession of AstraZeneca's backup tapes in Sweden and the United Kingdom to independently undertake restoration in the United States isn't going to significantly speed production of their contents to plaintiffs. On the contrary, it's likely to result in further delay and increased costs as I'd need to secure competitive bids, arrange transport and otherwise put together a suitable restoration environment for a sizable and highly customized database. Even if I could miraculously accelerate the restoration process, I cannot do the same for defendant's review. If the court wishes to accelerate review, it need only set a suitable deadline.

Unless AstraZeneca's in-house restoration effort stumbles, I recommend the best course is to allow AstraZeneca to continue with its ongoing restoration, closely monitoring progress and performance. The tapes can always be taken away, but it's not warranted at this juncture.

V. Other Issues:

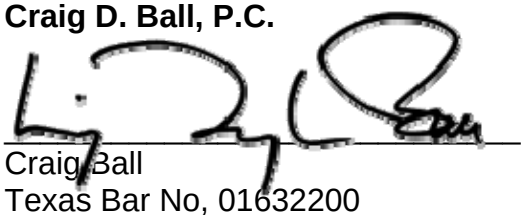
There are several issues for which there are yet no definitive resolutions. Among them:

1. If one accepts that AstraZeneca has a duty to preserve potentially-relevant, Seroquel-related GEL intermediate content, does this duty apply only to particular custodians, business units domestically, globally or to just English-language documents?
2. If one accepts that AstraZeneca has a duty to preserve potentially-relevant, Seroquel-related GEL intermediate content, was such duty triggered at filing and service of this action, or did it require some specific inquiry into such matters at a subsequent date?

Although I hold opinions on these matters, those views aren't grounded on special technical expertise or experience but simply grow out of my legal training and experience in court. As such, I don't feel those opinions warrant special consideration, and I so I've not offered them.

Respectfully submitted,

Craig D. Ball, P.C.



Craig Ball
Texas Bar No, 01632200
1101 Ridgecrest Drive
Austin, Texas 78746
TEL: 512-514-0182
FAX: 512-532-6511
E-MAIL: craig@ball.net
WEB: www.craigball.com

CERTIFICATE OF SERVICE

I hereby certify that on April 8, 2008, I transmitted the foregoing to chambers via e-mail pending filing using the CM/ECF system to afford counsel the opportunity to identify anything herein requiring special handling pursuant to applicable confidentiality obligations or protective orders. I further certify that I have served a copy of the forgoing on Plaintiffs' Liaison Counsel and Defendants' Liaison Counsel.

Craig Ball
Texas Bar No, 01632200
1101 Ridgecrest drive
Austin, Texas 78746
TEL: 512-514-0182
FAX: 512-532-6511
E-MAIL: craig@ball.net
WEB: www.craigball.com

ADDENDUM

Pertinent text of February 12, 2008 e-mail from Craig Ball to ESI liaison counsel for both sides, relating to a proposed sampling protocol for GEL backup tapes:

…
I believe that I am obliged to determine the nature and extent of the loss of relevant ESI, if any, purged from GEL during a period when AstraZeneca was under a preservation duty in connection with the matters at issue in this case. My issues are pretty simple: Does AZ have the relevant ESI? What form is it in? What has been purged? How much was lost? What form was it in? Are there ways we can go about recovering lost relevant ESI? How difficult and costly are they?

I am not getting very far going about the effort as I have, and after so many frustrating months at it, it's time to fashion a better solution. We can chase hither and yon in hopes of finding the right people with a sufficiently clear years-old recollection of the contents of GEL and who perhaps kept copies. Alternatively, we can turn to a ready source that we know contains telling examples of the ESI we seek. The latter is likely to be the most expedient, objective and cost-effective source; but, the best and brightest way to know that is by sampling.

Directive
I direct the parties to (jointly or separately) propose a sampling protocol to be applied to the GEL back up tapes for the primary purpose of assessing the extent, relevance and composition of ESI, if any, formerly in GEL but that AstraZeneca did not retain while under a preservation duty in connection with matters at issue in this cause.

I further direct that such proposed protocol seek, as feasible, to meet the following goals:

1. It should target areas of GEL deemed more likely than not to contain Seroquel-related content relevant to the issues in this cause.
2. It should minimize or eliminate duplication of GEL content preserved by AstraZeneca's U.S. Clinical Development Group after March 2006.
3. It should minimize or eliminate duplication of GEL content preserved after December 21, 2007.
4. It should provide an efficient, reliable mechanism (e.g., hash analysis or other techniques) to compare the contents of potentially-relevant areas of GEL where ESI was non-retained with the corresponding areas and content on the sampled tapes reflecting intervals prior to non-retention.
5. The protocol shall identify ESI found on the sampled tapes but now absent from GEL and catalog all such items, by file name, file type and relevant metadata (including hash value, if calculated). It must encompass both ESI in the nature of documents and in other potentially relevant forms (e.g., communications, annotations, objects and the like).
6. Any potentially-relevant non-retained content restored from tape should be preserved in a readily accessible manner.

