CARLTON FIELDS
Memorandum

To: Special Master Ball

From: Robert Pass

Date: December 4, 2007

Re: AstraZeneca/Seroquel Litigation: Proposed Plan Regarding Drafts of Documents Housed on GEL

I. INTRODUCTION

You have asked AstraZeneca to develop plans to (1) preserve drafts and comments created on GEL after a document becomes final and approved; and (2) identify and produce Seroquel-related drafts of documents finalized on the GEL database that have not previously been produced, including comments made to documents on GEL, to the extent they currently exist. This memorandum sets forth AstraZeneca's response. AstraZeneca submits this memorandum as an *ex parte*, *in camera* response. Neither this memorandum nor its contents may be disclosed to the plaintiffs.

II. WHAT IS GEL AND WHAT DOES IT DO?

GEL stands for Global Electronic Library. GEL was designed to meet AstraZeneca's business need for a creation, storage and retrieval database for regulatory data, including information subject to U.S. and foreign regulatory authority inspection, and correspondence between AstraZeneca and various regulatory authorities. Indeed, its primary purpose is to create, store, and retrieve information subject to inspection by regulatory agencies.

GEL is not a Seroquel-specific database. It is instead a company-wide database that stores regulatory submissions related to dozens of AstraZeneca prescription pharmaceutical products filed in dozens of countries. GEL is used in 75 sites and over 50 countries. It includes documents in over 40 languages ranging from Norwegian to Thai. It is one of the most mission-critical computer systems in AstraZeneca.

At the present time, GEL houses approximately 1.75 million documents. It currently contains approximately 126,504 Seroquel documents, including a number of drafts. Because Seroquel remains a successful product marketed throughout the world, GEL is used to create or edit additional documents almost every day.

Documents can be created, edited, and commented on, directly in GEL. Alternatively, documents are often created and commented on in another system (Word, PDF, Excel) and imported into GEL. Comments, of course, also can be made in hard copy.

At the present time, thousands of AstraZeneca employees have permissions to access, author, edit, revise, or comment on documents in GEL. Among the most significant departments whose employees author or edit documents on GEL are Chemical Manufacturing and Control, Non-Clinical Affairs and Safety Assessment, Clinical Development, and Regulatory Affairs. Numerous departments such as Drug Safety and Study Delivery author documents on behalf of Clinical Development. Currently, 1,183 GEL users have access to draft clinical Seroquel GEL documents alone. Over 400 employees in Regulatory Affairs have access to Seroquel-related documents in GEL. Of course the historic numbers dating back to 2003 are even larger. More than 800 users have created versions of documents within the Seroquel cabinet. This number does not include users who have merely reviewed or commented on drafts.

There are separate "folders" in GEL for each of the above-named AstraZeneca departments that deal with Seroquel. Each department is responsible for its own section of materials provided to regulators; however, only the Regulatory Affairs department actually submits documents and interfaces directly with the regulators. In other words, GEL is managed in a decentralized fashion. There is no single user or manageable group of users that can speak to other users' practices with respect to the retention or non-retention of all draft documents on GEL. Nor is there a single user or manageable group of users that can speak to all other users' practices with respect to the retention or non-retention of draft documents off GEL – that is, on hard drives, in paper format, in email files, compact discs, etc. This, and the large and widespread number of GEL users, makes it exceedingly difficult for AstraZeneca to collect and produce and certify completion of production of all drafts and comments that originated in GEL.[1]

The business purpose of GEL is not to serve as an archive for intermediate data that exists between creation and finalization of a document, but to serve as, like its name implies, a "global electronic library" for submission to regulatory bodies. GEL's non-retention of intermediate data once the final version of a document in the database is approved is consistent with this purpose because it serves the critical business function of ensuring that only approved and validated information gets submitted to regulatory authorities. Given this overriding business purpose, GEL deletes the drafts, revisions, comments and annotations of a submission (the "intermediate data") once that document is approved as a final, completed version ready to be submitted to a government health authority or reviewed by such an authority. However, only GEL

[1] The problem is exacerbated by the fact that it is difficult to determine whether a given draft stored in, for example, an email, or existing in hard copy, originated in GEL or elsewhere, such as Word or Excel. AstraZeneca's preservation efforts were designed to maintain the actual documents including drafts of regulatory submissions, not to recreate the exact system from which a given document originated.

