



**IN THE CIRCUIT COURT OF
KANAWHA COUNTY, WEST VIRGINIA**

IN RE DIGITEK® LITIGATION

CIVIL ACTION NO. 08-C-5555

THIS DOCUMENT APPLIES TO ALL CASES

CASE MANAGEMENT AND SCHEDULING ORDER NO. 1

This Order shall govern all Digitek® cases in the State of West Virginia (1) transferred to this Court by the Mass Litigation Panel for consolidation under the style *In re: Digitek® Litigation*, Civil Action No. 08-C-5555; and (2) all related cases originally filed in this Court. This Order applies to all Plaintiffs in West Virginia state actions and to Defendants Actavis Totowa LLC, and Actavis Inc. and Actavis Elizabeth, LLC (“Defendants Actavis”)¹ and Defendants Mylan Pharmaceuticals, Inc., UDL Laboratories, Inc., Mylan Inc., and Mylan Bertek Pharmaceuticals, Inc. (“Defendants Mylan”)².

All subsequent Orders of this Court with the designation “All Actions” entered in *In re: Digitek® Litigation* (“Digitek® Litigation”) shall likewise apply to all cases that are, or become, part of the Digitek® Litigation, regardless of whether that case was part of the Digitek® Litigation when the Order was entered.

This Order substantially reflects the Case Management and Scheduling Order (Pretrial Order #16) entered by the Honorable Joseph R. Goodwin from the United States District Court for the Southern District of West Virginia, *In Re Digitek® Products Liability Litigation*, MDL No. 1968 (“Digitek® MDL”). The parties intend to coordinate discovery with the Digitek® MDL to the extent practicable in order to promote efficiency and to reduce duplication and cost.

¹ Defendants Actavis maintain that Actavis Elizabeth, LLC is not a proper party and explicitly do not waive any argument regarding their inclusion in this litigation.

² Defendants Mylan maintain that Mylan Inc., and Mylan Bertek Pharmaceuticals, Inc. are not proper parties and explicitly do not waive any argument regarding their inclusion in this litigation.

I. SERVICE OF PROCESS

To eliminate disputes over service of process and to reduce the expense of service of process, Defendants Actavis and Defendants Mylan agree to waive service of process in this action and agree to accept service of the Summons and Complaint in the above-referenced matter by registered mail, return receipt requested, upon the following:

For Defendants Actavis:

Richard A. Dean, Esq.
Tucker Ellis and West LLP
1150 Huntington Building
925 Euclid Avenue
Cleveland, Ohio 44115

For Defendants Mylan:

Harvey L. Kaplan, Esq.
Shook Hardy and Bacon LLP
2555 Grand Boulevard
Kansas City, Missouri 64108

Service will be effective only if addressed as above, or if perfected in accordance with the service provisions of the West Virginia Rules of Civil Procedure. For service under this section, a copy of each notice of Service of the Summons and Complaint shall be provided to Defendants' Liaison Counsel and Plaintiffs' Liaison Counsel.

The Court orders that service effected in accordance with this section shall be deemed good and sufficient service on Defendants Actavis and Defendants Mylan (collectively "Defendants"). By agreeing to this waiver of service, Defendants Actavis and Defendants Mylan do not waive any claims, affirmative defenses or other defenses of any nature whatsoever except for those relating to service of process. If service is perfected under the West Virginia Rules of Civil Procedure, Defendants Actavis and Defendants Mylan do not waive any claims, affirmative defenses or other defenses of any nature whatsoever, including those related to service of process. Service of process will be perfected ten (10) days after service via registered mail. This procedure shall apply to Digitek® product liability cases filed

in courts in West Virginia unless service is otherwise perfected under the West Virginia Rules of Civil Procedure, and not to any other litigation.

Defendants' responsive pleadings, including W. Va. R. Civ. P. 12 motions, filed under this section shall be due forty-five (45) days after service.

II. PLEADINGS AND MOTIONS

A) Pleadings. Deadlines for answers or responses to the Complaints in all individual actions are subject to the West Virginia Rules of Civil Procedure, except as otherwise set forth herein.

