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

Amended Third Status Report of Craig Ball, Special Master - ESI
December 17, 2007

1. Status Summary

The deadlines imposed by the court have helped to sharpen focus and shorten tempers. Since my last report, much more time is being devoted to the ESI issues, but the hours invested are less productive because we must return to issues long discussed but unresolved. Where my *assisting* has sometimes proven insufficient, *directing* has been frustrating. The shortcomings in AstraZeneca's handling of ESI continue to prove deeper and broader than those identified by the Court heretofore that led to my appointment. Large swaths of clearly relevant ESI were overlooked or shelved, including some flagged as relevant by AstraZeneca custodians. These failures were not attributable to vendor error, but the result of internal mismanagement and inadequate oversight at AstraZeneca.

But, the picture is not all bleak. Progress has been made, and information about databases and other sources of ESI once cocooned in opacity is emerging, enabling the plaintiffs to narrow their requests and the parties to find common ground on methods to insure data integrity and forms of production.

2. Databases

On November 4th and 5th, counsel for the parties and their technical representatives met with me in the New York offices of defense counsel, Dechert, LLP, for a mediated Rule 26(f) conference devoted to resolution of database issues. I invited plaintiffs' counsel to select the city (from various options accommodating travel) and defense counsel to select the meeting venue. I directed the parties to address the most difficult matters first in hopes that solving the toughest problems would enable us to breeze through less nettlesome issues. On the first day, it took ten contentious hours to work through two databases known as Clintrace and SAM, a process complicated by AstraZeneca's counsel withdrawing a number of times to consult with in-house counsel or vendor representatives. It took another eight hours the following day to hammer out agreements concerning six more databases. Though some difficulty stemmed from a lack of clear communication from a technical representative, other AstraZeneca technical representatives were candid and creative in forging technical solutions to production issues. Their participation and knowledge were invaluable to achieving even the relatively modest progress made.

As I look at the simplicity of the database agreements (Exhibit A), I'm hard-pressed to explain why it has been so challenging to get to this point. We worked hard and the plaintiffs were well-prepared, reasonable and cooperative. Yet there remains much to be done, and we will meet again in Orlando on January 3rd and 4th, 2008. Notwithstanding, I see no reason to extend the deadlines currently applicable to database production. With reasonable diligence, they can and should be met. Absent strict deadlines, I'm concerned that insufficient attention may be directed at the responsive ESI within databases.

2.1 GEL

One seemingly intractable database dispute involves the Global Electronic Library (GEL) database that AstraZeneca characterizes as one of its "most mission-critical computer systems." GEL is not exclusively devoted to Seroquel, but it stores Seroquel regulatory submissions. Importantly, it serves as a workspace for the discussion and evolution of such submissions, supporting the ability of contributors to offer commentary and submit alternate language and drafts respecting proposed regulatory submissions. Until a submission is finalized, GEL serves as a virtual meeting room where issues of what to share or withhold from regulators would be exchanged, discussed and memorialized in various draft documents.

Once a submission is finalized (by human, not machine determination), GEL flushes away or, as the defendant prefers, "non-retains" the drafts, revisions, comments and annotations of a submission. It appears that, notwithstanding its preservation obligation, AstraZeneca made a business decision to continue its practice of discarding or "non-retaining" Seroquel-related drafts, revisions, comments and annotations from within GEL. AstraZeneca has so far been unable to identify the nature of this "non-retained" Seroquel-related data or to ascertain whether it has been preserved anywhere else in any form. Certainly, it is not all gone, but how much is lost and who holds what remains unclear.

When the "non-retention" first came to light, AstraZeneca said it would put to rest concerns about non-preservation by securing an affidavit from the so-called "owner" of the GEL database, a Ms. Bradley who was believed to have kept her own copies of GEL submissions. When pressed to produce the promised affidavit, it came to light that Ms. Bradley could not so attest and that there were multiple persons—perhaps 20, 30 or 40--with ownership in the GEL database. Over the course of weeks of inquiry concerning GEL, it now appears that thousands of AstraZeneca employees have permission to access, author, edit, revise, or comment on documents in GEL, so it would seem that the comments and contributions of legions may have been "non-retained" and may need to be reconstructed—a task made immensely more difficult because AstraZeneca reportedly kept no record of what Seroquel-related content the GEL database administrators relegated to "non-retained" status. Even then, there is no assurance that the commentary, drafts and other communications created within GEL *ever* existed outside or GEL or were otherwise preserved by contributors.

