UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545
This Document Relates to All Cases	Master Docket Case No. 1:14-cv-01748 Hon. Judge Matthew F. Kennelly

JOINT STATUS REPORT
FORAPRIL 21, 2015 CASE MANAGEMENT CONFERENCE

The Court directed counsel to file this joint report regarding the status of the parties' discussions, agreements and disagreements on the proposed agenda items for the April 21, 2015 case management conference. Since the last case management conference, the parties conferred and made progress toward agreement on the agenda items, as follows:

I. Proposed Amendments to Master Complaint and CMO 18: The operative Master Complaint names Acrux Ltd and Acrux DDS Pty Ltd as defendants. The Acrux defendants are alleged to have entered into a license agreement with the Eli Lilly defendants for the commercialization of Axiron. Representatives of the PSC and counsel for Acrux are in negotiations to amend the Master Complaint and Master Short-Form Complaint to substitute Acrux Commercial Pty Ltd as a named defendant in place of Acrux Ltd. Counsel are also in negotiations to amend Case Management Order No. 18 to add provisions governing service of process as against the Acrux defendants.

II. Defendants' Statement Regarding Outstanding Plaintiff Fact Sheet Issues:

a. On March 3rd, the Court entered Amended CMO 9 establishing a PFS deadline for all pending cases (771 cases against AbbVie) on May 8th. Further, Amended CMO 9 urges

plaintiffs' counsel to submit PFS's before the due date in AbbVie-only cases, to avoid the obvious inefficiency and delay that would result from all plaintiffs waiting until the last possible day to meet their obligations. To date, AbbVie has received a total of 301 PFS's – fewer than half of what is owed – and two thirds of those PFS's (211) have such incomplete and deficient medical authorizations that AbbVie is unable to begin medical record collection. Specifically, the authorizations are unsigned, undated and/or do not specify the healthcare provider to whom they may be directed. As AbbVie is not allowed to input names of providers in blank authorizations, (contrary to Plaintiffs' suggestion below) and plainly cannot sign authorizations on Plaintiffs' behalf, these are useless. Further, AbbVie has received only 34 additional PFS's since Amended CMO 9 was entered.

The slow submission of Plaintiff Fact Sheets along with the overwhelming authorization deficiencies is an issue AbbVie has raised at the last two Case Management Conferences and has yet to see any noticeable attempts by plaintiffs to remedy. AbbVie has repeatedly reached out to Plaintiffs' Co-Lead Counsel to discuss what can be done to assure prompt and non-deficient compliance by plaintiffs. This issue is of significant concern to AbbVie because it affects the size of the pool of cases eligible for selection as discovery bellwether cases and potentially the integrity of the bellwether selection process. The lack of fully compliant PFS's also affects AbbVie's ability to analyze these claims in time to submit a proposal for the process of selecting discovery bellwether cases currently due in July.

Plaintiffs' Response: Just two days ago, *o*n April 14, 2015, Plaintiffs received from AbbVie's counsel a list of law firms that had provided allegedly deficient medical authorizations. Counsel stated that the "most significant problem is authorizations that are served without the provider information and un-signed authorizations." To Plaintiffs' review, AbbVie only

identified one firm that had served unsigned authorizations. The rest of the alleged deficiencies relate to instances where counsel omitted medical provider addresses or dates with the intention that this information should be left blank to allow Defendants a certain measure of flexibility. Moreover, Plaintiffs' service of undated authorizations presumably stems from the very language of the PFS that Defendants negotiated and which requires that authorizations are to be "completed and signed (but undated)." *See D.E. 392, p. 33, at XI. A.* Two days after AbbVie sent their list of alleged authorization deficiencies, Plaintiffs received Defendants' Status Report statement above, which seems to inflate the issue significantly. While AbbVie's new counsel wants to make PFS deficiencies a major issue in this litigation and try to re-negotiate seemingly all aspects of the PFS process and requirements, the request to leave the authorizations undated was made by his co-counsel and agreed to by all Defendants' counsel so that the defense could have more flexibility when using them.

