UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON

IN RE DIGITEK®
PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER #37
(Memorandum Opinion and Order re Appeal of Pretrial Order #27)

On July 1, 2009, the Honorable Mary E. Stanley, United States Magistrate Judge, entered Pretrial Order #27. Pretrial Order #27 resolved the Plaintiffs' motion to expand and define the scope of discovery. As stated by the Magistrate Judge:

> Plaintiffs seek to expand the scope of discovery from Digitek® only to include all manufacturing processes of the Actavis Totowa Little Falls, New Jersey facility for all product lines. (Motion, # 144, at 6.) Plaintiffs assert, based on Rule 30(b)(6) depositions and review of documents, that there was extensive commingling of product lines within the Actavis plant and that "[t]here is no way to separate out the Digitek® product line from that of any of the other 105 product lines manufactured contemporaneously at the Little Falls plant. All equipment and all personnel were interchangeably utilized to manufacture all products." *Id.*

(PTO #27 at 2-3). Over the course of her 17-page opinion, the Magistrate Judge set forth the parties' respective arguments. Additionally, she quoted the governing standard found in Federal Rule of Civil Procedure Rule 26(b) and discussed the allegations in the Master Complaint and other materials before her. Rather than adopting the Plaintiffs' request for a wide-ranging expansion of discovery resulting in an immense expenditure of time, money, and resources by both sides, and the court, the Magistrate Judge chose a suitably tailored approach. Her depth of reasoning requires the

lengthy quote:

> After careful review of the FDA materials and other exhibits submitted by the parties, the court is persuaded that Plaintiffs have shown good cause for a limited expansion of the scope of discovery. For the most part, the exhibits support a conclusion that Digitek® was produced uniquely, with equipment which was not widely used for other products. Of concern is the FDA's observation that "[i]nvestigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy." (# 147-3, Ex. 2, at 12.)
>
> Plaintiffs' contention that an incident involving one product "would be similar or even identical" to an incident involving Digitek® is too speculative to justify the enormous and expensive expansion of discovery they seek.
>
> In order to strike a balance between a too-stringent limitation to Digitek® production only and a too-broad expansion to all product lines, the court finds that Plaintiffs have shown good cause for a modest expansion of the scope of discovery to include records of Little Falls production and the use of equipment for products other than Digitek®, which immediately preceded the use of that equipment for the production of Digitek® [referred to hereafter as "precursor discovery"]. That is, if the 50 cubic foot blender was used to blend a product other than Digitek®, ("product A"), and the blender was next used to blend Digitek® or one of its precursors, then the scope of discovery will include the batch record for product A. If records indicate that a blender was used for product A and was immediately thereafter used for Digitek®, a fair assumption can be drawn that the blender was not cleaned between uses. If compression and tableting equipment was used for product B immediately before a batch of Digitek®, then the batch record and associated testing data for product B is discoverable, including any indications of equipment malfunctions or the use of inappropriate dies. Assuming that a plaintiff experienced an adverse drug event or other injury associated with digitalis toxicity, and linked that event with the ingestion of Digitek®, it is the court's intention that such plaintiff should be able to trace backwards the lot number of his prescription to the manufacture of those tablets, and to determine the likelihood that the Digitek® contained only the ingredients it was supposed to contain, in the specified amounts. In light of the FDA warning letters, if the court were to refuse to expand discovery to records which reflect the use or misuse and operation or malfunctioning of equipment immediately before each batch of Digitek®, Plaintiffs would be unduly limited in their ability to determine whether a given batch of Digitek® was more likely than not "adulterated" and/or associated with an adverse drug event, other injury or death.

(PTO #27 at 14-16).

On July 16, 2009, the Defendants objected. They assert that the Magistrate Judge erred in

the following respects:

1) PTO #27 should be vacated because the Magistrate Judge specifically found that Digitek® was manufactured uniquely, and that it would be too speculative to expand discovery from one product to another, yet permitted discovery of non-Digitek® product information in her conclusion. The relief ordered is at odds with her factual findings and the factual evidence of record;

2) The Magistrate Judge's finding that information in non-Digitek® records might lead to relevant evidence should be vacated because there is no factual evidence of record to support the finding and in fact, there is sworn evidence of record to the contrary;

3) The Magistrate Judge's reliance on FDA letters to expand discovery is legally and factually erroneous. The FDA letters make no observations about Digitek® in regard to digoxin dosage -- the issue in this litigation -- and the references to "adulteration" in these letters have a specific meaning under federal regulations; that meaning has no bearing on whether a drug is deemed "safe" or "unsafe" under the regulations, or legally "defective"; and

4) PTO #27 does not reflect that the Magistrate Judge, in entering her compromise order, weighed the burden and expense to Defendants against the relevancy or benefit of the expanded discovery; because the documents are irrelevant, Plaintiffs should bear some portion, if not all, of the cost associated with producing non-Digitek® documents if PTO #27 is not vacated.

(Defs.' Objecs. at 2-3).

II.

Federal Rule of Civil Procedure 72(a) governs appeals from rulings of a magistrate judge on nondispositive matters:

> When a pretrial matter not dispositive of a party's claim or defense is referred to a magistrate judge to hear and decide, the magistrate judge must promptly conduct the required proceedings and, when appropriate, issue a written order stating the decision. A party may serve and file objections to the order within 10 days after

> being served with a copy. A party may not assign as error a defect in the order not timely objected to. *The district judge in the case must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law*.