B) Class Certification.

1) Plaintiffs' deadline to request class certification of any wrongful death, personal injury or medical monitoring putative class is one hundred eighty (180) days from the date of this Order. Plaintiffs' motion and brief in support shall be filed and served within one hundred ninety (190) days from the date of this Order. Plaintiffs' deadline to request class certification of any other putative classes is one hundred and ninety-four (194) days from the date of this Order. Plaintiffs' motion and brief in support shall be filed and served within two hundred and four (204) days from the date of this Order.

2) Discovery on class issues shall be subject to the time limitations set out in Section VI(G) below.

3) Defendants' response brief(s) to Plaintiffs' motion(s) for class certification shall be filed and served thirty (30) days after the filing of each respective class

certification motion(s) and accompanying brief(s), with any reply in accordance with the West Virginia Rules of Civil Procedure.

III. DISCOVERY

A) Plaintiffs' Fact Sheet.

1) In every case currently part of the Digitek® Litigation and in all other cases that become part of the Digitek® Litigation by virtue of being filed in or transferred to this Court, each Plaintiff shall complete and submit a Plaintiff Fact Sheet ("PFS") to defense counsel.

2) Within seventy-five (75) days of the date of this Order for cases currently pending in the Digitek® Litigation, or within sixty (60) days of the date on which an action is filed in or transferred to and docketed in the Digitek® Litigation, a Plaintiff who is subject to this Order shall serve the named Defendants in that case with:

(a) A completed PFS. Plaintiffs shall sign the completed PFS and provide an executed Affidavit attesting that the information contained therein is true and correct to the best of the Plaintiff's knowledge, information and belief, formed after due diligence and reasonable inquiry.³

A completed PFS shall be considered interrogatory answers under W. Va. R. Civ. P. 33, responses to requests for production under W. Va. R. Civ. P. 34, and will be governed by the standards applicable to written discovery under W. Va. R. Civ. P. 26 through 37. The interrogatories and requests for production

³ If the Plaintiff is suing in a representative or derivative capacity (e.g., on behalf of an estate, as a survivor, and/or as an assignee or subrogee), the PFS shall be completed by the person with the legal authority to represent the estate or the person under legal disability.

in the PFS shall be answered without objection.

This section does not prohibit a Plaintiff from withholding or redacting information based upon a recognized privilege. If information is withheld or redacted on the basis of privilege, Plaintiff shall provide Defendants with a privilege log. In the event that a dispute arises concerning the completeness or adequacy of a Plaintiff's response to any request contained in the PFS, this Section shall not prohibit the Plaintiff from asserting that his or her response is adequate.

(b) Authorizations for the release of records. Plaintiffs shall provide addressed authorizations for each health care provider, including hospitals, clinics and outpatient treatment centers, and any other custodian of records identified in Plaintiff's Fact Sheet. Defendants shall provide a copy of any records received by the use of such authorization to Plaintiffs upon receipt, and Plaintiffs will reimburse the reasonable copying costs.

(i) Plaintiffs shall provide undated authorizations.

(ii) Undated authorizations constitute permission for Defendants to date (and where applicable, re-date) authorizations before sending to records custodians.

(iii) The Court encourages counsel for Plaintiffs to have their clients execute a sufficient number of undated, blank authorizations in order to assure the ability to obtain records promptly.

(c) Records in Plaintiffs' Possession. Plaintiffs shall provide the documents listed below that are currently in Plaintiffs' possession or in the possession of Plaintiffs' Counsel.

(i) Medical records in Plaintiffs' possession establishing that Plaintiff was prescribed Digitek® and the date(s) on which each prescription issued.

(ii) Pharmacy records in Plaintiffs' possession establishing that Plaintiff actually purchased and received Digitek®, including pharmacy records of all dates on which Plaintiff filled and/or refilled a prescription for Digitek®, as well as any records of prescriptions for any other form of digoxin which was prescribed or dispensed to Plaintiff.

(iii) Medical records in Plaintiffs' possession documenting the alleged injury that Plaintiff claims to have suffered as a result of Digitek® ingestion.

