

***Geralynn Boone v. Boehringer Ingelheim Pharmaceuticals, Inc., Et Al. (SC 20200)***

**Facts**

In 2003, the decedent began taking the anticoagulant Warfarin in order to treat a condition which causes blood clots. The use of Warfarin to treat this condition required monitoring (blood tests and dose titrations) to ensure that the concentration of medication was within an acceptable therapeutic level. In November 2010, the decedent was recommended by her doctor that she switch to the drug Pradaxa, which was manufactured and sold by the defendants. In October 2010, the defendants had received approval from the FDA to begin selling Pradaxa which was approved for use without blood monitoring or dose titration. The decedent took Pradaxa for some time without significant side effects.

On March 5, 2014 the decedent was admitted to the hospital with a gastrointestinal bleed. The decedent underwent kidney dialysis to remove the Pradaxa from her blood. However, the decedent's kidney failed and on March 25, 2014 she died. The plaintiff filed suit alleging: (1) the defendant negligently failed to give adequate warnings, directions, and instructions to guard against the risk of bleeding caused but Pradaxa, (2) the defendants negligently failed to test, study, and investigate the benefits of establishing a therapeutic range for Pradaxa, and (3) Pradaxa was defectively designed due to the absence of reversal agent. The trial court granted the defendant's motion for summary judgement on the plaintiff's third claim relating to the absence of a reversal agent, as it was preempted by federal law.

In a pretrial motion, the plaintiff asked the court to instruct the jury that the defendants past actions of losing or destroying relevant files constituted spoliation. The trial court granted the motion and provided such instructions to the jury. The jury returned a verdict finding the plaintiff had failed to prove that the defendant's wrongful conduct caused the decedent's death.

A judgement was subsequently rendered in favor of the defendant. The plaintiff appealed, arguing that the court improperly precluded certain evidence and arguments related to spoliation which consequently denied the jury the context which they needed in order to draw an adverse inference against the defendant.

In 2012 Pradaxa was involved in federal litigation in which sanctions were sought against them. In 2013, Judge Herndon issued a mandatory injunction requiring the defendants to present any undisclosed materials. The plaintiff then requested production of custodial files from the defendant's employee, Lehr. However, the documents had been destroyed by the defendants prior to the plaintiff requesting them. The court found that a reasonable person would have placed a litigation hold on Lehr's materials and the defendants had failed to do so in bad faith. The court then placed immediate sanctions on the defendants.

In 2018 the plaintiff requested a spoliation charge based on the defendants' failure to maintain the files at issue. The plaintiff requested that the jury be instructed of the spoliation which would allow them to draw an adverse inference. The trial court granted the plaintiff's request whereby the parties agreed to be bound by the discovery process which occurred in the federal litigation against the defendant. The plaintiff was, however, not permitted to reference the spoliation charges during opening statements or the evidentiary portion of the trial. At the close of the trial, the court instructed the jury of the spoliation charges, and that they were permitted to, but not required to, draw an adverse inference that the destroyed files would have been unfavorable to the defendants. The jury ultimately found in favor of the defendant. The plaintiff then filed a motion to set aside the verdict on the basis that the jury had been improperly instructed. The trial court determined that this claim was without merit.

## **Induced Error Doctrine**

The court first noted that the trial court has inherent discretionary powers and discretionary decisions will be overturned only when there has been clear abuse of the court's discretion. The court found that the trial court's application of the induced error doctrine was proper. The result of this doctrine is that, "a party who induces an error cannot be heard to later complain about that error." The court found that because the plaintiff themselves had requested that the trial court structure the proceedings as they did, they cannot now argue that the court, in doing so, acted inadequately. The courts may not, "allow a [party] to pursue one course of action at trial and later, on appeal, argue that a path [they] objected should now be open to [them]". The plaintiff was not forced to seek this specific structure for the proceedings and had other procedural options available to them. The trial court, therefore, did not abuse their discretion in their handling of the spoliation issue in the present case.

## **Noncontradictory Rebuttal**

The plaintiff additionally argued that the trial court had improperly excluded testimony. The plaintiff attempted to include the testimony as rebuttal to testimony of the defendants' witnesses. The appellate court found that the trial court correctly sustained the defendants' objection to the testimony because the testimony did not in any way refute the evidence already presented, but merely served to bolster the plaintiff's case.

## **Federal Preemption**

The plaintiff next claimed that the trial court improperly granted the defendant's motion for summary judgment, based on a preemption analysis, regarding their failure to develop a reversal agent, Praxbind, for Pradaxa. The defendant argued that because the FDA had not approved the defendant's Praxbind prior to the decedent's death, the plaintiff could not pursue a

claim based on its absence. The appellate court found that the trial court properly granted summary judgement because Praxbind was not approved until after the decedent's death, it would not have been possible for the defendants to satisfy their state law duty without marketing an unapproved drug, against federal law. The appellate court found that the trial court correctly granted summary judgement for this claim on preemption grounds.

### **Improper Jury Instruction**

The plaintiff next claimed that the trial court abused its discretion by instructing the jury that the jury could not find the defendants liable for the failing to conduct tests described in an exhibit. The trial court found, however, that the trial court had properly instructed the jury in this regard because the plaintiff had "improperly used the exhibit to advance a preempted failure to test claim in closing argument." The court had found that the evidence presented could not be used to prove that the defendants had acted negligently in failing to properly investigate in order to gain approval of the 110-milligram dose of Pradaxa. This was again because a claim based on said failure would be preempted by federal law. The trial court found that the plaintiff's argument suggested that the defendant could be held liable for failing to carry out the investigation and tests. The appellate court found that the trial court, in light of this, had acted properly in instructing the jury that the defendant could not be held liable for their failure to conduct the investigation and testing.

Lastly, the plaintiff claimed that the trial court had caused unfair prejudice against her because they had singled out her argument concerning the exhibit, suggesting to the jury that the plaintiff had done something wrong. The appellate court rejected this argument and ruled that the trial court had acted properly. The trial court's instructions were brief, contained no

reprimanding, and contained neutral language. Again, the appellate court found that the trial court did not abuse their discretion in this instruction to the jury.