Decker, Brian

From:	Pass, Robert W. [RPass@CarltonFields.com]
Sent:	Wednesday, January 02, 2008 9:14 AM
To:	Decker, Brian
Subject:	FW: PLANET Database Production
Attachments:	12_20_07.pdf

is this it?

From: Larry J. Gornick [mailto:lgornick@lskg-law.com]
Sent: Friday, December 21, 2007 2:26 PM
To: Kerns, Kevin
Cc: Adupre@mccarter.com; Jim Freebery; Pass, Robert W.; cfield@daylightforensic.com; Bill.Adams@fticonsulting.com; McConnell, Stephen; Craig Ball; Dennis Canty; Pederson, Mike; Sedgh, Jonathan; Jaffe, Jonathan
Subject: RE: PLANET Database Production

Kevin, AZ has failed to honor the express written terms of its agreement as recorded by Master Ball and has also violated more general agreements as well as specific assurances it provided to plaintiffs over the course of our database mediation on 12/3 and 12/4. The express terms of the agreement are as follows: "Astra Zeneca will produce, without redaction, all Seroquel-related content (i.e. article abstracts, metadata and comments)." AZ has violated these terms in the following ways:

1. AZ only produced data from the "front-end of Planet." Nothing in our agreement or discussions supports such a limitation.
2. AZ queried only 64 fields for Seroquel related content. The Planet database has at least 130 fields. Again, nothing in our agreement or discussions supports such a limitation.
3. The search terms AZ used are deficient, and therefore, we have likely not even received "all Seroquel related content" from the subset of data that AZ chose to search. Notably missing from the search term list is the product code, "ser".

AZ has violated the fundamental general principle underlying the database mediation that plaintiffs would receive reasonably searchable databases with equivalent functionality to what AZ has. By providing plaintiffs with ASCII unformatted text files (some of which are thousands of pages long) rather than structured data, Astra Zeneca has destroyed the structure of the Planet database. The way you have provided the data to us has destroyed our ability to search isolated fields for text or even to search or retrieve isolated records. AZ clearly has those capabilities. Further, it is troubling that AZ's plan is to provide us with the Planet database in pieces, at different times, without even telling us that that is what you are doing. Would you ever have told us that you had only searched the "front-end" if we had not raised these issues? When can we expect to receive the rest of the database?

AZ has also violated specific assurances provided to us at the database mediation to the effect that if you could produce data in XML format you would, if you could not, you would produce the data in one of the other formats we requested in our RFPs, and if that could not be done you would talk to us. You didn't do this. This is particularly troubling given the fact that the Planet documentation provided to us by AZ expressly states that "the result [of a search] is an XML string."

You are correct that this is a very straightforward database, yet you gave us less than all the data you agreed to give us and you provided it in a particularly limiting format despite the fact that you could have easily given it to us in XML if you had so chosen. This one should have been easy. These difficulties do not bode well for the remainder.

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-----Original Message-----
From: Kerns, Kevin [mailto:kevin.kerns@dechert.com]
Sent: Thursday, December 20, 2007 5:43 PM
To: Larry J. Gornick
Cc: Adupre@mccarter.com; Jim Freebery; rpass@carltonfields.com; cfield@daylightforensic.com; Bill.Adams@fticonsulting.com; McConnell, Stephen; Craig Ball; Dennis Canty; Pederson, Mike; Sedgh, Jonathan; Jaffe, Jonathan
Subject: RE: PLANET Database Production

Larry:

Please see attached.

- Kevin

From: Jaffe, Jonathan [mailto:jjaffe@weitzlux.com]
Sent: Wednesday, December 19, 2007 12:41 PM
To: Kerns, Kevin
Cc: Adupre@mccarter.com; Larry J. Gornick; Jim Freebery; rpass@carltonfields.com; cfield@daylightforensic.com; Bill.Adams@fticonsulting.com; McConnell, Stephen; Craig Ball; Dennis Canty; Pederson, Mike; Sedgh, Jonathan
Subject: PLANET Database Production

Dear Mr. Kerns:

Yesterday, Plaintiffs received production of the PLANET database extract.

It was not produced in any of the four formats specified by Plaintiffs in our RFP or as discussed in our meetings in New York. The records provided have on average 20 fields. I believe AstraZeneca had agreed to provide all 140 fields for each record in our discussions in New York, with our understanding that many of them might be blank for many records. The search also did not search for Seroquel by product code, "ser," which is something that I would have thought would have been included.

If I recall we breezed through this database because there was no issue with redaction, there were no fields being withheld, and this database produces XML by default.

I also recall that we agreed that if a database could not be produced in XML or in one of the alternative formats specified that we would talk about it before production.

1/2/2008

Appendix A (below) is the exact text submitted by Special Master Ball in the appendix to his most recent report to the court detailing our agreement in NY.

Appendix B (below) is a literal extract of what was produced from the first file starting with "SEARCH STATEMENT" and going to through the first two records. Each record was produced in the same format.