AstraZeneca takes the position that because plaintiffs asked for "relevant Seroquel and Seroquel related data from GEL," plaintiffs have not asked for production of ESI *purged* from GEL. Consequently, AstraZeneca denies it has an obligation to locate or produce the Seroquel ESI it "non-retained."

AstraZeneca seems unwilling or unable to address the issue of why it was appropriate to "non-retain" responsive Seroquel ESI within GEL when it kept no record of the data it periodically purged by manual—not mechanical--intervention. But, except to establish the fact and extent of non-retention, that isn't my issue. My goal is to insure that an appropriate retention mechanism is in place going forward to stem further data loss and to assess what cost-effective measures might be employed to mitigate past "non-retention" of Seroquel-related ESI.

AstraZeneca's approach to the GEL investigation has been frustratingly circular. It denies that data has been purged from GEL, but concedes that it has been "non-retained." It was there one day, but the next, someone's business-as-usual actions made it "non-retained." AstraZeneca insists that *nothing* was purged, but keeps no record of what it "non-retains." It argues a cascading legal hold (that hopefully reached GEL contributors) was a sufficient substitute for preserving relevant GEL content, but so far declines to ascertain whether *anyone* actually retained GEL contributions outside of GEL. AstraZeneca assumes that GEL content was somehow preserved outside of GEL by individual contributors, but can offer no explanation how comments and drafts created *within* GEL might find their way *out* of GEL to a contributor's local hard drive or network storage area.

AstraZeneca's obtuse refusal to refute or confirm the apparent destruction of Seroquel-related ESI in GEL is an impediment to fashioning a cost-effective approach to mitigate loss of relevant and discoverable ESI. To its credit, AstraZeneca reports it is testing a method to preserve Seroquel-related ESI in GEL and expects to implement same next week.

In short, AstraZeneca is now doing a fine job fashioning locks for the door, but insists the barn isn't empty and the cows aren't gone. The herd was simply "non-retained."

I will continue to explore ways to effect minimally-disruptive preservation of Seroquel data while assessing the magnitude of data loss and appropriate means to mitigate such loss. Hopefully, the truth about GEL will soon out and perceptions off the mark will be set right. My concern going forward is that the "non-retention" seen in GEL may be mirrored in other Seroquel-related databases.

3. Request for Clarification or for Additional Specific Authority

In its appointment order, the court mandated that I "assist and, when necessary, direct the parties in completing required discovery of electronically stored information with reasonable dispatch and efficiency." Lately, I've attempted to assist and then direct concerning a form and method of ESI production, but the defendant will not comply.

Your order states that, "The SP-ESI may seek from the Court clarification of these duties and any additional specific authority he deems necessary." Accordingly, though I feel the appointment order clearly affords me the authority the defendant contests, I'm seeking the Court's express authority to prevent use of a seriously flawed production methodology. However, if the Court feels it cannot afford me that express authority, then I ask that the Court please consider the following recommendations to guide its own judgment in resolving the issue.

3.1 Background

AstraZeneca originally undertook production of ESI in the form of TIFF image files paired with load files containing the full searchable text of the images along with certain metadata and Bates numbering. The Court is aware of the many problems attendant to this approach; suffice to say, AstraZeneca and its then-vendors proved incapable of effecting a functional TIFF production. Once reconciled that its prior efforts were irretrievable, AstraZeneca elected to replace much of its afflicted TIFF production with ESI in native electronic formats.

During the database conference in New York, I learned that AstraZeneca intends to return to TIFF and load file production for items it redacts, estimated to be as much as 15% of its production for certain collections. To do so, AstraZeneca will employ optical character recognition (OCR) to loosely reconstruct the electronic searchability of information ***not*** redacted. Though a less-than-optimum method, TIFF redaction wouldn't be a cause for significant concern for word processed documents and e-mail because it's minimally adequate when applied to ESI that formats to letter-size page format and is basically a "flat" text document containing little or no three-dimensional data or numeric information. Of significant concern, however, is AstraZeneca's avowed intention to use TIFF redaction for more complex file types, particularly spreadsheets, because doing so will destroy the usability of the evidence and corrupt its contents.

