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**IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF ILLINOIS
SPRINGFIELD DIVISION**

ROBBY MOHR, Individually and as Administrator of Estate of Jolee Mohr,	)	
Plaintiff,	)	NO. 09-3170
vs.	)	
TARGETED GENETICS, INC., ABBOTT LABORATORIES, INC., and WESTERN INSTITUTIONAL REVIEW BOARD, INC.,	)	
Defendants.	)	

OPINION

RICHARD MILLS, U.S. District Judge:

This case is before the Court on the Plaintiff's motion to remand, Defendant Abbott Laboratories, Inc.'s motion to dismiss, and Defendant Western Institutional Review Board, Inc.'s motion to dismiss and, in the alternative, motion to strike.

I. FACTUAL BACKGROUND

The Plaintiff's complaint alleges claims for personal injury and wrongful death stemming from Jolee Mohr's participation in a clinical trial

for an investigational gene therapy for rheumatoid arthritis. Mohr, who was 36, died on July 24, 2007. According to the complaint, Defendant Targeted Genetics, Inc. designed and manufactured the gene therapy at issue, tgAAC94, and Defendant Western Institutional Review Board, Inc. ("WIRB") supervised the clinical trial and designed its protocol. In February 2007, Mohr's treating physician, Dr. Robert Trapp, informed her that he considered her to be a good candidate for a clinical trial utilizing gene therapy sponsored by Targeted Genetics titled, "A Phase ½ Study of Repeat Intra-Articular Administration of tgAAC94, a Recombinant Adeno-Associated Vector Containing the TNFR:Fc Fusion Gene, in Inflammatory Arthritis Subjects with and without Concurrent TNF-alpha Antagonists" ("the experiment").

At some point, Mohr was prescribed Humira, a TNF inhibitor manufactured by Abbott. Abbott states that this drug is an FDA-approved prescription medication for the treatment of rheumatoid arthritis. Moreover, Abbott neither contributed to the design or manufacture of tgAAC94 nor participated in any way in the clinical trial that is the focus of

the complaint. Abbott claims that its sole connection to the events recited in the complaint arises from Mohr's use of Humira.

The Plaintiff alleges that the experiment involved gene transfer in which subjects were injected with millions of particles of tgAAC94, which contained an Enbrel gene. Enbrel is also a TNF inhibitor. The Plaintiff claims that it is well-known that patients treating with TNF inhibitors, such as Humira, should not be placed on any other TNF inhibitor as such combinations can cause serious adverse reactions, including death. Targeted Genetics contracted with WIRB to serve as the federally required institutional review board. Those Defendants designated and approved Dr. Trapp to serve as Principal Investigator for the experiment conducted at his site, "The Arthritis Center." The Protocol which governed the experiment was designed and approved by WIRB and Targeted Genetics.

On February 26, 2007, Mohr received her first injection. The Plaintiff states that it was not known whether she received the virus vector or placebo. Mohr suffered no ill effects from this injection, nor did she discern any benefit. On July 2, 2007, Dr. Trapp injected the virus vector directly

into Mohr's joint. Immediately thereafter, Mohr began to experience nausea and pain; by the next afternoon she started vomiting and her temperature rose to 101 degrees. By July 7, 2007, Mohr's temperature reached 104 degrees and she was admitted to the emergency room. Her condition quickly deteriorated. By July 9, physicians at St. John's hospital in Springfield noted that she had an elevated liver enzyme and white blood count. By July 18, Mohr was suffering from liver and kidney failure, loss of blood and sepsis. She was transferred to the University of Chicago Hospital as a potential liver and kidney transplant.

Mohr died on July 24, 2007. According to the Plaintiff, the cause of death was a direct and proximate result of her participation in the experiment or as a result of the experimental drug combined with intake of Humira. Specifically, Mohr suffered from histoplasmosis, a potentially deadly fungal infection and known adverse reaction to TNF blockers, such as Humira.

The Plaintiff further alleges that, on September 4, 2008, in response to a number of deaths involving histoplasmosis in patients treating with

TNF blockers, the FDA ordered Abbott to incorporate stronger warnings into Humira's label, in addition to the mandated black box warning regarding infection risk already in place, advising of the risk of fungal infections and histoplasmosis in particular.

Abbott contends that, in contrast to the factual allegations levied against Targeted Genetics and WIRB, the Plaintiff's "bare-bones allegations" asserted against it constitute nothing more than "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," which are not enough to sustain a claim under Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949-50 (2009). Thus, Abbott alleges that the claims asserted against it must be dismissed for failure to state a claim under Rule 12(b)(6).