The format of the production was not XML, does not delineate the fields, does not preserve the field types, does not include all fields

Appendix C (below) is from the documentation provided by AstraZeneca to the Plaintiffs in advance of the meet and confer on the PLANET database. In the documentation, it states that records can have up to 130+ attributes. It also states that each attribute is indexed.

Appendix D (below) states that the results of the search are **returned in XML**, which is precisely why we specified that format. If you note from the example provided in the documentation, that does not resemble what was produced.

Since this was the easy database, I want to believe that perhaps some signals got crossed and our agreements forged in NY were not communicated to the individuals responsible for the production. Is this the case, or have you changed your stance on the production of this database? If the former, when can we expect a redelivery with all the data included, in an XML format as described in the AstraZeneca documentation?

Thank you,
Jonathan Jaffe

APPENDIX A

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

APPENDIX B

SEARCH STATEMENT

Date: 2007-12-12
Query: (quetiapine or seroquel or ICI 204636) or (bd=quetiapine or de=quetiapine)
Document Group: All document groups
Limit: None

1.
Accession number: 200600745292
Document group - DG: PostMarketSurveillance
Accession number - AN: 200600745292
Authors - AU: Olfson M, Marcus SC, Corey Lisle P, Tuomari AV, Hines P, L'Italien GJ
English title - TI: Hyperlipidemia following treatment with antipsychotic medications
Source - SO: American Journal of Psychiatry 2006;163(10):1821-1825
Batch - BA: PMWK5007
Journal - JN: American Journal of Psychiatry
Journal synonyms - JS: 0002-953X, AJPSA, Am J Psychiatry, American Journal of Psychiatry
ISSN - IS: 0002-953X
Year of publication - YR: 2006
Volume - VO: 163
Issue/Part - IP: 10
Pages - PG: 1821-1825
Language - LG: English
Author Institution - IN: Olfson, Mark: Department of Psychiatry, Columbia University, NY State Psychiatric Institute, 1051 Riverside Dr., Unit 24, New York, NY, US, 10032, mo49@columbia.edu
Additional information - AI: This project was supported by a grant from Bristol-Myers-Squibb
Author abstract - AA: Objective: This study attempted to estimate the relative risk of developing hyperlipidemia after treatment with antipsychotics in relation to no antipsychotic treatment. Method: A matched case-control analysis was performed with pharmacy and claims data from California Medicaid (Medi-Cal). Patients were excluded if they were treated for medical disorders or prescribed medications known to increase their risk of hyperlipidemia. Cases were ages 18 to 64 years with schizophrenia, major depression, bipolar disorder, or other affective psychoses and incident hyperlipidemia. Cases were matched to up to six control subjects by age, sex, race, and psychiatric diagnosis. Both groups were prescribed either no antipsychotic medication or had two or more prescriptions for one and only one antipsychotic medication during the 60 days prior to the first indication of hyperlipidemia (cases) or matched index date (controls) in the billing record. Conditional logistic regressions were used to derive odds ratios and 95% confidence intervals (95% CIs) of each antipsychotic medication in relation to no antipsychotic medication. Results: A total of 13,133 incident cases of hyperlipidemia were matched to 72,140 control subjects. As compared with no antipsychotic medication, treatment with clozapine (odds ratio: 1.82, 95% CI: 1.61-2.05), risperidone (odds ratio: 1.53, 95% CI: 1.43-1.64), quetiapine (odds ratio: 1.52, 95% CI: 1.40-1.65), olanzapine (odds ratio: 1.56, 95% CI: 1.47- 1.67), ziprasidone (odds ratio: 1.40, 95% CI: 1.19-1.65), and first-generation antipsychotics (odds ratio: 1.26, 95% CI: 1.14- 1.39), but not aripiprazole (odds ratio: 1.19, 95% CI: 0.94-1.52) was associated with a significant increase in risk of incident hyperlipidemia. Conclusions: These findings suggest that most commonly prescribed antipsychotic medications increase the risk of developing hyperlipidemia in patients with schizophrenia or mood disorders. (PsycINFO Database Record (c) 2007 APA, all rights reserved) (journal abstract). This abstract has been supplied by AstraZeneca to you under license from the copyright owner, and may not be recopied or redistributed outside AstraZeneca without permission from the copyright owner.
External terms - XD: Human. Male. Female. Adulthood (18 yrs & older). Young Adulthood (18-29 yrs). Thirties (30-39 yrs). Middle Age (40-64 yrs), *Cholesterol.
*Neuroleptic Drugs. *Risk Factors. *Schizophrenia. *Side Effects (Drug). Drug Therapy
AZ copyright - CG: no
Origin - OG: PsycINFO (Ovid)
Therapy area - TA: TA: neuroscience
Entry date - EN: 20071212