In the past two days, the PEC has endeavored to communicate with the approximately 50 plaintiffs' law firms named in AbbVie's list of alleged authorization deficiencies. The PEC relates that the vast majority of the allegedly deficient plaintiffs' counsel were completely unaware of any authorization deficiency and had not received any correspondence or deficiency letter from any Defendant related to their authorizations. Indeed, this underscores that this is more an issue AbbVie wants to take to the Court, than one it wants resolution of. Nevertheless, every plaintiffs' counsel with whom the PEC communicated confirmed that the issue has or will be resolved immediately.

b. At the March 20th Case Management Conference, AbbVie raised a concern that some plaintiffs who had not furnished medical records with their Plaintiff Fact Sheets might be withholding such documents based on a work-product or other objection. AbbVie proposed and

the Court accepted the idea of sending letters to all plaintiffs' counsel from whom no medical records were provided with their PFSs, advising them of their obligation and inviting them to identify an objection that might require resolution. AbbVie was pleased that the overwhelming majority of plaintiffs' counsel responded by either providing medical records or stating that they yet did not have any (but would provide them when they collected them). In other words, they did not object. Further, in discussions with Plaintiffs' Co-Lead Counsel, AbbVie has learned that Plaintiffs' leadership believes that all medical records in counsel's possession should be provided to AbbVie, along with the fact sheets. As of this week, only one lawyer, Michael London, appeared to have an objection and still has not agree to produce records consistent with all other Plaintiffs. Contrary to the plain language of Amended CMO 9, Mr. London makes a strained argument that he is not obligated to produce medical records collected by counsel. He also appears to be asserting a vague work product objection. As efforts to resolve the issue have been unsuccessful AbbVie will file a motion to compel to formally address the issue but also believes that, given the position of the Plaintiffs' Co-Lead Counsel and the stated intent to comply by the majority of firms, it may be possible to resolve this impasse by a clarifying directive from the Court at the upcoming status conference.

Plaintiffs' Response: The PSC raised objection and concern to the process as it was yet another amendment to the PFS; that other such records in Defendants counsel possession were expressly excluded from the Deposition Protocol CMO; and that if this would be the new process, we would need to have clear parameters and process. These concerns were raised on March 27, 2015. However, it was not until this week, that AbbVie finally sought to address them, and not until late today that the parties spoke. Because the PSC understood the PFS process not to require production of medical records that counsel themselves obtained, but rather

only production of medical records that a plaintiff himself specifically obtained, the PSC wanted to be sure we fully understood AbbVie's request to modify the PFS process and definitions that made it clear that records obtained by counsel need not be provided.

c. Around March 15th, Defendants filed motions to dismiss the below cases for plaintiffs' failure to serve Plaintiff Fact Sheets. Defendants are prepared to address the status of each motion.

Lesa Young v. AbbVie Inc. and Abbott Laboratories, Case No. 1:14-cv-02829
Wayne Witter et al. v. AbbVie Inc. and Abbott Laboratories, Case No. 1:14-cv-03623
Wayne Morgan v. AbbVie Inc. and Abbott Laboratories, Case No. 1:14-cv-05002
David Florio et al. v. AbbVie Inc. and Abbott Laboratories, Case No. 1:14-cv-04659
Richard Fowler v. AbbVie Inc. and Abbott Laboratories, Case No. 1:14-cv-04438
Randy Wood v. Eli Lilly & Co.; Lilly USA, LLC, Case No. 1:14-cv-07475
Timmy Smith v. Eli Lilly & Co.; Lilly USA, LLC, Case No. 1:14-cv-07000

III. Status of negotiations on Plaintiffs' Interrogatories and Adverse Event

Database production: There were two central disputes in Plaintiffs' Motion to Compel against AbbVie. The parties have resolved the first issue, related to interrogatories. On March 16, 2015, the PSC served an amended first set of Interrogatories. The parties have conferred about that amended set of Interrogatories and AbbVie's responses are due next week. On April 13th, AbbVie's counsel contacted the PSC to ask for a short extension of that deadline, which the PSC has agreed to accommodate and the parties are merely figuring out the new response date (or dates as some responses may require more time than others). The parties are still negotiating the second prong of the Motion to Compel, the production of the Adverse Event Database. On April 9, AbbVie's counsel provided to the PSC some data that was extracted from their Adverse Event Database for entries related to AndroGel. The PSC is analyzing that information and anticipates that the parties will have at least one more conversation about the information before the status conference on April 21st.

***IV. Report on search term negotiations*:** Work by the PSC and AbbVie to test the scope and format of the proposed search terms has progressed and it is possible an agreement could be reached soon.