Abbott further asserts that, to the extent that the Plaintiff's conclusory claims against Abbott are premised on injuries allegedly resulting from the combined use of Humira and the investigational gene therapy, such claims are subject to dismissal under the "learned intermediary" doctrine. Specifically, "manufacturers of prescription drugs have a duty to warn

prescribing physicians of the drugs' known dangerous propensities, and the physicians, in turn, using their medical judgment, have a duty to convey the warnings to their patients." Kennedy v. Medtronic, Inc., 366 Ill. App.3d 298, 305 (1st Dist. 2006). The Plaintiff contends that the learned intermediary doctrine does not apply because Abbott did not warn physicians of the precise risk.

II. ANALYSIS

(A)

Abbott first alleges that Plaintiff has asserted nothing more than conclusory statements against it. Specifically, the connection between Abbott and the events recited in the complaint arises from Mohr's concomitant use of Humira with the investigational gene therapy treatment during the clinical trial. Abbott further contends it is significant that the Plaintiff does not and cannot allege that Abbot approved of or participated in any way in the decision to design the clinical trial to include participants concomitantly using both tgAAC94 and another immunosuppressive TNF inhibitor, such as Humira.

Two counts are asserted against Abbott: strict liability and wrongful death. In citing paragraph 54 of the complaint, Abbott contends that Plaintiff has merely recited the proverbial "laundry list" of elements of a product-liability claim. Abbott alleges that these "bald assertions of wrongful conduct" are insufficient to pass muster under the Iqbal pleading standard. According to Abbott, the allegations amount to nothing more than "naked assertions devoid of further factual enhancement." See Iqbal, 129 S. Ct. at 1949. Because the Plaintiff has pleaded only an "unadorned, the-defendant-unlawfully-harmed-me accusation," Abbott alleges that the claims asserted against it should be dismissed.

In response, the Plaintiff alleges that the basic factual claims asserted in the complaint against Abbott are as follows:

a. For seven years preceding her death, Ms. Mohr was treated for rheumatoid arthritis which was under control with various established treatments and drugs.

b. Ms. Mohr was treating with Humira for a period of time preceding her death as prescribed by her treating physician.

c. Ms. Mohr's treating physician recommended that she enroll in the experiment involving a genetically modified virus containing a TNF inhibitor.

d. Patients on TNF inhibitors such as Humira should not be placed on other TNF inhibitors.

e. On July 2, 2007, after receiving her second course of the experimental drug, Ms. Mohr experienced acute adverse symptoms consistent with the known adverse effects of TNF blockers, which escalated at an alarming rate until her death on July 24, 2007.

The Plaintiff contends that these factual allegations provide support for a finding that Mohr's untimely death was either caused by Humira, the experimental drug, or a combination of the two. The Plaintiff further asserts that, when these facts are taken as true under the first part of the Iqbal analysis, they provide sufficient factual matter to support a determination that the complaint establishes plausible claims for products liability and wrongful death against Abbott pursuant to the second prong.

The Court has reviewed the complaint's allegations which are directed

against Abbott and agrees that they do not meet the Iqbal standard. The complaint includes little more than the "magic words" which are typically used to support a product liability claim. As Abbott notes, moreover, the Plaintiff has alleged no specific facts which establish tortious conduct on its part. Having concluded that dismissal is appropriate on this basis, the Court declines to address Abbott's alternative argument.

Based on the foregoing, the Court will Allow Abbott's motion to dismiss. However, the Plaintiff will be given leave to file an amended complaint.

(B)

WIRB moves to dismiss Counts I and II of the Plaintiff's complaint pursuant to Rule 10(b) of the Federal Rules of Civil Procedure and Section 2-622 of the Illinois Code of Civil Procedure, 735 ILCS 5/2-622 and, in the alternative, moves pursuant to Rule 12(f) to strike certain allegations in Count II.

Counts I and II are directed against WIRB and Targeted Genetics. Count I is a Survival Act claim for negligence in the manner in which the

Defendants conducted a clinical research study that allegedly caused Jolee Mohr to sustain injuries which ultimately led to her death. Count II is based on the same operative facts as Count I but asserts a Wrongful Death Act claim. WIRB contends that Counts I and II should be dismissed because the Plaintiff improperly asserts multiple claims against multiple Defendants in the same counts.