Fed. R. Civ. Proc. 72(a) (emphasis added). The United States Court of Appeals for the Tenth Circuit has observed as follows:

> Rule 72(a), and its statutory companion, *see* 28 U.S.C. § 636(b)(1), place limits on a party's ability to seek review of a magistrate judge's non-dispositive order. . . .
>
> In reexamining this question, the district court *was required* to "defer to the magistrate judge's ruling unless it [was] clearly erroneous or contrary to law."

Allen v. Sybase, Inc., 468 F.3d 642, 658 (10th Cir. 2006) (emphasis added). A decision is clearly erroneous "when, after reviewing the entire record, a court 'is left with the definite and firm conviction that a mistake has been committed.'" *Thorne v. Wyeth*, Civ. No. 06-3123, 2007 WL 1455989, at * 1 (D. Minn. May 15, 2007) (Magnuson, J.) (quoting *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948)). A decision is "contrary to law" when it "fails to apply or misapplies relevant statutes, case law or rules of procedure." *Transamerica Life Ins. Co. v. Lincoln Nat'l Life Ins. Co.*, 592 F. Supp.2d 1087, 1093 (N.D. Iowa 2008).

The Defendants' first and second assertions contend that the precursor discovery (1) "is at odds with . . . [the Magistrate Judge's] factual findings and the factual evidence of record"[,] and (2) based upon the Magistrate Judge's faulty assumption that the Plaintiffs allege cross contamination of Digitek® with the substances manufactured prior to it. Regarding the first assertion, the Magistrate Judge observed that the Plaintiffs' initial request was overbroad. She then carefully devised a more particularized approach. She concluded that the examination of precursor information may reasonably lead to the discovery of admissible evidence respecting Digitek®. The

conclusion is rational. Regarding the second contention, the allegations in the Master Complaint are broader than the Defendants assert. For example, the Plaintiffs allege that the recalled Digitek® qualifies as an adulterated drug. As will be seen, that allegation alone is sufficient to support the narrow cross-contamination analysis offered by the Magistrate Judge.[1] The balance of the Defendants' subarguments on this point also fail to demonstrate that PTO # 27 is either clearly erroneous or contrary to law.

The Defendants' third assertion is based in part upon their view that the Plaintiffs are attempting in Count Five of the Master Complaint to pursue a private right of action under the Federal Food, Drug, and Cosmetic Act ("FDCA"). The Plaintiffs have since clarified that they intend only to use discrete portions of the FDCA to support a negligence *per se* claim, an approach that I have initially sanctioned in PTO # 33. That portion of the Defendants' third assertion is thus without merit. The remainder of the Defendants' third assertion is based upon their more limited understanding of the Plaintiffs' theory of the case, which has perhaps not yet fully gelled. As noted in Rule 26(b)(1), and as analyzed by the Magistrate Judge, however, one must refer to the complaint when determining the proper scope of discovery. The Master Complaint specifically alleges adulteration generally. (*See* Mast. Compl. ¶ 93 ("Defendants' acts constitute an adulteration and misbranding as defined by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 331, and the regulations promulgated there from and constitutes a breach of duty under the theory of negligence *per se*."). Title 21 U.S.C. 351(d) deems a drug adulterated "[i]f it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly

[1]Defendants assert that the batch records mentioned by the Magistrate Judge do not contain any information concerning the cleaning of equipment between the different drug batches that are run. They do not contend that the batch records lack other information that the Magistrate Judge deemed worthy of investigation. (*See* PTO #27 at 16 mentioning the discoverability of "associated testing data . . . [and] any indications of equipment malfunctions or the use of inappropriate dies.").

or in part therefor. " 21 U.S.C. § 351(d).[2] The definition is broad enough to contemplate the theory examined by the Magistrate Judge and the limited discovery she ordered.[3]

The Defendants' fourth assertion is that the Magistrate Judge failed to weigh the burden and expense to the Defendants against the relevancy or benefit of the expanded discovery. That is plainly not the case. The Magistrate Judge quoted that portion of Rule 26(b)(2)(C) requiring consideration of the burden and expense of the proposed discovery. Taking note of that, she chose a much narrower and reasoned approach. As the Defendants admit, the Magistrate Judge explicitly indicated that the burden and expense of the requested discovery was an important matter:

> Plaintiffs' contention that an incident involving one product "would be similar or even identical" to an incident involving Digitek® is too speculative to justify the enormous and expensive expansion of discovery they seek.

(PTO # 27 at 15). Accordingly, the Defendants' argument fails. Their remaining arguments also fail to clear the high bar set by Rule 72(a).

Based upon the foregoing discussion, the Magistrate Judge chose a reasonable and prudent means for allowing Plaintiffs access to discovery and, at the same time, turned away the overbroad and expensive fishing expedition they originally proposed. Her order is neither clearly erroneous nor contrary to law.

The court **DIRECTS** the Clerk to file a copy of this memorandum opinion and order in 2:08-

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[2]Defendants also fault the Magistrate Judge, by her review of the FDA warning letters, as "suggesting that the FDA's observations should have some bearing on the scope of discovery in the Digitek cases." (Objecs. at 8). I note that excerpts from the warning letters appear in the Master Complaint. As the Plaintiffs more particularly articulate the nature of, and investigate, their claims, reference to the content of the warning letters is appropriate, whether by the Plaintiffs or the Magistrate Judge.

[3]Defendants also suggest that the FDA warning letters support a view that they were only required to investigate other lots of Digitek® tablets rather than other products that did not contain digoxin. If true, the assertion is inconsequential. The inquiry under Rule 26(b)(1) is guided not by the warning letters but by the scope of the Master Complaint.

md-1968 which shall apply to each member Digitek-related case previously transferred to, removed to, or filed in this district, which includes counsel in all members cases up to and including civil action number 2-09-cv-00900. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: August 10, 2009