Lilly and Plaintiffs had previously deferred the negotiation of search terms until an agreement was reached between Plaintiffs and AbbVie since such agreement would serve as a model. Since Plaintiffs and AbbVie have not reached agreement yet, Lilly and Plaintiffs have now agreed to begin substantive discussions about search terms. Plaintiffs provided Lilly's counsel with the most recent search term list supplied to AbbVie. Lilly responded by providing Plaintiffs with its proposed list. Negotiations are ongoing.

V. Plaintiffs' Statement Regarding the Status of other pending discovery matters due from Defendants

i. AbbVie: To date, AbbVie has produced approximately 94,300 documents (over 3 million pages)[1] and AbbVie has continued to produce documents on a rolling bi-weekly basis, including materials from the *King v. Solvay* whistleblower litigation. The *King* production is scheduled to be completed by May 5th per prior agreement of the parties. As the PSC informed the Court in connection with the March Case Management Conference, the PSC notified AbbVie of what it believes to be an alarming amount of missing metadata within the documents produced from the *King* litigation received to date. The missing metadata eliminates important evidence and makes review of the produced documents increasingly and unnecessarily difficult. The parties have conferred about this issue as well as other problems the PSC has encountered with AbbVie's production. AbbVie has provided a technical fix to some of the problems, however, there are still some unresolved problems which make the PSC's review of

[1] This excludes a production from April 9th which has not yet been loaded or analyzed by the PSC.

the documents difficult and put the parties on unequal footing with regard to documents. The parties are continuing to seek solutions and common ground. Two of the biggest problems are: (a) the amount of missing metadata from the documents received from the *King* production; and (b) the lack of page breaks, which prevent the PSC from knowing where in a large document a term is found.

Missing metadata: The fact that the *King* documents are missing so much metadata that was agreed to and ordered in Exhibit A to CMO 15 (Amended) is quite startling to the PSC, especially in light of the fact that AbbVie never reached out to the PSC to discuss these issues in advance of making the production. A simple look at the numbers for just one metadata field — the Custodian field — shows the magnitude of the problem. In the first *King* production, there were 1,090 documents produced and 601 (55%) of them are missing data in the "Custodian" field such that the PSC has no way of knowing whose file it was in. In the second *King* production, there were 6,389 documents and 3,816 (60%) did not have a custodian identified. In the third *King* production, 2,909 documents were produced and 1,707 (59%) did not identify the custodian in the metadata.[2] And this is only one of several missing or inaccurate metadata fields.[3] In the second *King* production, the PSC found a hand-written document that does not have the custodian identified in the metadata and it does not have the author identified in the

[2] A fourth *King* production was made on April 9, 2015, but the PSC has not yet had a chance to load it into their document review platform and perform the necessary analysis of that production.

[3] AbbVie has taken the position during the meet-and-confer process that the metadata is missing because portions of the *King* documents existed only in paper and had to be scanned and OCR'ed. While a scanned copy of an email will not have metadata identifying the individuals in the "To" or "From" fields, the collecting party will still know where the document was collected from (*e.g.*, whose custodial file the document was collected from) — whether it was the computer of a particular individual or a binder on the desk of a particular individual — thereby identifying the custodian or custodians. This information is critical for the PSC to be able to effectively review the documents and prepare the case for depositions and trial and needs to be provided to the PSC in the "custodian" field of the load file that accompanies the production.

metadata. The face of the document does not identify the author or who may have received it. Without this metadata there is no way for the PSC to link this document to a witness so there is no manner to determine who should be examined about it at a deposition. As the Court can see from the above numbers, this is the case for close to 60% of the *King* production. While AbbVie has agreed to find out if the original collection set for the *King* production still exists, to date, AbbVie has been unwilling to have the technology vendors communicate directly to try to "brainstorm" about possible fixes to the many problems with their production of materials from the *King* action.

AbbVie Response: Over the last couple of weeks, AbbVie has endeavored to respond to Plaintiff's inquiries regarding the documents produced in *King v. Solvay*, including but not limited to whether any additional information is readily available. As explained to plaintiffs, the *King* documents are being produced in the same manner and format they were produced in the *King* litigation and in the same manner and format they were provided to AbbVie's counsel in this litigation. AbbVie has not withheld any metadata that was provided to it or otherwise done anything to make the production less advantageous to plaintiffs in this case than it was in *King*. Moreover, AbbVie and Plaintiffs stand in the same position regarding their ability to review and glean information from this universe of documents – there is nothing that AbbVie's counsel has access to from the production that plaintiffs' counsel does not. While AbbVie continues to seek the answers to Plaintiffs questions regarding the original *King* document collection and production, AbbVie is charged only with producing the *King* production *qua* the *King* production. It did not agree to take on the burden nor should it now be asked to fix a historic production from a different litigation. Doing so will merely increase cost and delay.

