NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

SUPERIOR COURT OF NEW JERSEY
COUNTIES OF
ATLANTIC AND CAPE MAY

CAROL E. HIGBEE, P.J.Cv.

1201 Bacharach Boulevard
Atlantic City, NJ 08401-4527
(609) 343-2190

MEMORANDUM OF DECISION ON MOTION
Pursuant to Rule 1:6-2(f)

CASE:	**In re Reglan Litigation**
DOCKET #:	**Case No. 289**
DATE:	**May 4, 2012**
MOTION:	**Motion of Defendants Morton Grove Pharmaceuticals, Inc. and Wockhardt USA, LLC, to Dismiss Plaintiffs' Complaint**
ATTORNEYS:	**Robert E. O'Malley, Esq., Segal, McCambridge, Singer & Mahoney, Ltd., Chicago, Illinois and Andrew E. Anselmi, Esq., McCusker, Anselmi, Rosen & Carvelli, P.C., Florham Park, New Jersey for Defendants** **Theodore Oshman, Esq., Oshman & Mirisola, L.L.P., New York, New York and W. Paulette Francois, Esq., Winkler, Eisenberg & Jeck, P.C., Philadelphia, Pennsylvania for Plaintiffs**

Having carefully reviewed the papers submitted and any response received, I have ruled on the above Motion as follows:

Morton Grove is the holder of Abbreviated New Drug Application ("ANDA") and manufactures and distributes the syrup form of metoclopramide. Generally, the brand or NDA

holder is responsible for conducting testing, and ensuring the accuracy and adequacy of the product's label. By contrast, generic manufacturers are only responsible for ensuring that their product's composition is the bioequivalent of the brand. 21 C.F.R. § 314.94(a)(7); 21 U.S.C. § 355(j)(2)(A). After Wyeth left the market in 2002, there was no NDA holder for the syrup metoclopramide, and as a result, the remaining manufacturers of the syrup metoclopramide were all ANDA holders. Subsequently, in 2006, the FDA unilaterally designated Morton Grove as the Reference Listed Drug ("RLD"), turning Morton Grove's product into the reference source for future applicants for establishing bioequivalence. The purpose of this designation is so that subsequent ANDA applicants can provide information to the agency demonstrating bioequivalence to the approved product and that its label reflects the most current version approved by the FDA. See 21 C.F.R. §§ 314.94(a)(3), a(7)-(8).

Now, defendant Morton Grove contends that as a generic manufacturer, all claims against it should be dismissed as preempted under Mensing because it does not have any responsibilities beyond that of any other ANDA holder. But plaintiffs are seeking to impose responsibilities on Morton Grove by arguing that as an RLD, it has stepped into the shoes of an NDA holder and has become, in fact, the brand-name manufacturer. Plaintiffs, relying on policy arguments, assert that finding for the defendants would render the RLD regulations and the FDA warning scheme a nullity, because no manufacturers would then ever be able to change a label independently once the name-brand pioneer leaves the market. However as the defendants point out, under the current regulations, the FDA will take full responsibility for labeling changes in such circumstances if necessary—not the ANDA holder whose product was unilaterally designated as the RLD. See FDA Notice, Determination that Brethine (Terbutaline Sulfate) Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 72 Fed. Reg. 39629, 39630 (July 19, 2007); see also FDA Notice, Determination that OPANA ER (Oxymorphone Hydrochloride)

Extended-Release Tablets, 7.5 Milligrams and 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 76 Fed. Reg. 53908, 53909 (Aug. 30 2011); FDA Notice, Determination that TALWIN COMPOUND (Aspirin; Pentazocine Hydrochloride) Tablets, 325 Milligrams; Equivalent to 12.5 Milligram Base, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 76 Fed. Reg. 53,907, 53908 (Aug. 30, 2011); FDA Notice, Determination that PENTETATE CALCIUM TRISODIUM (Trisodium Calcium Diethylenetriaminepentaacetate) Solution for Intravenous or Inhalation Administration, Equivalent to 1 Gram Base/5 Milliliters (Equivalent to 200 Milligrams Base/Milliliter), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 76 Fed. Reg. 51,991, 51,992 (Aug. 19, 2011); FDA Notice, Determination That INVERSINE (Mecamylamine Hydrochloride) Tablet and Six Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 76 Fed. Reg. 45,267, 45,267 (July 28, 2011); FDA Notice, Determination That NUVIGIL (Armodafinil) Tablets, 100 Milligrams and 200 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 76 Fed. Reg. 44,012, 44013 (July 22, 2011).

Having read all the papers and having considered all the arguments put forth, it is clear that this is an unsettled and novel area of the law. Following review of the FDA regulations cited above, this court does not find any support for plaintiffs' contention that once an ANDA holder is designated by the FDA as an RLD, it can simply take advantage of the CBE process to strengthen its label independently. Plaintiffs fail to cite to any case, statute, or regulation that supports the argument that the product labeling can be unilaterally altered without FDA's prior approval simply because the generic manufacturer has been designated as an RLD. It is very difficult to conclude that the FDA's unilateral designation is sufficient to automatically transform Morton Grove, an ANDA holder, into an NDA holder. In fact, the FDA regulations are clear in putting the agency in charge when no NDA holder is in the market. In the absence of a brand

RLD product in the market, the FDA has explicitly stated that when an NDA, designated as the RLD is discontinued for reasons other than safety or effectiveness, the "[a]pproved ANDAs that refer to the NDAs . . . are unaffected by the discontinued marketing of the products subject to those NDAs . . . . If FDA determines that labeling for these drug products should be revised to meet current standard, ***the agency*** will advise ANDA applicants to submit such labeling." See FDA Notice, Determination that MOTRIN (Ibuprofen) Tablets and Four Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 75 Fed. Reg. 48,352, 48,353 (Aug. 10, 2010) (emphasis added).

At this point in time, this court refrains from imposing additional obligations over and above what the regulations have indicated. The court concludes that Mensing's preemptive impact on plaintiffs' claims against Morton Grove is not diminished by the fact that Morton Grove has been designated as an RLD, because this designation does not turn it into a brand-name manufacturer. The court does not find sufficient authority to find that a unilateral RLD designation by the FDA converts an ANDA holder into an NDA holder. Accordingly, defendants' motion to dismiss all counts against Morton Grove and Wockhardt USA is hereby GRANTED.

CAROL E. HIGBEE, P.J.Cv.