WIRB states that in paragraph 42 of Count I of the complaint (that is also incorporated in Count II), the Plaintiff purports to assert claims against Targeted Genetics and WIRB for medical malpractice (¶ 42 e-g, I-k), lack of informed consent (¶ 42c, l, o), negligence in the manner in which the clinical research study was designed, implemented and performed (¶ 42 a-b, d, h, m-n), and negligence per se (¶ 42p). The Plaintiff also purports to allege a separate claim against Targeted Genetics and WIRB for willful and wanton misconduct. (¶ 43).

WIRB notes that Plaintiff has not alleged any basis upon which joint and several liability would be applicable in this case. There are no allegations which would attribute the acts of Targeted Genetics to WIRB (or

vice versa) based upon a contractual agreement, respondeat superior, or similar relationship. Moreover, the Defendants have different and distinct duties with respect to the Plaintiff.

Although the complaint may not be in total compliance with Rule 10(b), the Court is unable to conclude that dismissal would be an appropriate sanction for such a violation. As the Plaintiff asserts, WIRB does not allege that it is difficult to determine what claims are being asserted against which Defendant or that the complaint is so vague and ambiguous as to preclude a reasonable response. Thus, it does not appear that WIRB has been prejudiced in any significant manner. Accordingly, its motion to dismiss Counts I and II based on the Plaintiff's technical violation of Rule 10(b) will be Denied.

WIRB also asserts that Counts I and II should be dismissed because those counts include claims against WIRB for medical negligence, though the Plaintiff did not include the requisite affidavit or report from a healthcare professional pursuant to 735 ILCS 5/2-622. The Defendant contends that, although the complaint is not labeled as such, there can be

no dispute that Plaintiff has purported to assert claims for medical negligence against WIRB. In particular, WIRB points to paragraph 42 of the complaint (which is also incorporated in Count II). Paragraph 42 appears to include allegations which could be described as claims for medical negligence.

In response, the Plaintiff states that Section 2-622 applies only to "healing art malpractice," which does not encompass institutional review boards such as WIRB. The Plaintiff claims not to allege that WIRB provided medical care to Mohr. Although the counts (particularly certain language in Paragraph 42) appear to include allegations that could be described as the provision of medical care by the Defendants, the Court at this stage of the litigation will credit the Plaintiff's statement that it is not making such an allegation. Accordingly, the motion to dismiss for failure to comply with the Illinois Healing Arts Malpractice Act will be Denied.

WIRB also moves to strike the reference to the term "heirs-at-law" from paragraph 50 of Count II of the Plaintiff's complaint. The Court will Allow the motion, but permit the Plaintiff to file an amended complaint and

omit the reference to "heirs-at-law" and include instead the term "surviving spouse."

(C)

The Plaintiff has moved, pursuant to 28 U.S.C. § 1447, to remand this action to the Circuit Court of the Fourth Judicial District in Christian County, Illinois. In its notice of removal, Abbott alleges that there is diversity of citizenship and the amount in controversy exceeds $75,000. Alternatively, Abbott asserts that the complaint raises a federal question.

The Plaintiff disputes that there is diversity of citizenship based on the inclusion of Abbott, a domestic defendant and "indispensable party" according to the Plaintiff. The Plaintiff also disputes Abbott's contention that there are federal claims.

Because the Plaintiff presumably will be filing an amended complaint, the Court will defer ruling on the Plaintiff's pending motion to remand until after the first amended complaint is filed. Following the filing of an amended complaint, the parties may request leave to file supplements to their previous filings pertaining to remand.

Ergo, the motion to dismiss filed by Defendant Abbott Laboratories, Inc. [d/e 13] is ALLOWED. However, the Plaintiff will be granted leave to file an amended complaint. Any amended complaint shall be due within thirty days.

The motion to dismiss and, in the alternative, motion to strike filed by Defendant Western Institutional Review Board, Inc. [d/e 11] is ALLOWED IN PART and DENIED IN PART. The motion to strike is ALLOWED as to the term "heirs-at-law" in paragraph 50 of Count II of the complaint. The Plaintiff may remedy this error in its amended complaint. The motion to dismiss is DENIED in all other respects.

The Court hereby DEFERS ruling on the Plaintiff's motion to remand [d/e 6], until after the Plaintiff has filed an amended complaint. The first amended complaint shall be filed within thirty days.

ENTER: November 18, 2009

FOR THE COURT:

s/Richard Mills
United States District Judge