2.
Accession number: 200700745291
Document group - DG: PostMarketSurveillance
Accession number - AN: 200700745291
Authors - AU: Marder, Stephen R
English title - TI: Lessons from each drug trial
Source - SO: American Journal of Psychiatry 2007;164(3):375-376
Batch - BA: PMWK5007
Journal - JN: American Journal of Psychiatry
Journal synonyms - JS: 0002-953X, AJPSA, Am J Psychiatry, American Journal of Psychiatry
ISSN - IS: 0002-953X
Year of publication - YR: 2007
Volume - VO: 164
Issue/Part - IP: 3
Pages - PG: 375-376
Language - LG: English

Author Institution - IN: Marder, Stephen R.: Semel Institute for Neuroscience, UCLA, Mental Illness Research, Education and Clinical Center, VA West Los Angeles Health Care Center, MIRECC 210A, 11301 Wilshire Blvd., Los Angeles, CA, US, 90073-1003, marder@ucla.edu

Author abstract - AA: Comments on an article by T. S. Stroup et al. (see record 2007-07370-011). Speculations about mild extrapyramidal side effects as an explanation for the differences among the drugs examined in the study are only weakly supported by the data. Nevertheless, they suggest an important principle for treating schizophrenia. Finding an antipsychotic regimen that patients can live with comfortably is an essential part of an effective management strategy. Each antipsychotic trial provides an opportunity to understand the factors--particularly the side effect sensitivity--that may affect how a patient feels while taking the next drug. (PsycINFO Database Record (c) 2007 APA, all rights reserved). This abstract has been supplied by AstraZeneca to you under license from the copyright owner, and may not be recopied or redistributed outside AstraZeneca without permission from the copyright owner.
External terms - XD: Human. *Chronic Illness. *Drug Therapy. *Neuroleptic Drugs. *Perphenazine. *Schizophrenia. Olanzapine. Quetiapine. Risperidone
AZ copyright - CG: no
Origin - OG: PsycINFO (Ovid)
Therapy area - TA: TA: neuroscience
Entry date - EN: 20071212

APPENDIX C

1.1 Amir Database Structure

The Amir database contains the article meta-data. Each document contains 130+ attributes that describe the article in question. Each attribute is indexed using a subset of the following index-types:

1. Phrase index

2. Range index for strings (using lexicographical order)

3. Range index for numbers (floating point)

4. Aggregation index (counting documents sharing attribute values)

The index types assigned to each attribute are configurable, and decided during database creation.

1.1.1 Quick Search

The quick search function takes six parameters: *first, last, sort_attribute, sort_direction, document_group*, and *query*. The parameter query contains the actual search string. First, last, sort_attributes, and sort_direction are for presentational purposes, whereas document_groups is a parameter that decides a user's authorization groups.

The search function executes queries according to the planet query language. The index types that can be queried are range indexes and phrase indexes. It is possible to access individual attributes or perform searches on all attributes supporting the given index type. Section 3.6 on the query language describes how access to different indexes is achieved.

APPENDIX D

The result is an XML string containing information regarding execution time, number of hits, and a search result containing a list of enumerated records. The list is sorted based on the sort attributes and sort direction given as parameters to the search function, and restricted to the enumeration interval given by the parameters first and last. The information presented is the attributes stated as presentation attributes in the table *planet_configuration*. Recall that *planet_configuration* reflects the information in the configuration file *config_plan_table.xml*.

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<?xml version='1.0' encoding='ISO-8859-1'?>
  <response>
    <server>
      <hostname>apwxp-lab03.apptus.local</hostname>
    </server>
    <quick_search>
      <time>93</time>
      <query>
        <line>first=1&amp;last=10&amp;sort_attribute=DOI&amp;
               sort_direction=asc&amp;document_group=Planet%20Core&amp;
               query=therapy</line>
        <parameters>
          <parameter>
            <name>last</name>
            <value>10</value>
          </parameter>
          <parameter>
            <name>query</name>
            <value>therapy</value>
          </parameter>
          <parameter>
            <name>sort_direction</name>
            <value>asc</value>
          </parameter>
          <parameter>
            <name>first</name>
            <value>1</value>
          </parameter>
          <parameter>
            <name>document_group</name>
            <value>Planet Core</value>
```

```
            </parameter>
            <parameter>
                <name>sort_attribute</name>
                <value>DOI</value>
            </parameter>
        </parameters>
    </query>
    <result>
        <result first="1" last="10" hits="7386" search_words="therapy">
            <record>
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                <doc_seq>3877</doc_seq>
                <AA>It has long been ...</AA>
                <AC>
                </AC>
                <AF>yes</AF>
                <AI></AI>
                <AN>198600000938</AN>
                <AS></AS>
                <AU>
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                </AU>
                ...
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                ...
                <IS>0264-7494</IS>
                ...
                <JN>British Journal of Parenteral Therapy</JN>
                ...
                <PO>20061202</PO>
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                <YR>1986</YR>
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            </record>
            ...
            <record>
                <tno>10</tno>
                ...
            </record>
        </result>
    </result>
</quick_search>
</response>
```