

## Product Liability - USA

### New Jersey punitive damages analysis ignores established precedent

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#### **New Jersey's punitive damages law Courts' recognition of manufacturers' immunity from punitive damages Evasion of established New Jersey law Comment**

Since 2008 New Jersey law has effectively granted pharmaceutical manufacturers immunity from punitive damages claims. While New Jersey state courts continue to recognise and enforce that immunity, some recent federal court rulings have refused to follow New Jersey law, creating unnecessary inconsistency and uncertainty with respect to how the state's punitive damages law should be applied.

#### **New Jersey's punitive damages law**

Under New Jersey statute, punitive damages may not be awarded against a prescription drug or medical device manufacturer if the product that caused the plaintiff's harm received pre-market approval by the Food and Drug Administration (FDA).(1) The statute provides an exception where the manufacturer knowingly withheld or misrepresented information required to be submitted under FDA regulations.(2) However, in *McDarby v Merck & Co, Inc* a New Jersey appellate court held that the exception was preempted by federal law because "policing fraud on the FDA through a tort action could interfere with how the FDA might wish to police that kind of fraud itself".(3) Therefore, *McDarby* combines with New Jersey statute essentially to create complete immunity for manufacturers of FDA-approved drugs.

The principle of '*dépeçage*' (where different issues within a case may be governed by the laws of different states) can extend this immunity to cases arising outside New Jersey. This legal structure allows courts to apply different states' laws to separate issues within a case. In numerous states, courts analysing failure-to-warn claims against pharmaceutical manufacturers based in New Jersey have held that even when such claims are subject to a different state's tort law, New Jersey law must be applied to the punitive damages claims. Courts reason that because punitive damages are intended to punish and deter specific conduct, the law of the state in which that conduct occurred should apply. The conduct at issue in punitive damages claims involves the manufacturer's decisions regarding labelling and warnings, which generally occur at corporate headquarters.

#### **Courts' recognition of manufacturers' immunity from punitive damages**

Since *McDarby* New Jersey state courts have upheld pharmaceutical manufacturers' immunity from punitive damages. For example, a 2011 New Jersey state court, practising *dépeçage*, applied Virginia product liability law and New Jersey punitive damages law to a case involving injuries to a Virginia resident. The court emphasised that New Jersey law must be applied to the plaintiff's punitive damages claim, because New Jersey was the state in which the conduct occurred that allegedly caused the plaintiff's injuries. Such conduct included the corporate decisions relating to the marketing, distributing and selling of the product at issue, as well as the manufacturer's interactions and correspondence with the FDA. The court explained that because the purpose of punitive damages is to punish conduct that causes injury, a court must apply the law of the forum in which that injury-causing conduct occurred.(4)

*Irby* cited cases from New Jersey, New York and North Carolina that had applied one state's laws to liability and New Jersey law to punitive damages, declaring that:

*"New Jersey law shall govern punitive damages because New Jersey has a more significant relationship as to that issue... If there was willful corporate misconduct on [Defendant's part] that occurred in New Jersey, then New Jersey should punish Defendant to prevent such conduct in the future."*

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Addressing the argument that manufacturers' immunity offended the intentions of New Jersey's punitive damages statute, the court stated: "*McDarby* was decided [in 2008] and is binding on this court. Unless and until the legislature enacts legislation overturning *McDarby*, this court remains bound by the case law."

Similarly, federal courts both in and outside New Jersey have reaffirmed the immunity granted by *McDarby*. The District of New Jersey dismissed a plaintiff's punitive damages claims against the manufacturer of heparin, citing *McDarby* and concluding: "It is undisputed that heparin is an FDA-approved drug product; thus, the Court finds that all claims for punitive damages stated in the second amended complaint are dismissed."<sup>(5)</sup>

In 2013 district courts in Florida and Oregon did the same. In its opinion applying New Jersey law, the District of Oregon declared that because *McDarby* "continues to be the highest court decision in New Jersey to address the viability of the exception to New Jersey's ban on punitive damages provided for in § 2A:58C-5(c)", the plaintiff could not bring a punitive damages claim against a New Jersey-based drug manufacturer.<sup>(6)</sup>

### **Evasion of established New Jersey law**

Despite this, certain jurisdictions have ignored *McDarby* to assess punitive damages against New Jersey-based defendants. These courts have undermined the New Jersey law on punitive damages in two ways:

- by applying other states' punitive damages laws to cases against New Jersey-based manufacturers; and
- by rejecting *McDarby*.