Page Breaks: During the time the parties were negotiating the format of production (TIFF vs. Native) the PSC raised the issue of one problem with a TIFF production is that if "page breaks" are not inserted when we search for a word, we will identify documents that word is found in, but we will ***not*** be able to identify where in the document the word is found. By way of example, if we are searching for the word "red" we would know it exists in a document, but not know if it is on page 1, page 45 or page 359. This becomes a large problem in longer documents, which are common in pharmaceutical litigation, especially documents contained in the IND/NDA production. During those discussions the PSC was assured by AbbVie's counsel that this problem would not occur. The productions made to date do not contain page breaks so Plaintiffs are now in the very position they sought to avoid and were promised they would not experience. Without knowing where the searched for terms appear in the document, the PSC is simply not on a level playing field with the producing party. Again, the PSC has asked AbbVie to have the technical people get together to attempt to reach a solution to this problem, however, to date, AbbVie has been unwilling to have the technology vendors communicate directly to try to "brainstorm" about possible fixes to their production.

***AbbVie Response*:** To begin, Plaintiffs' recitation of the current status of this issue is inaccurate. At the last meet and confer on this issue on April 8th, Plaintiffs agreed that they would discuss potential solutions to their perceived problem with their technology vendor and would provide AbbVie with their proposal for consideration. This has not happened. More importantly, however, this is an attempt by Plaintiffs to re-litigate an issue that was fully briefed and argued and on which the Court has ruled. Plaintiffs raised this exact same argument in their briefing on ESI production format and protocol. Having fully considered the argument and finding it unpersuasive, the Court "approve[d] defendants' proposal for TIFF-format

production." Case Management Order No.10. Despite full resolution of this issue, AbbVie was willing to entertain a solution if Plaintiffs could provide one that would not add delay or cost to the document production process. AbbVie is still waiting for that proposal.

VI. Non-AbbVie Core Defendants: Discovery efforts are ongoing. There are no significant developments to report at this time.

***VII. AbbVie Statement on Production of Non-Custodial Files*:** In addition to the millions of pages of documents that have already been produced, including many non-custodial productions such as all IND/NDA documents and correspondence with the FDA; organizational charts; standard operating procedures; labeling; and documents related to the September 2014 FDA Advisory Committee, AbbVie continues to collect, review and produce from numerous non-custodial sources. AbbVie has collected for review several network share drives from departments such as Marketing, Medical Affairs, and Regulatory Affairs. AbbVie has also collected sharepoints for its Safety Review Teams. AbbVie is currently processing collections from its Global Labeling System which includes not just labeling content but regulatory communications regarding labeling. As noted above, AbbVie is also negotiating with Plaintiffs regarding a production from its Adverse Events Database. Pursuant to recent discussions with Plaintiffs regarding their amended interrogatories, AbbVie is also in the process of investigating its ePASS system to produce information regarding AndroGel related promotional and educational materials.

***VIII. State/federal coordination*:** The parties have no major developments to report. Counsel continue to update the list identifying all state court TRT cases, including the parties, attorneys, jurisdiction, judge and status, pursuant to CMO 17. Defendants have been negotiating for entry of identical or substantially similar discovery-related orders in Cook County and

Pennsylvania and have continued to apprise the judges in those cases of updates in the MDL. In addition, Defendants have been producing documents in the MDL and state courts and are attempting to coordinate across litigations to achieve uniformity in ESI search terms. Defendants will use their best efforts to coordinate discovery and case schedules in the MDL proceeding with discovery and case schedules in the state court cases. Plaintiffs' State-Federal Liaison Counsel will continue to communicate with plaintiffs' counsel in the state court cases regarding the status, schedule, and developments in the MDL proceeding and in the various state court cases.

IX. ANDA Motions to Dismiss: Pursuant to Case Management Order No. 20, certain defendants who sell testosterone replacement therapies ("TRTs") that were approved pursuant to Abbreviated New Drug Applications ("ANDAs") will move to dismiss the master complaint and any and all individual complaints that contain allegations and causes of actions with respect to their TRTs approved pursuant to ANDAs on the ground that plaintiffs' claims are preempted under the doctrine of impossibility preemption, as reflected in the U.S. Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, 564 U.S. ---, 131 S. Ct. 2567, *reh'g denied*, 132 S. Ct. 55 (2011), and *Mutual Pharm. Co. v. Bartlett*, 570 U.S. ---, 133 S. Ct. 2466 (2013). The parties are meeting and conferring regarding a proposed briefing schedule and page limits for the briefs, for which they intend to request the Court's approval (if they are able to reach agreement) or the Court's guidance (if they are not able to reach agreement). The parties also will seek the Court's guidance with regard to a hearing date for oral argument on the motion.

