

## Products Liability Law Daily Wrap Up, TOP STORY—MEDICAL DEVICES—S.D.W. Va.: \$1,175,000 punitive damage award against mesh implant maker survives constitutional challenges, (Jan. 21, 2015)

By Pamela C. Maloney, J.D.

A jury award of \$1,175,000 in punitive damages against the manufacturer of a synthetic mesh product used to treat pelvic organ prolapse was not excessive under the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution, a federal district court in West Virginia ruled in response to the manufacturer's request for remitter in the first case in this MDL to reach a jury verdict. The court also ruled that Georgia's punitive damages statute governing tort actions did not violate the Equal Protection Clause or the Takings Clause of the U.S. Constitution (*Cisson v. C.R. Bard, Inc.*, January 20, 2015, Goodwin, J.).

**Background.** The patient, Donna Cisson, had filed a products liability action against C.R. Bard, the manufacturer of the Avaulta Plus, a synthetic mesh product used to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI) in women. According to the complaint, which stated set forth both design defect and failure-to-warn claims, Cisson experienced severe complications, including pain, scarring, and inflammation after the mesh product was implanted to treat her POP. In 2011, Cisson had the device removed; however, the arms of the device could not be removed and she continues to suffer from pelvic pain and discomfort. Following a trial, the jury awarded Cisson \$250,000 in compensatory damages and \$1,175,000 in punitive damages. In response to Bard's motion for a directed verdict, the court found that the jury's verdict was supported by sufficient evidence. Bard then moved to remit the punitive damages from \$1,175,000 to \$250,000, arguing that the award was constitutionally excessive. Cisson filed an ancillary motion seeking a declaration that Georgia's statute governing punitive damages in tort actions, Ga. Code Ann. §51-12-5.1, was unconstitutional in that it required her to pay 75 percent of her punitive damages award to the state.

**Companion decision.** In addition to rejecting both these motions, the court, in a separate opinion, denied Bard's motion for a new trial on the grounds the district court erred by excluding evidence of Bard's compliance with the Federal Drug Administration's 510(k) process, admitting the Material Safety Data Sheet (MSDS) into evidence, and allowing Cisson to assert that the manufacturer should have performed pre-market human clinical testing without the support of competent expert testimony. Bard also asserted that the court's causation ruling was unfair. For complete details on this companion ruling, please see the summary entitled "\$2 million jury verdict survives challenge by mesh implant manufacturer" in today's issue.

**Excessiveness of punitive damages.** The Due Process Clause of the U.S. Constitution prohibits the imposition of grossly excessive or arbitrary punishments on a tortfeasor. The U.S. Supreme Court has identified three "guideposts" for courts to use in determining whether an award is grossly excessive: (1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases.

Based on the evidence presented, the West Virginia court concluded that the punitive damages award in this case passed constitutional muster under all three guideposts. Specifically, with regard to the first guidepost, the court found that Bard's conduct was reprehensible because the company had a longstanding and continuous habit of refusing to modify its tortious conduct, had continued to use resin in its mesh products despite its knowledge of its risk, and had deceived its suppliers as to the intended use for their resin.

As for the second guidepost, the court found that the ratio between the compensatory award and the punitive damages award, which was seven times greater, did not exceed the acceptable single-digit ratio set by the U.S. Supreme Court, and reflected the jury's assessment of Bard's reprehensible conduct.

Finally, there was no comparable civil penalty available against which to compare the punitive damages award. The court rejected Bard's argument that the court should compare the award against the civil penalties available for violations of Safe Medical Devices Act of 1990. Pursuant to that Act, a medical device manufacturer was subject to a maximum civil penalty of \$1,000,000 for failing to comply with federal requirements concerning risk evaluation and mitigation, safety label, and clinical trial. According to the court, the Act does not take into

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account the consequences of any one violation nor does it address duty, causation, or injury. Thus it was not a comparable civil penalty for purposes of applying the third guidepost.

Having rejected Bard's contention that the amount of the award was unconstitutionally excessive, the court evaluated Bard's remaining arguments in support of remittitur and found them unpersuasive. The punitive damages award was not duplicative of the compensatory award nor was it without purpose in light of the reprehensibility of Bard's conduct; the extent, duration, and likelihood of recurrence of Bard's wrongdoing; and Bard's intent in committing the wrong.

**Constitutionality of punitive damages statute.** In step with Bard's constitutional challenge, the patient raised the argument that Georgia's statute governing punitive damages in tort actions violated the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution. Specifically, the patient argued that the statute unconstitutionally distinguishes between products liability plaintiffs who are allowed to retain only 25 percent of any punitive damages award, and other tort plaintiffs who are allowed to retain 100 percent of a punitive damages award. The patient also claimed that the Georgia statute violated the Takings Clause of the Fifth Amendment to the U.S. Constitution.

*Equal protection challenge.* In considering the constitutionality of the punitive damages statute, the Supreme Court of Georgia had determined that the statute furthered the legitimate state interest of deterring conduct that had the potential of harming all citizens, not just the plaintiff, and of compensating the citizenry, as well as the plaintiff, for having to bear the potential risk. This holding had been reaffirmed by the court in two subsequent cases. Because the federal district court was bound to interpret the purpose of the statute as stated by the state's high court and must "generally accord the legislation a 'strong presumption of validity' by applying a rational basis standard of review, the West Virginia court concluded that there was a rational basis for allocating the punitive damages award between the citizenry and the patient. Thus, there was no equal protection violation and the patient's ancillary motion was denied on this point.

*Takings Clause challenge.* The court also found no basis for determining that the statute violated the Takings Clause because punitive damages did not qualify as property for purpose of the clause. Punitive damages were, by their very nature, contingent and discretionary; they were not awarded as a matter of right. Therefore, the patient had no cognizable property right under the Takings Clause.

The case is Civil Action No. 2:11-cv-00195.

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Companies: C.R. Bard, Inc.

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