3) Every Plaintiff is required to provide Defendants with a PFS that is substantially complete in all respects. "Substantially complete in all respects" requires that a Plaintiff:

(a) Answer every question in the PFS and leave no blanks, even if a Plaintiff can only answer the question in good faith by indicating "not applicable" or "I don't know";

(b) Provide the requested records authorizations; and

(c) Produce the documents requested in Section III(A)(2)(c)(i)-(iii), or a statement certifying that there are no responsive documents.

4) Any Plaintiff who fails to comply with the PFS obligations under this Order may be subject to having his or her claims, as well as any derivative claim(s), dismissed for good cause. Good cause shall exist where (1) the Plaintiff has failed to submit a PFS, or (2) the Plaintiff has failed to substantially complete the PFS in all respects, and the PFS thus contains a material deficiency (i.e., a deficiency that prejudices Defendants through a failure to provide necessary information, thereby impeding Defendants' access to material and relevant evidence), and (3) Defendants establish to the Court that they have exhausted all efforts described in paragraph (5) below. Any dismissal may be with or without prejudice as the Court may determine in any individual case.

5) If a Plaintiff fails to timely submit a PFS, or if Defendants receive a PFS in the allotted time but the PFS is not "substantially complete" in all respects, Defendants' Lead Counsel shall send a deficiency letter by facsimile and U.S. mail to Plaintiffs' Liaison Counsel and Plaintiffs' individual representative counsel, which will allow that Plaintiff an additional thirty (30) days to serve a PFS that is "substantially complete" in all respects. The deficiency letter shall include a warning that the case is subject to dismissal under this Order if a PFS substantially complete in all respects is not received within thirty (30) days of service of the deficiency letter. This letter shall include sufficient detail for the parties to meet and confer regarding the alleged deficiencies. Should a Plaintiff fail to cure the deficiencies identified and fail to provide

responses that are substantially complete in all respects (including the requested documents and signatures on all applicable authorizations) within thirty (30) days of service of the deficiency letter, Defendant may seek an Order to Show Cause why the case should not be dismissed. Any such filing shall be served on Plaintiffs' Liaison Counsel and the Plaintiffs' individual representative counsel, with any response to such filing to be submitted within ten (10) days following the date of service. Any such filing should include the efforts the Defendants made to meet and confer regarding the alleged deficiencies in the PFS and failure to cure.

6) In the event that an institution or medical provider to whom any authorization is presented refuses to provide records in response to that authorization, Defendants shall notify Plaintiffs' Liaison Counsel, and the individual Plaintiff shall execute and return within 30 days whatever form is required by that institution or provider, such as a form with an original signature, a notarized form, or the institution's own form. Should a particular form be required, Defendants will provide it to Plaintiffs' Liaison Counsel.

7) To resolve disagreements regarding the ability of Defendants to have ex parte contact with any treating physician, whether it be the result of Defendants seeking medical records of a Plaintiff that has provided a PFS or by some other means, the parties are ordered as follows:

(a) Counsel for Defendants Actavis and Defendants Mylan agree that they will not conduct ex parte communications about any particular Plaintiff with Plaintiff's treating physicians without notice to Plaintiffs' Liaison Counsel.

Should the parties be unable to reach agreement about those communications, counsel for Defendants Actavis and Defendants Mylan will not conduct any such communications until the Court has resolved the issue.

(b) In connection with its regulatory obligations to investigate reports of adverse events associated with its products, Defendants Actavis and Defendants Mylan will continue its practice of requesting medical records from physicians and/or their attorneys, and may seek follow-up information from physicians by telephone or otherwise. Outside counsel for Defendants Actavis and Defendants Mylan will not initiate, prompt, participate in, or otherwise be involved with any such regulatory compliance contacts.

(c) If Counsel for Defendants Actavis and Defendants Mylan have been contacting, and continue to contact, potential consulting and testifying medical experts, they will refrain from discussing the medical history of an individual Plaintiff if it is discovered that the individual Plaintiff is, or was, a patient of any of those experts. Counsel for Defendants will inform the expert(s) of this restriction.