Local Administrators (GLAs) or Document Management Specialists have the authority to approve documents. This deletion function is the "default" setting of the system. It was set up that way as a matter of business practice at the time the database was created. Unless a GLA or Document Management Specialist changes the default setting, deleted intermediate data is not retrievable from within GEL once the document has been approved.

AstraZeneca implemented preservation steps long before plaintiffs requested discovery from the GEL database and before plaintiffs made accusations regarding the deletion of drafts from GEL. Although these retention steps are not infallible, AstraZeneca believes they were reasonable efforts to preserve documents under the circumstances of this litigation.[2] There has been no systematic "purging" of documents from GEL, and AstraZeneca strongly objects to the use of the term "purge" as entirely inaccurate in this context. Since September 2003, AstraZeneca's Legal Department has disseminated retention notices reasonably calculated to instruct employees with documents relevant to the litigation to preserve such documents. Indeed, by the time plaintiffs first aired concerns about preservation of documents on GEL in November 2007, key business leaders for years had been cascading messages to employees under their direction reminding them of the obligation to preserve draft documents. In addition, since 2006, the U.S. Clinical Development GLAs routinely have been changing the default setting and saving drafts of documents finalized on GEL. As such, drafts of clinical documents (probably the largest group of "key" documents housed on GEL) created since March, 2006 should be maintained on GEL and can be produced from GEL.

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[2] Miller v. Holzman, 2007 WL 172327 (D. D.C. Jan. 17, 2007) ("The obligation to preserve electronic data and documents 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 data.") (quoting The Sedona Conference, Best Practices Recommendations & Principles for Addressing Electronic Document Production, 44 (2004 Annotated Version)); see also Sedona Principle 5, The Sedona Principles (Second Edition 2007), available at www.thesedonaconference.org; Zubulake v. UBS Warburg LLC, 220 F.R.D. 212, 217 (S.D.N.Y. 2003) ("What is the scope of the duty to preserve? Must a corporation, upon recognizing the threat of litigation, preserve every shred of paper, every e-mail or electronic document, and every backup tape? The answer is clearly, "no.").

III. ASTRAZENECA'S PLAN FOR PRESERVING DRAFTS OF DOCUMENTS ON GEL GOING FORWARD.

In the last conference call, you rejected an AstraZeneca proposal designed by Carmen Field to retain drafts of documents on GEL going forward and requested that AstraZeneca come up with a new plan that reduces the potential for human error. AstraZeneca is close to completing a plan that will do so. AstraZeneca continues to believe that the steps it is currently taking to preserve documents constitute a reasonable and appropriate approach to document retention and that no reasonable plan can completely guarantee the elimination of human error. However, it is willing to take the steps suggested herein in a good faith effort to accommodate your concerns and those of the plaintiffs and to avoid needless litigation.

AstraZeneca proposes enhancing the AZ Export utility to extract drafts from GEL and running this utility on a daily basis. The extracted data will be stored outside GEL. We believe this will satisfy the vision of retaining virtually all draft Seroquel documents and metadata going forward in time. The extraction would only affect the Seroquel cabinet. It also would not require a change in the existing business practice or retraining in how users use GEL.

This proposal can be implemented in part beginning on Friday, December 7, 2007, but it will take more than a few days to fully implement. As the AZ Export Utility currently stands, it cannot extract GEL annotations. In addition, there is a continuous need for a person to check the results every day; this checking function would need to be automated in order for the Export Utility to serve the requested purpose on a long-term basis. Thus, in order to retain all Seroquel draft documents and metadata on GEL, the AZ export utility first would need to be enhanced and retested. AstraZeneca proposes beginning using the AZ Export Utility at the first opportunity that would not impact GEL operations, which would be this coming weekend. However, because of the need for enhancement and retesting, the plan may not be fully implemented until as late as December 21, 2007. In the meantime, drafts should continue to be routinely maintained by AZ employees through the steps described above.