### **Evading manufacturers' immunity by applying other states' punitive damages laws**

In 2013 a federal district court in Missouri held that Missouri law should apply to punitive damages claims brought against a New Jersey-based pharmaceutical company.<sup>(7)</sup> Applying *dépeçage*, the *Prather* court found that under the most significant relationship test used in Missouri choice-of-law, the alleged "misconduct" occurred in Missouri – even though the court cited only the "conduct causing the injury", not the conduct that led to the claim for punitive damages.<sup>(8)</sup>

In California in 2012, a federal district court avoided applying New Jersey law by finding that that the state with the predominant interest in regulating a defendant's conduct was the state in which the plaintiff's injury occurred, rather than that in which the defendant company was located and where its alleged wrongdoing was committed.<sup>(9)</sup>

### **Rejection of *McDarby* preemption**

One outlying court has imposed punitive damages by applying New Jersey punitive damages law but refusing to acknowledge *McDarby* preemption. On two occasions Judge Spratt in the Eastern District of New York has declared that *McDarby* was wrongly decided and New Jersey's statutory exception was therefore not preempted by FDA regulations.<sup>(10)</sup> Although he correctly applied New Jersey law to the issue of punitive damages, Spratt cited *Wyeth v Levine* in reasoning that the presumption against preemption is equally applicable to punitive damages as to compensatory damages and therefore the *McDarby* rationale had been eroded.

This rejection of *McDarby* contradicted the preemptive effect of *Buckman* in a strained effort to levy punitive damages on pharmaceutical manufacturers. Contrarily, a Maryland federal district court, after conducting a lengthy preemption analysis, succinctly stated why the New Jersey punitive damages exception was preempted:

*"Simply put, Plaintiff's claim for punitive damages requires a state fact finder to determine what was required to be submitted to the FDA, whether it was submitted to the FDA and, whether the FDA would have made a different approval decision had it been provided with the correct or missing information. Plaintiff's claim thus requires a fact finder to make these types of determinations as a matter of state law even though federal law makes such determinations the exclusive province of the FDA. Accordingly, Plaintiff's claim for punitive damages poses an obstacle to the objectives and purpose of the [Food, Drug and Cosmetic Act (FDCA)], and is therefore preempted by the FDCA."<sup>(11)</sup>*

Juries should not be substituting their judgment for that of the FDA.

### **Comment**

New Jersey-based pharmaceutical manufacturers, whose allegedly wrongful acts occur within New Jersey's borders, are clearly entitled to near-complete immunity from punitive damages. Although foreign jurisdictions seeking to punish injuries to their states' residents have begun to find ways to impose punitive damages, state and federal courts in New Jersey insist that the protection provided by statute and the *McDarby* rule continues to apply. New Jersey manufacturers seeking that immunity should minimise or eliminate punitive damages liability by attacking punitive damages

claims early, invoking *dépeçage* (when applicable) and aggressively pursuing the protection that *McDarby* provides.

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#### Endnotes

- (1) NJ Stat Ann § 2A:58C-5(c).
- (2) *Id.*
- (3) 401 NJ Super. 10 (2008) (quoting *Buckman Co v Plaintiffs' Legal Comm*, 531 US 341, 347 (2001)).
- (4) *Irby v Novartis Pharms Corp*, 2011 NJ Super Unpub LEXIS 3188 (November 18 2011).
- (5) *Stanger v APP Pharms., LLC*, 2010 US Dist LEXIS 126876, at \*12 (DNJ November 30 2010).
- (6) *Stromenger v Novartis Pharms Corp*, 941 F Supp 2d 1288 (D Or 2013).
- (7) *Prather v Organon USA, Inc (In re Nuvaring® Prods Liab Litig)*, 4:08-MD-1964-RWS, 4:08-CV-00558-RWS, 2013 US Dist LEXIS 99734 (ED Mo July 12 2013).
- (8) *Id* at \*79-\*80.
- (9) *Hill v Novartis Pharms Corp*, 2012 US Dist LEXIS 38516 (ED Cal March 21 2012).
- (10) *Forman v Novartis Pharms Corp*, 793 F Supp 2d 598, 610 (EDNY 2011); *Davids v Novartis Pharm Corp*, 2013 US Dist LEXIS 147481, at \*4-\*5, \*23-\*25 (EDNY November 22 2013).
- (11) *Zimmerman v Novartis Pharms Corp*, 889 F Supp 2d 757, 776 (D Md 2012).

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