Dated: April 16, 2015

Respectfully submitted,

/s/ Trent B. Miracle

Trent B. Miracle
SIMMONS HANLY CONROY
One Court Street
Alton, IL 62002
Telephone: (618) 259-2222
Facsimile: (618) 259-2251
tmiracle@simmonsfirm.com

Plaintiffs' Co-Lead Counsel

Ronald Johnson, Jr.
SCHACHTER, HENDY & JOHNSON PSC
909 Wrights Summit Parkway, Suite 210
Ft. Wright, KY 41011
Phone: (859) 578-4444
Fax: (859) 578-4440
rjohnson@pschachter.com

Plaintiffs' Co-Lead Counsel

Christopher A. Seeger
SEEGER WEISS LLP
77 Water Street
New York, NY 10005
Phone: (212) 584-0700
Fax: (212) 584-0799
cseeger@seegerweiss.com

Plaintiffs' Co-Lead Counsel

David M. Bernick
DECHERT LLP
1095 Avenue of the Americas
New York, NY 10036
Tel: (212) 698-3500
Fax: (212) 698-3599
david.bernick@dechert.com

Hope S. Freiwald
DECHERT LLP
Cira Center
2929 Arch Street
Philadelphia, PA 19104

Tel: (215) 994-2514
Fax: (215) 994-2222
hope.freiwald@dechert.com

Attorney for AbbVie Inc. and Abbott Laboratories

David E. Stanley
Janet H. Kwuon
REED SMITH LLP
355 S. Grand Avenue, Suite 2900
Los Angeles, CA 90071
Tel: (213) 457-8000
dstanley@reedsmith.com
jkwuon@reedsmith.com

Attorneys for Eli Lilly and Company and Lilly USA LLC

Andrew K. Solow
KAYE SCHOLER LLP
250 West 55th Street
New York, NY 10019
Tel: (212) 836-7740
Fax: (212) 836-6776
andrew.solow@kayescholer.com

Pamela J. Yates
KAYE SCHOLER LLP
1999 Avenue of the Stars, Suite 1700
Los Angeles, CA 90067
Tel: (310) 788-1278
Fax: (310) 788-1200
pamela.yates@kayescholer.com

Attorneys for Endo Pharmaceuticals Inc. and Auxilium Pharmaceuticals, Inc.

Loren H. Brown
Cara D. Edwards
DLA PIPER LLP (US)
1251 Avenue of the Americas
New York, NY 10020
Phone: (212) 335-4500
Fax: (212) 335-4501
loren.brown@dlapiper.com
cara.edwards@dlapiper.com

Matthew A. Holian
Jessica C. Wilson
DLA PIPER LLP (US)
33 Arch Street, 26th Floor
Boston, MA 02110
Phone: (617) 406-6000
Fax: (617) 406-6001
Email: matt.holian@dlapiper.com
Email: jessica.wilson@dlapiper.com

Attorneys for Pfizer Inc. and Pharmacia & Upjohn Company LLC

Joseph P. Thomas
Jeffrey F. Peck
K.C. Green
Jeffrey D. Geoppinger
ULMER & BERNE LLP
600 Vine Street, Suite 2800
Cincinnati, OH 45202
Phone: (513) 698-5000
Fax: (513) 698-5001
E-mail: jthomas@ulmer.com

Attorneys for Actavis, Inc., Actavis Pharma, Inc., Anda, Inc., Watson Laboratories, Inc., a Nevada corporation, and Watson Laboratories, Inc., a Delaware corporation

James W. Matthews (*pro hac vice*)
Robert W. Sparkes, III (*pro hac vice*)
K&L GATES LLP
State Street Financial Center
One Lincoln Street
Boston, MA 02111
Tel: (617) 261-3100
Fax: (617) 261-3175
E-mail: james.matthews@klgates.com
E-mail: robert.sparkes@klgates.com

CERTIFICATE OF SERVICE

I hereby certify that on April 16, 2015, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Trent B. Miracle