Although AstraZeneca is willing to consider, and is considering, other possible solutions, we believe this option is the most efficient and least intrusive available to a critical AstraZeneca computer system.

Estimated date of deliverable: Begin implementation December 7, 2007, complete implementation expected by December 21, 2007.

IV. RESPONSE TO REQUEST FOR PLAN FOR PRODUCING DRAFTS AND COMMENTS FOR FINALIZED GEL DOCUMENTS.

The second question you have raised relates to the extent that AstraZeneca employees have printed out, saved to their hard drive or email files, or otherwise preserved, drafts of documents authored or edited on GEL. You have requested that AstraZeneca devise a plan to "produce" all such draft documents.

As a threshold matter, the premise of the question appears to be that the GEL database was designed for the business purpose of capturing and archiving drafts of FDA submissions. But that would not be correct and would be contrary to how the company does business. As discussed above, at its creation in 2002, GEL was designed to serve as a repository of finalized regulatory documents; it was never designed – nor has it ever operated – to house drafts of those documents in perpetuity or even after finalization of the documents. This does not, however, mean that drafts of documents finalized on GEL have not been preserved. As discussed above, AstraZeneca has implemented what it believes to be reasonable and appropriate efforts to preserve documents under the circumstances of this litigation. Accordingly, if drafts were saved to a custodian's email folder or hard drive, they will have been produced in accordance with the general production procedures implemented in the litigation.[3] 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. If drafts of documents finalized on GEL are ever requested in a request for production (RFP), they will be produced, as appropriate, in response to such a request after adjudication of objections, if any.

Ultimately, regardless of what drafts of submissions are housed where, the threshold inquiry remains whether documents are reasonably calculated to lead to admissible evidence. Obviously, not all 126,504 Seroquel documents currently housed on GEL are relevant to this litigation.[4] In addition, for certain other categories of documents housed on GEL, although the final version of the document might be of marginal relevance, the draft iterations of those documents are, at best, of *de minimis* probative value.[5] Moreover, some documents on GEL are so large that it would be unduly burdensome to produce every iteration and comment prior to final. As you are aware, NDA and IND submissions can be hundreds of thousands of pages long.

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[3] AstraZeneca has made productions from more than 100 custodians, many of which are employees in Clinical Development, Regulatory Affairs, and Drug Safety who authored or edited drafts of documents finalized in GEL.

[4] Manufacturing and supply documents, for example, are not relevant to the present inquiry because the manufacturing and supply processes are not relevant to any claim in the litigation. Nor are global regulatory documents submitted to foreign regulatory agencies, which merely reflect nuances of local laws and regulations.

[5] Examples would include study protocols, particularly if the study's end points did not involve a disease state at issue in the litigation.

Not all drafts of documents housed on GEL are relevant and therefore discoverable in the litigation merely because they matured into final, approved GEL submissions. Rather, for the inquiry to be reasonably calculated to lead to admissible evidence, it must focus on the substance of the documents, not the document management system on which they were created.[6] AstraZeneca respectfully submits that it is the plaintiffs' responsibility to articulate which draft regulatory submission documents they consider to be relevant to their claims and to make a formal request for them, not AstraZeneca's responsibility in the first instance to conduct a boundless search for all drafts of 126,504 documents to determine whether they were drafted on GEL and, if so, determine how the author and commenters have maintained them.[7]

Thus, the initial question in a production analysis must concern what the plaintiffs have requested and not requested in RFPs. Plaintiffs' RFP # 8 requests that AstraZeneca produce the following documents: "All relevant Seroquel and Seroquel-related data from GEL ... including the tables and fields identified ..." (Request #1). In accordance with Magistrate Judge Baker's recent order, AstraZeneca intends to produce documents responsive to this RFP as part of its rolling database production, which must conclude by March 14, 2008. Such production shall be in accordance with the mediation to be held in New York on December 4 and 5, 2007, or if no resolution is reached at mediation, in accordance with further meet and confer sessions, and if necessary, motion practice before the Court. This production will include drafts residing on GEL.