B) Defendants.

Defendants are currently obligated to produce documents pursuant to a schedule approved and ordered by the Digitek® MDL pursuant to Pretrial Order #16.

IV. PRIVILEGED DOCUMENTS

A) Any party who withholds the production of requested documents or materials, regardless of the manner in which they are kept or maintained, on the ground of any privilege or

application of the work-product doctrine must specify in writing, as to each document or thing not produced, the specific privilege(s) or doctrine(s) relied upon to withhold each document (“Privilege Log”).

B) Each Privilege Log shall describe each document or thing to which a privilege or work product protection is asserted in sufficient detail to reasonably permit the party seeking discovery to assess whether or not to dispute the assertion. Details include, but are not limited to:

- 1) Custodian or source;
- 2) Date;
- 3) Author(s);
- 4) The starting and ending production number for documents produced, but redacted on the ground of privilege;
- 5) Recipient(s) (for e-mail and hard-copy communications such as letters and internal memoranda);
- 6) cc(s) (for e-mail and hard-copy communications such as letters and internal memoranda);
- 7) bcc(s) (for e-mail and hard-copy communications such as letters and internal memoranda);
- 8) Specification of the privilege claimed; and
- 9) A description of the document and the basis for the privilege claim.

C) The parties will produce privilege logs in Excel format or a similar electronic format that allows for text searching and organization of data.

D) A party will produce a privilege log within thirty (30) days of its production of documents for which any privilege is asserted to apply, and within the same time period following any subsequent or rolling productions.

V. DOCUMENT PRODUCTION PROTOCOL

The Parties will follow the document production protocol ordered in the Digitek® MDL in Pretrial Order No. 20, a copy of which is attached to this Order. Exhibit A to the document production protocol attached to Digitek® MDL Pretrial Order No. 20, may be obtained by an attorney in the Digitek Litigation from Plaintiffs' Liaison and Lead Counsel, Carl N. Frankovitch, Esquire.

VI. DISCOVERY DATES AND ORDER

A) Discovery Upon Defendants

If Plaintiff intends to propound Interrogatories upon Defendants, they shall do so no later than June 1, 2009. If Plaintiff intends to propound Requests for Production of Documents upon Defendants, they shall do so no later than June 1, 2009. Plaintiff shall be limited to 40 Interrogatories, including all discrete subparts, but may request leave of Court for additional Interrogatories if necessary.

B) Company Witness Depositions

The depositions of Defendants' company witnesses shall be concluded by December 1, 2009. Notices for the depositions of these witnesses will be issued from the Digitek® MDL and will be cross-noticed in the Digitek® Litigation.

C) Liability Expert Discovery

- 1) Plaintiffs shall serve their reports from non-case specific liability experts

no later than January 1, 2010.

2) The parties shall complete their depositions of Plaintiffs' non-case specific liability experts no later than March 12, 2010.

3) Defendants shall serve their reports from non-case specific liability experts no later than March 31, 2010.

4) The parties shall complete their depositions of Defendants' non-case specific liability experts no later than June 11, 2010.

D) Division of Cases and Trial Pool Cases

To efficiently manage discovery for all currently pending and future cases in the Digitek® Litigation, the cases will be divided into groups, with each group having a separate scheduling order. Within ten (10) business days of the completion of the first wave of Plaintiffs' Fact Sheets under Section III(A)(2), the Court shall schedule a hearing for purposes of selecting the initial trial pool of cases ("Group 1"). No later than five (5) days before the hearing, Plaintiffs shall select six (6) cases and the Defendants shall select six (6) cases, and each side shall exchange lists of such selections and submit them to the Court outside the LexisNexis File & Serve system. Within ten (10) days after the scheduled hearing, the Court shall select a total of no more than six (6) of the proposed trial pool cases to constitute Group 1. The six (6) cases not selected shall constitute the waiting list for Group 1, and shall have priority for trial selection in Group 2.

At the first hearing before the Court to select Group 1, the parties and the Court will determine a schedule to select the remaining groups, with the intent to make selections in a timely fashion and to allow enough time for discovery for each group as set forth below.