I *advised* AstraZeneca that it <u>should not</u> employ TIFF redaction and OCR for items like spreadsheets that will be rendered unusable and corrupted by the process. AstraZeneca's counsel indicated that defendant would not accept my guidance in that regard. Accordingly, I *directed* AstraZeneca not to employ redaction methods or forms of production that would operate to deprive the plaintiffs of relevant and discoverable ESI by rendering that ESI unusable, unsearchable and unintelligible.

In a discussion with one of AstraZeneca's technical representatives, a 150 page Excel spreadsheet was offered as an example of an item subject to AstraZeneca's redaction process. In the example, the spreadsheet would be TIFFed, redacted and the unredacted portions subjected to optical character recognition, all irretrievably corrupting the numerical data and stripping away the formulae and other embedded content essential for usability.

To underscore why this is so destructive and should be prohibited, the following explains the impact of each stage of the AstraZeneca redaction process as applied to spreadsheet data:

3.2 Conversion to TIFF Distorts and Strips Essential Information

Spreadsheets commonly exceed the bounds of an 8½ x 11 inch page; thus, when TIFFed, content confusingly spans multiple images. Column and row relationships are interrupted and difficult to interpret.

Beneath cells are formulae *entered by the user.* These formulae are as much core evidence in the document as any calculated values in that they establish the dependency and sensitivity of values, and formulae are principally what distinguish a spreadsheet from a word-processed table. *Formulae make the numbers dance.* Without them, cell values are runes bereft of rhyme or reason. Converting the spreadsheet to TIFF image format *strips away all these underlying formulae*, destroying spreadsheet function and undermining a key advantage of native production.

Finally, converting to TIFF means the data is no longer intelligible as data. TIFF is a picture of a printout--essentially static ink on a virtual page--and no more electronically searchable than the first Gutenberg Bible impressed with movable type.

3.3 Optical Character Recognition Corrupts the Unredacted Data

But it gets worse. To this point, the data has been folded across unnatural dimensions, stripped of its usability and much of its user-entered information and rendered so as to eliminate electronic searchability. Now, AstraZeneca redacts those portions of the information it asserts it is entitled to remove.

After redaction, AstraZeneca's obligation is to *produce* the *remaining* information in a reasonably usable and electronically searchable manner. So, AstraZeneca proposes to (actually or virtually) lay the redacted carcass on a scanner and employ OCR to synthesize a semblance of the electronic searchability the Rules require. When the optically recognized data is text, this more-or-less works because spell checkers can catch many errors. There will still be corruption--at least several words on a page will be changed to say something different than the original--but if those words don't happen to be ones key to word search or other purposes, electronic searchability is re-established...more-or-less.

When the data is numeric, there are no means to spell-check the inevitably myopic OCR. Wrong numbers replace right ones and the data becomes wholly untrustworthy. Now the spreadsheet lies to a reader.

This is the condition in which AstraZeneca proposes to produce readacted ESI to the plaintiffs: Usability: gone. Searchability: crippled. Integrity: gone. Content: affirmatively misrepresented.

As I expressed it to counsel: “The contemplated redaction is a miracle drug with one minor side effect: it kills every patient who takes it.”

3.4 AstraZeneca’s Opposition

Counsel for AstraZeneca responded to my directive on December 14, 2007, stating, “We continue to believe that AstraZeneca's agreement to produce TIFF redactions is consistent with Case Management Order No. 2, the instructions set forth in Plaintiffs' Rule 34 Requests for Production, and the letter and spirit of existing law under Fed. R. Civ. P. 34. Unfortunately, if Plaintiffs' counsel act on the concerns you have raised regarding the form of production such that there is no longer an agreement between the parties, we will have little choice but to raise this issue on substantive and procedural grounds with Judge Baker.”

