

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF KENTUCKY  
NORTHERN DIVISION  
ASHLAND

Civil Action No. 16-57-HRW

BONNIE DARBRO  
and  
JERRY GIBSON,

PLAINTIFFS,

v.

MEMORANDUM OPINION AND ORDER

BOEHRINGER INGELHEIM  
PHARMACEUTICALS, INC.,  
BOEHRINGER INGELHEIM GMBH & CO.,  
BOEHRINGER INGELHEIM INTERNAT'L GMBH,  
and  
ELI LILLY & COMPANY,

DEFENDANTS.

This matter is before the Defendants' Motions to Dismiss [Docket Nos. 20 and 21]. The motions have been fully briefed by the parties [Docket Nos. 20-1, 28, 29, 30 and 31]. For the reasons stated herein, the Court finds that dismissal would not be appropriate at this time.

I.

This case arises out of Plaintiff Bonnie Darbro's alleged development of diabetic ketoacidosis ("DKA") shortly after she began taking Jardiance. Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") holds the New Drug Application ("NDA") for Jardiance, and BIPI and Eli Lilly and Company ("Lilly") co-market and distribute the product.

In their Complaint, Plaintiffs state that Plaintiff Bonnie Darbro was prescribed Jardiance to treat her diabetes by her physician [Complaint, Docket No. 1, ¶ 32]. Jardiance (*empagliflozin*) was approved by the FDA in August 2014 as a safe and effective for the treatment of Type 2

diabetes. *Id.* ¶ 21. Plaintiffs allege that Ms. Darbro began treatment with Jardiance “in or about October 14, 2014, primarily to treat diabetes.” *Id.* ¶ 32. Approximately 10 days after beginning treatment with Jardiance, Plaintiffs allege that Ms. Darbro developed and was diagnosed with DKA “resulting in admission to the intensive care unit.” *Id.* ¶ 37. In addition to developing DKA, Plaintiffs allege that Ms. Darbro experienced “severe and permanent physical and emotional injuries . . . pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future” and “other related health complications.” *Id.* ¶¶ 45, 66.

Based on these allegations, Plaintiffs filed this civil action, seeking “actual compensatory, and punitive damages from Defendants and asserting thirteen causes of action: (Count I) Products Liability – Design Defect (Strict Liability); (Count II) Products Liability – Failure to Warn (Strict Liability); (Count III) Willful and Wanton Conduct or Gross Negligence; (Count IV) Negligence; (Count V) Breach of Express Warranty; (Count VI) Breach of Implied Warranty; (Count VII) Fraudulent Misrepresentation; (Count VIII) Negligent Misrepresentation; (Count IX) Negligent Design; (Count X) Fraudulent Concealment; (Count XI) Fraud; (Count XII) Violation of the Kentucky Consumer Protection Act (“KCPA”); and (Count XIII) Loss of Consortium on behalf of Plaintiff Jerry Gibson. Plaintiffs assert each of these thirteen claims against all named Defendants based on their alleged role in the design, manufacture, marketing, advertisement, licensing, distribution, and sale of Jardiance. *Id.* ¶¶ 1, 5.

Defendants seek dismissal of all claims asserted herein, arguing that the Complaint pleads insufficient facts and recites conclusory allegations, thereby failing to meet threshold federal pleadings requirements, and it asserts several claims not recognized under Kentucky law.

Defendant Lilly also argues that all claims asserted against are preempted and, as such, fails to state a claim upon which relief can be granted.

## II.

The purpose of a motion to dismiss is to allow a defendant to test whether, as a matter of law, the plaintiff is entitled to legal relief. *See, Mayer v. Mylod*, 988 F.2d 635, 638 (6<sup>th</sup> Cir. 1993). In scrutinizing a complaint under Rule 12(b)(6), the Court is required to “accept all well-pleaded factual allegations of the complaint as true and construe the complaint in the light most favorable to the plaintiff.” *Dubay v. Wells*, 506 F.3d 422, 426 (6th Cir.2007). A complaint need not contain “detailed factual allegations”. However, it must allege more than “a formulaic recitation of the elements of a cause of action.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). A complaint will withstand a motion to dismiss if it “contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009). A complaint has “facial plausibility” if the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603, 609 (6th Cir.2009) (*quoting Iqbal*, 129 S.Ct. at 1949).

## III.

Defendants’ arguments urging dismissal elevate form over substance. Defendants implore this Court to engage in a word by word dissection of the Complaint, suggesting, in effect, that the trees should obscure the forest. The Court disagrees. At the very least, the sequence of events alleged by Plaintiffs, to-wit, that Ms. Darbro was prescribed a medication designed and distributed by the Defendants and a mere 10 days after after she began taking the drug, she

developed a serious illness, requiring hospitalization, present a plausible scenario of negligence and perhaps other wrongdoing. Without the benefit of discovery, indeed the first interrogatory has yet to be served, the first deposition yet to be noticed, there is not much more to discern. Such is the point of discovery, is it not? Defendants' argument that Plaintiffs' case is lost is woefully premature.

The Court finds that Plaintiffs have plead sufficient facts upon which one could draw a reasonable inference that the Defendants are liable for the misconduct alleged, thereby passing *Iqbal* muster.

This is not to say that Plaintiffs will ultimately prevail. However, if Plaintiffs' claims are to fail before a trial, they will fail upon summary judgment, not at this early juncture of the case.

#### IV.

Accordingly, **IT IS HEREBY ORDERED** that Defendants' Motions to Dismiss [Docket Nos. 20 and 21] be **OVERRULED**.

This 31<sup>st</sup> day of March, 2017.



Signed By:  
Henry R. Wilholt, Jr.  
United States District Judge