E) Discovery Initiation Date

Discovery will begin for each group pursuant to the schedule provided below. In the event that additional groups are necessary, their discovery initiation dates (“DID”) will begin thirty (30) days after the last group’s DID.

<u>Group Number</u>	<u>Discovery Initiation Date</u>
Group 1	160 days after entry of this Order
Group 2	220 days after entry of this Order
Group 3	280 days after entry of this Order
Group 4	340 days after entry of this Order
Group 5	400 days after entry of this Order
Group 6	460 days after entry of this Order

F) Scheduling Orders

Each group will have its own scheduling order based upon its DID. The orders will proceed as follows.

1) Fact Discovery

(a) No later than 90 days after the DID, the parties shall complete basic fact discovery, including but not limited to the depositions of Plaintiffs, Plaintiffs’ Digitek[®]-prescribing physicians, physicians who treated Plaintiffs for alleged digoxin toxicity, and pharmacists who filled Plaintiffs’ prescriptions for Digitek[®].

(b) After completion of the basic fact discovery outlined in paragraph 1(a), the parties will appear before the Court for a Case Management Conference.

At that time, each party will present to the Court their choice of three (3) cases that they believe to be representative plaintiffs for trial. No later than 105 days after the DID, the Court will determine which three (3) cases will be selected for trial.

(c) The parties shall complete fact discovery in the three (3) trial cases no later than 150 days after the DID.

2) Expert Discovery

(a) The three (3) trial plaintiffs shall serve their case-specific expert report(s) on causation and damages no later than 150 days after the DID.

(b) The parties shall complete the depositions of Plaintiffs' case-specific experts in the three (3) trial cases no later than 210 days after the DID.

(c) Defendants shall serve their case-specific expert report(s) on causation and damages in the three (3) trial cases no later than 240 days after the DID.

(d) The parties shall complete the depositions of Defendants' case-specific experts in the three (3) trial cases no later than 270 days after the DID.

3) Filing of Dispositive and *Daubert/Wilt* Motions

(a) All dispositive motions and *Daubert/Wilt* motions shall be filed and served no later than 310 days after the DID.

(b) All responses to dispositive motions and *Daubert/Wilt* motions shall be filed and served no later than 340 days after the DID.

(c) All replies in support of dispositive motions and *Daubert/Wilt*

motions shall be filed and served no later than 370 days after the DID.

(d) A hearing will be scheduled by this Court for disposition of all dispositive and *Daubert/Wilt* motions no later than 400 days after the DID.

4) Pretrial Conference

The Court will schedule a pretrial conference no later than 415 days after the DID at which time the Court will schedule the trial dates for the three (3) trial cases with the first trial to begin no later than 450 days after the DID.

G) Class Certification Discovery.

1) In addition to any other discovery sought, beginning on July 1, 2009, Defendants may serve a single set of interrogatories and a single set of requests for admission related to class certification issues on each of the named Plaintiffs listed in the Class Action Cases.

2) Beginning on July 30, 2009, Defendants may depose treating physicians of named class members and other fact witnesses with knowledge of facts relevant to class action issues.

3) Depositions of any named Plaintiffs in the Class Action Cases on class certification issues may be taken in this proceeding at any time, consistent with the need to complete such depositions before Defendants' briefing on class certification issues is due to be submitted. Discovery taken under this subparagraph shall not limit the Defendants' ability to take additional non-duplicative discovery as part of their defense of the merits of any named Plaintiff's claim.

4) In addition to any other discovery sought with respect to individual cases,

the proposed class representatives may serve a single set of interrogatories, production requests and requests for admission in aid of their motion for class certification, without prejudice to their right to seek additional discovery with leave of Court. Plaintiffs may also take depositions necessary to support their motion for class certification and limited to class certification issues. Should the parties not be able to agree to the number and scope of these depositions, they will apply to the Court for a determination.

H) Discovery Disputes. The Court urges the parties to meet, confer and reach agreements on all disputed matters.

ENTER: April 13, 2009

/s/ Alan D. Moats
Lead Presiding Judge