I wrote AstraZeneca’s counsel that, “I do not view it as my role to shepherd methodologies that I know to be faulty and which will ultimately deprive either party or the court of information to which they are entitled under the Rules and the law. The Court is the ultimate arbiter of these matters, but it is my obligation to help the court appreciate the technical issues and their impact on the integrity of the process and the evidence. I'm not content to report that we used industry standard methods to produce useless, corrupted evidence. Redaction in the manner described above merely defers intractable problems to a point where they cannot be readily resolved and thus stands in opposition to the mandate of Rule 1.”

I added:

> Principle 12 of The Sedona Principles puts it this way:
>
> "Absent party agreement or court order specifying the form or forms of production, production should be made in the form or forms in which the information is ordinarily maintained or in a reasonably usable form, taking into account the need to produce reasonably accessible metadata that will enable the receiving party to have the same ability to access, search, and display the information as the producing party where appropriate or necessary in light of the nature of the information and the needs of the case."
>
> The commentary to Principle 12 expressly addresses the effort to substitute a TIFF and load file for multidimensional data, observing, "it does not work well for certain types of electronically stored information such as spreadsheets and dynamic databases."
>
> One thing that should be clear from my prior e-mail and accepted by anyone with more than passing experience in this discipline is that producing a complex numeric spreadsheet in TIFF then reconstructing its contents via OCR does not work. The result is not usable, and it denies the receiving party the same ability to access, search and display the information as the producing party. Worse, it is a

> method that will--*not "may" but will*--alter the content of the load file so as to affirmatively and undetectably misstate the values contained in the original.
>
> Willfully pursuing a course of conduct that, beyond doubt, alters evidence and destroys its utility is, at best, a sharp practice evincing a lack of good faith. We are officers of the court and owe more than a smirk and a snicker to the integrity of process. Our duty is to preserve evidence and get it before the trier of fact in a fair, honest and efficient way. As I believe that those are values shared by all counsel in this matter, I trust just a reminder will be sufficient to move the parties to rectify the problem. I know I wouldn't want to be put in the posture of fighting for the right to corrupt and cripple evidence when I can well protect my clients' legitimate interests without so doing.

3.5 SM-ESI's Authority to Direct Method and Format

My position is that effective redaction of ESI must be tailored to the nature of the data and balance the legitimate need to withhold certain data against the duty to produce other data. That is, redact as warranted, but use the right tool for the task. TIFF-OCR has its place for some data and not for other. Here, there are simpler, better, cost-effective alternatives suited to each type of ESI that protect the legitimate interests of both sides far better than the corruptive TIFF-OCR method AstraZeneca is determined to employ.

In its appointment order, this Court stated, "Issues as to means and methods for efficiently obtaining discoverable ESI are for the Special Master….He is authorized to resolve issues as to search terms and protocols, formatting and other technical matters."

I believe this language empowers me to bar AstraZeneca from employing a method and format with respect to redaction that I know to be faulty and corrupting, particularly when there are reasonable, cost-effective alternatives. I trust I have this authority concerning ESI issues whether they stem from misdirection on the part of the plaintiff, the defendant or both. Here, defendant seeks to capitalize on the plaintiff's boilerplate language concerning TIFF redaction and a Case Management Order issued to govern a now-abandoned TIFF production.

3.6 Request for Clarification

I ask the Court to confirm that I indeed have the authority expressed in the appointment order of October 5, 2007 and to clarify same for my benefit and the benefit of the parties. The parties are free to seek your review of anything I direct them to do, but I would prefer they treat my directives concerning matters squarely within my area of responsibility as issued in your stead until you otherwise direct. I would rather be overruled than ignored.

4. Conclusion: Some Progress

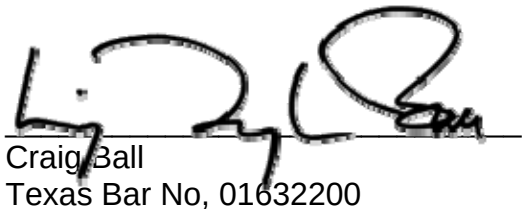
My current sense is that improved controls and oversight are in place to insure completeness and integrity of the ESI from the agreed-upon custodians and collections. I've been gratified by the attention to detail evident in discussions with AstraZeneca's consultant, Carmen O. Field. Ms. Field's careful detective work has turned up other significant omissions in AstraZeneca's prior discovery efforts; sometimes confirming that problems flagged by the

plaintiffs but given short shrift by the defendant were, in fact, genuine concerns. While it may seem strange to commend a vendor for surfacing failures on the part of her client, it is only through such candor and unflinching introspection into this deeply flawed history that we can restore confidence in the process going forward.