Moreover, although plaintiffs have made specific RFPs for drafts of discrete categories of regulatory documents, they have never asked for all drafts of regulatory submissions that are housed on GEL. Or put differently, Plaintiffs have self-identified the issue of "drafts" but only shown interest in the production of drafts of very specific categories of the numerous regulatory documents submitted by AstraZeneca. AstraZeneca has timely responded to the RFPs with which it has been served and is either producing documents, standing on its objections, or litigating its objections with respect to these requests.

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[6] Fed. R. Civ. P. 34(b)(1)(A) (A request for the production of documents "must describe with reasonable particularity each item or category of items to be inspected); see also American Standard Inc. v. Humphrey, __ F. Supp. 2d __, 2007 WL 1812506, *5 (M.D. Fla., June 22, 2007) (concluding it would "impose and undue burden" on defendant to try and locate all documents prepared by defendant while employed by company when plaintiff's request did "not provide any guidance regarding what sort of 'documents' it is seeking").

[7] Fed. R. Civ. P. 26(b)(1) ("The frequency or extent of use of the discovery methods set forth in subdivision (a) shall be limited by the court if it determines that ... (iii) the discovery is unduly burdensome or expensive, taking into account the needs of the case, the amount in controversy, limitations on the parties' resources, and the importance of the issues at stake in the litigation."); see also Goland v. CIA, 607 F.2d 339, 353 (D.C.Cir.1978) ("It is unreasonably burdensome to request information that would require a page-by-page search through the 84,000 cubic feet of documents in the [CIA] Records Center."); Church of Scientology v. IRS, 792 F.2d 146, 151 (D.C. Cir. 1986) (a "search through every file in [the IRS'] possession to see if a reference to Scientology appeared," was unduly burdensome); Krohn v. Dep't of Justice, 628 F.2d 195, 198 (D.C. Cir. 1980) (It was unreasonably burdensome to require a search of the files of over 5,000 criminal cases upon a general request for data to be gleaned from documents which have not been created).

AstraZeneca's plan for production therefore would focus on drafts of specific categories of documents deemed relevant or likely to lead to the discovery of relevant evidence, not all documents currently housed on GEL regardless of relevance. AstraZeneca is willing to investigate and produce drafts of documents of key regulatory submissions (e.g., those discussing Seroquel benefit/risk profile) and safety documents, provided plaintiffs first serve additional RFPs that make targeted requests for such documents and AstraZeneca is given the opportunity to object to those requests as appropriate and litigate any disputes that cannot be resolved through negotiation. If plaintiffs request drafts of additional regulatory documents, AstraZeneca will consider any such requests in good faith and investigate the location of responsive documents. At bottom, however, the appropriate question is whether requested drafts of documents finalized on GEL are relevant to the litigation, or likely to lead to the discovery of admissible information, not simply whether the finalized version of a draft document happens to be housed on GEL.

In sum, AstraZeneca respectfully must oppose engaging in a non-custodial production process for all of an extremely broad category of documents that numbers in the hundreds of thousands and that would be a tremendous burden to search and certify as complete, especially considering that there has been no request for production from the plaintiffs and no opportunity to AstraZeneca to object to or otherwise litigate the appropriateness of such discovery demands.[8]

In the meantime, AstraZeneca continues to believe that draft documents created in GEL are appropriately being preserved, and is willing to implement the above-described plan to ensure near-complete retention going forward.

[8] Fed. R. Civ. P. 34(b)(2)(D) (a party may state an objection to a request for production of electronically stored information. Additionally, if a party objects to a requested form, or if no form was specified in the request, the party must state the form or forms it intends to use.)