I further direct that AstraZeneca furnish to the plaintiffs sufficient information about the size and composition of the GEL tape back up collection to enable the plaintiffs to fashion a properly targeted and effective sampling proposal. Such information should, as known or as may be ascertained from existing logs, labels, indices or records, include the number and types of tapes, the date each tape set was recorded, the size and scope of each back up and any other information going to the contents of the tapes that can be obtained without restoration of the tape.

I emphasize that I am seeking a **sampling** proposal, *not* a broad-based restoration. The proposals should be **narrowly** tailored to meet the primary purpose of assessing the probable extent, relevance and composition of non-retained GEL ESI. If the samples reveal that relevant data was lost but can be cost-effectively recovered from tape, a subsequent or broader sample may be warranted.

I will set deadlines for providing information on the tapes and submission of proposed protocols in the call on 2/12/08. This issue should be first on our agenda.

I acknowledge that, by proposing a sampling protocol at my direction, AstraZeneca is not waiving its right to object to implementation of such protocol. If Astra Zeneca claims that a burden or cost is excessive, or that costs should be shifted or shared, AstraZeneca should be prepared to present competent evidence of such burden and cost to me, along with evidence justifying cost allocation. I may seek to resolve those issues by directive or defer the cost allocation issue to the court with my recommendation. Either way, I need evidence if AstraZeneca intends to pursue these issues.

Mr. Pass: You misapprehend me when you suggest it is not within my purview to fashion and implement a sampling protocol for ESI on back up tapes. It seems to me that few tasks fall more squarely within the ambit of a Special Master for Electronically Stored Information than to judiciously fashion a protocol for sampling of ESI on back up media as a means to assess the nature and extent of lost ESI on more accessible media. Whether we look to the case law, the Sedona Principles, the Rules or simply the court's appointment order, this seems precisely--almost classically--the sort of task the court has entrusted to me. I am not the first to turn to sampling as a means to balance the need for ESI against the burden of restoring tapes, and courts that have employed sampling of tapes did so on less compelling circumstances than we face here.

Nonetheless, I trust the directive is clear, but I'd be pleased to clarify any aspect of it in our call later this morning.

Thank you.

Craig Ball

Text of February 16, 2008 e-mail from Craig Ball to ESI liaison counsel for both sides, relating to a proposed sampling protocol for GEL backup tapes and analysis of U.S. Clinical Development production:

To All Counsel:

I'm electing not to comment on the specifics of these exchanges in an effort to afford the parties maximum latitude to resolve issues before I may be obliged to do so by directive. Additionally, I see little need to address jointly much of which I've addressed with each side in *ex parte* conversations they're sought. I would, however, like to share a couple of observations in an effort to bring the dispute closer to resolution.

Mr. Pass makes several worthwhile points, among them that no proposal to produce is going to be satisfactory if the information sought is truly gone. I think on that issue, we will all benefit from implementation of a sensible and appropriately narrow sampling effort directed to the GEL back up tapes. It's possible the tapes come too late in the Seroquel approval process to be of much value, but it's also possible that they will surface an exemplar GEL doc base or cabinet or project making crystal clear the nature and volume of data lost by finalizing a document. It occurs to me that an analysis of relevant US Clinical Development areas might help serve the same end.

One thing it has taken me a while to fully appreciate is that, despite what I perceived to be indications to the contrary, it was indeed feasible for persons subject to legal hold instructions to finalize documents in GEL and still retain the interim work product. I have to assume that's exactly what transpired with US Clinical Development after March 2006, and apparently the sky did not fall. I think we are all obliged to identify what led to and enabled the different conduct by the different groups and figure out how difficult it was for US Clinical Development to effectuate retention when finalizing documents compared to its colleagues who did not retain the drafts et alia.

Consequently, I don't think it wrong of Mr. Pass to suggest that the plaintiffs may be developing the basis for a sanctions motion at the same time that they are seeking further production. In fact, I think Mr. Pass is wise to force some of those issues onto the table. I see nothing wrong with the plaintiffs having dual motives. There's nothing inherently untoward about a party seeking sanctions anymore than there is for a party to defend against the allegation. I don't think either side must choose one course or the other.

Where I am confused is concerning what AZ's expectation might be in terms of securing a commitment or concession from the plaintiffs before it undertakes to recover "lost" GEL drafts and other content from accessible sources. If plaintiffs are free to pursue sanctions, what (if anything) are the plaintiffs obliged to surrender before AZ elects to implement its recovery plan (either as proposed by AZ's counsel or as it might be modified by agreement of the parties or otherwise)?

Put another way, if AZ thinks it has a good plan, what is AZ waiting for? Or, does implementation hinge upon the plaintiffs agreeing that execution of the proposed recovery

plan "cures" certain problems suspected to exist with GEL? Surely the tenor of all this is not, "We are only going to rectify this missing content problem if plaintiffs commit not to criticize us for it before the court." Or perhaps that exactly what's at issue.

In any event, I appreciate it that Mr. Pass' surreply gets us talking about the elephant in the room.

Craig Ball