Progress has been made in terms of identifying and expediting the production of clearly relevant ESI that was missed or improperly removed from the production process. This has taken longer than it should, but I am assured that migration of data to a new vendor and improved project management will soon bear fruit. Bill Adams, AstraZeneca's technical representative at new vendor FTI, is an experienced, knowledgeable expert who has demonstrated a willingness and ability to work cooperatively with his counterpart for the plaintiffs. The parties are not only better communicating; they are now speaking the same language. As replacement production is only beginning to emerge, it's premature to conclude that new approaches are working flawlessly, but expectations are high and, I hope, justified.

Respectfully submitted,

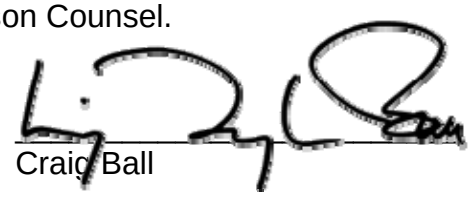
Craig D. Ball, P.C.



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 December 17, 2007, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system. I further certify that I have served a copy of the forgoing on Plaintiffs' Liaison Counsel and Defendants' Liaison Counsel.



Craig Ball

EXHIBIT "A"
Agreements Respecting Databases Concluded December 4th and 5th, 2007

Sales Insite
AstraZeneca will produce all Seroquel-related content in native forms (as maintained) with tables and metadata produced in XML.

Viewpoint
AstraZeneca will produce all Seroquel-related content in native forms (as maintained) with tables and metadata produced in XML.

Seroquel Lifecycle Scientific Database
Astra Zeneca will produce the complete contents in native format without redaction. AstraZeneca will additionally produce in native format, with metadata and without redaction, all documents linked to from within the spreadsheet.

Planet
AstraZeneca will produce, without redaction, all Seroquel-related content (i.e., article abstracts, metadata and comments).

Webstir
Without affecting objections, duties and agreements attendant to Case Specific Discovery, and without objections, duties and agreements in Case Specific Discovery affecting this agreement, AstraZeneca shall produce all Seroquel-related professional information requests (PIRs) and all standard responses in native format. AstraZeneca shall further produce the complete Paris_Inquiry table in XML (including the standard response coding identifier). Voluntary reporting physician identifiers may be redacted from reports flagged as adverse event reports.

Clintrace
1) AstraZeneca will identify fields and tables that are not reflected in the 2.10 Reference Guide.

2) Mr. Draper will detail table relationships for plaintiffs' technical staff via a written response.

3) AstraZeneca will produce the query or queries to be used to generate responsive material from the database.

4) AstraZeneca intends to redact patient and voluntary reporter identifying information and will produce the data after redaction as XML formatted information.

SAM
1) Within ten (10) business days after production of the Clintrace production (in the manner described above, and to be complete by January 2, 2008), Plaintiffs may designate up to five

hundred (500) SAM records by their corresponding Clintrace identifiers and AstraZeneca shall produce these designated records to Plaintiffs within ten (10) business days.
2) AstraZeneca has announced its intention to redact from these SAM records the information that identifies the patient, voluntary reporter and other AstraZeneca drug identifiers, and Plaintiffs reserve all rights to contest such redaction.

3) If Plaintiffs establish to the satisfaction of the Special Master for ESI that the SAM records establish a material and relevant pattern of omission or mischaracterization, the Special Master may direct AstraZeneca to furnish another five hundred (500) SAM records for production to Plaintiffs within ten (10) business days of such designation. Plaintiffs agree to conclude their demands for SAM records by receipt of a total of one thousand (1,000) such records.

Touchstone Interactive
AstraZeneca will produce all Seroquel-related content with associated metadata, current to the time of collection, and will deliver such ESI in the form of an operating environment and application software providing data access and functionality identical to that of AstraZeneca's users, plus access to all available versions of content. The deliverable for this ESI will be either a laptop computer or a virtual machine/virtual PC, the latter being the preferred format.