SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: BERGEN COUNTY

IN RE YAZ®, YASMIN®, OCELLA® LITIGATION

CASE NO. 287

CIVIL ACTION

FILED
OCT 12 2010
BRIAN R. MARTINOTTI
J.S.C.

*This Document Relates to All Actions*

**CASE MANAGEMENT ORDER NO. 13**
**(Production and Inspection of the Clintrace Database and Data)**

WHEREAS Bayer licenses database software called Clintrace from a third party that is used by Bayer in pharmacovigilance functions relating to adverse events reported to Bayer concerning its pharmaceutical products, including YAZ®, Yasmin®, and a generic version of Yasmin sold by Barr Laboratories, Inc. under the tradename Ocella®. Bayer claims that its license agreement prohibits it from providing a copy of the Clintrace software to the Plaintiffs. In order to provide the Plaintiffs with access to Bayer's information and data on its Clintrace database while protecting Bayer's license agreement obligations, it is **HEREBY ORDERED**:

1. Bayer shall make a fully functional and complete Bayer-licensed copy of Yasmin/YAZ/Ocella portion of the Clintrace database available for inspection pursuant to Rule 4:18-1 by the Plaintiffs and their experts on a Bayer-owned computer. As used herein, Yasmin, YAZ and Ocella includes the same pharmaceutical products that may be sold under other trade names. This copy of Clintrace will be made available in a private room in Pittsburgh, Pennsylvania at a Bayer facility. This copy of Clintrace shall be available throughout the course of the litigation. This copy of Clintrace shall have all of the data and all of the data fields relating to the products Yasmin, YAZ and Ocella that exist in the Clintrace database that Bayer uses in its day-to-day use of Clintrace, excluding any data or information that identifies, or could lead to the identity of, the person who is the subject of the adverse event report and the

reporter(s) of the adverse event. The copy of Clintrace shall also have all of the functions, features and capabilities that the Clintrace software can provide. Bayer has also agreed and will provide within the Clintrace copy an additional overlay search software module developed by Bayer. Bayer is not required to provide data for any product other than Yasmin, YAZ or Ocella. Bayer is not required to provide as part of this inspection(s) any other documents or materials relating to an adverse event report, including but not limited to patient medical records, which have been requested by Plaintiffs and shall be the subject of further discussions among the parties.

2. Bayer shall make arrangements for Plaintiffs to access Bayer's facilities in a manner that does not require the disclosure of the identity of any of Plaintiffs' experts to Bayer's security staff (or any employee of Bayer) or require the Plaintiffs' experts to sign any form of security log. By way of example, Plaintiffs' counsel shall be permitted to sign into security as "John Attorney plus one" in order to maintain the confidentiality of the identity of their experts.

3. In addition, Bayer shall produce to Plaintiffs a complete set of data exported from Clintrace into a Microsoft Excel table along with a description of any data field whose content is not otherwise apparent from the data field title.

4. Bayer shall take no steps to attempt to determine what searches have been run or what documents have been viewed, printed or downloaded by Plaintiffs' counsel or their experts. Bayer shall not create or maintain any search histories, result histories, or data files documenting any aspect of Plaintiffs' counsel's use of Clintrace.

5. Bayer shall ensure that all information and data contained on the copy of the Clintrace database made available to Plaintiffs reflects the identical data and information relating to Yasmin, YAZ and Ocella that can be contemporaneously viewed by Bayer employees on the

Clintrace database as of the date the data export was created. The parties recognize that this version of Clintrace may need to be updated and the parties shall discuss the issues of if and when such updates shall occur as well as how to address any switch by Bayer to different software to be used in the role that Clintrace currently fills.

6. Plaintiffs' counsel and their experts shall not make any attempts to copy the Clintrace software or to examine or inspect the Clintrace source code.

7. Inspection shall be arranged between counsel for the parties upon such dates and times as mutually agreeable. Any inspection shall occur only during the normal business hours of the Bayer facility. Plaintiffs are encouraged to coordinate with plaintiffs' counsel in the MDL and other state court cases to conduct joint inspections to limit potential disruption and time spent on arranging inspections.

8. Bayer has provided Plaintiffs with a demonstration of the Clintrace database and a copy of the manual used by its Pharmacovigilance personnel in entering and accessing data. Bayer will provide Plaintiffs with basic written instructions on how to access and open the Clintrace data export, how to access the search function, and how to create a download to a media device such as a thumb drive. Bayer is not required to provide any other instruction or personal assistance to Plaintiffs' representatives or experts. Notwithstanding any other provision in this CMO, Bayer is responsible for providing technical support and maintenance to make sure the hardware and software work properly for this inspection of Clintrace.

**IT IS SO ORDERED.**

Hon. Brian R. Martinotti, J.S.C.

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