Bausch v. Stryker Corp.: A Major Victory for Plaintiffs in Medical Device Cases

by Joshua L. Weisberg

Imagine a friend calls your office with the following story: A medical device that was implanted into her body has since been recalled by the manufacturer because it is defective. As a result of the defect, the device broke while in her body and caused her great harm. Your friend has a strong product liability claim against the manufacturer of the device, right?

Disturbingly, since the United States Supreme Court's 2008 decision in *Riegel v. Medtronic, Inc.*,[1] the answer many plaintiffs have received is they have no claim whatsoever, as hundreds of these types of claims have been dismissed with prejudice at the pleadings stage.[2] This has left victims of some of the most dangerous medical devices without a remedy.

This issue was recently addressed by the United States Court of Appeals for the Seventh Circuit in *Bausch v. Stryker Corp.*[3] As explained below, the *Bausch* decision represents a major victory for plaintiffs in medical device cases and goes a long way towards protecting the rights of people harmed by defective medical devices.

The Types of Medical Devices at Issue

Under federal law, medical devices are regulated differently based on their intended purpose and the level of potential risk they pose to a patient's safety.[4] Class I medical devices are considered the least dangerous devices and are subject to the least federal oversight.[5] Examples include elastic bandages and examination gloves.[6] Class II medical devices receive slightly greater federal oversight, and examples include powered wheelchairs and surgical drapes.[7]

The devices that pose the greatest potential risk to a patient's safety are Class III medical devices.[8] These are defined as medical devices used "in supporting or sustaining human life," or "for a use which is of substantial importance in preventing impairment of human health," or which "presents a potential unreasonable risk of illness or injury . . . ."[9] Examples include replacement heart valves, pacemakers, and hip replacement systems, all of which are implanted into human bodies.[10] As such, class III medical devices are the most dangerous types of medical devices.

The FDA has two different procedures for regulating Class III medical devices. First, the FDA may clear a Class III medical device for commercial distribution if it determines the device is "substantially equivalent" to another device already on the market.[11] Alternatively, if a Class III medical device is not "substantially equivalent" to another device already on the market, the manufacturer must submit a premarket approval application to the FDA.[12]

The right of plaintiffs to bring product liability claims after they are harmed by a Class III medical device that has received premarket approval from the FDA is what is at issue. Premarket approval is a rigorous process under which the FDA closely examines a specific device to determine whether it provides a "reasonable assurance" of "safety and effectiveness."[13] Once a device has received premarket approval, federal law requires the device to be manufactured in compliance with the specific terms set forth in its premarket approval application.[14]

Riegel v. Medtronic, Inc.

In *Riegel*,[15] the United States Supreme Court held a plaintiff's product liability claims against the manufacturer of a Class III medical device that had received premarket approval from the FDA were expressly preempted by Section 360k of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act.[16] Section 360k provides in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement— (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[17]

According to the Court, the term "requirement" under the Act means a device specific requirement.[18] Medical devices approved through the premarket approval process are subject to the device specific requirements in their premarket approval applications.[19] Thus, §360k prevents a state from imposing any requirement on devices that have received premarket approval that is "different from or in addition to" the requirements imposed by federal law.[20]

The Court explained that Riegel's common law claims for negligence and strict liability sought to impose device specific requirements that went beyond

what federal law required.[21] Accordingly, these claims were expressly preempted. The Court reasoned that because the FDA had already carefully balanced the potential costs and benefits of allowing this device into the marketplace during the premarket approval process, allowing a jury to second guess the FDA's analysis and impose more stringent requirements on the device manufacturer would upset the federal regulatory scheme.[22] Finally, the Court stated that while the dissent finds it "'difficult to believe that Congress would, without comment, remove all means of judicial recourse' for consumers injured by FDA-approved devices . . . , as we have explained, this is exactly what a preemption clause for medical devices does by its terms."[23]

Bausch v. Stryker Corp.

After *Riegel*, most plaintiffs bringing product liability claims against manufacturers of medical devices that received premarket approval have had their claims dismissed with prejudice at the pleadings stage.[24] Such was the case in *Bausch v. Stryker Corp.*[25]

In *Bausch*, the plaintiff alleged an artificial hip replacement system called the Trident System was implanted into her right hip in 2007. The Trident System received premarket approval in 2003. However, Bausch alleged that after receiving premarket approval, the Trident System was manufactured out of compliance with the terms set forth in its premarket approval application and in violation of federal law.[26]

According to Bausch, six days before the Trident System was implanted into her body, the FDA informed the defendants that it was manufacturing these devices in violation of federal safety laws. Moreover, a component of Bausch's Trident System was recalled after it was implanted into her body. Bausch alleged the recalled component failed while in her body causing her harm including the need for a second surgery to have the device removed and replaced. She brought strict liability and negligence claims under Illinois law against the manufacturers of the Trident System.[27]

The defendants brought motions to dismiss Bausch's claims for failure to state a claim upon which relief can be granted, arguing her claims were preempted pursuant to *Riegel*. Bausch argued her claims were distinguishable from the plaintiff's claims in *Riegel* because her claims were solely based on defendants' alleged violations of federal law. Therefore she argued her claims were not preempted because they did not impose any requirement on the device that was "different from or in addition to" those required by federal law.[28]

The district court disagreed and granted the defendants' motions dismissing Bausch's complaint with prejudice and without leave to amend. The Court explained that pursuant to the

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Supreme Court's decision in *Riegel*, Bausch's claims were preempted as a matter of law because state common law negligence and strict liability claims "by their very nature" are different from and in addition to federal law.[29] The essence of the court's decision was that once a medical device receives premarket approval from the FDA, the manufacturer is immune from civil liability even if the device is manufactured in violation of federal law.

The Seventh Circuit's Decision

On December 23, 2010, a unanimous panel of Chief Judge Easterbook, Judge Hamilton, and Judge Manion, reversed the decision of the district court and held Bausch should be allowed to pursue her state law product liability claims. The strongly worded opinion authored by Judge Hamilton frames the issue as follows:

> The central issue in this appeal is whether federal law preempts product liability claims against manufacturers of Class III medical devices where a patient claims that she was harmed by the manufacturer's violation of federal law. That statement of the issue may be a little startling. The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive. Nevertheless, manufacturers in this case and in others have asserted this theory of defense. As we explain below, the manufacturer's theory tries to stretch the Supreme Court's decisions in this field beyond the boundaries that were made clear in those decisions. Medical device manufacturers who subject their Class III devices to the rigorous premarket approval process are protected by federal law from civil liability so long as they *comply* with federal law. That protection does not apply where the patient can prove that she was hurt by the manufacturer's *violation* of federal law.[30]

In support of its holding, the seventh circuit explained that in *Riegel*, the plaintiff's claims were not premised on defendant's violation of federal law, but rather common law tort duties that required the device at issue to be safer than what federal law required.[31] The seventh circuit also emphasized the Supreme Court's statement in *Riegel* that "§360k does not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements."[32]

The seventh circuit held that because Bausch's negligence and strict liability claims were premised on defendants' violation of FDA regulations, her claims were not preempted, and her complaint

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should not have been dismissed.[33] Moreover, the court held that Bausch's claims would survive preemption even if the defendants complied with the specific requirements in the premarket approval application but failed to comply with the general Quality System Regulations and Current Good Manufacturing Practices applicable to all medical devices.[34]

The court observed that defendants' proposed distinction between a manufacturer's failure to comply with product-specific requirements as opposed to general federal requirements made no sense and would "leave injured patients without any remedy for a wide range of harmful violations of federal law."[35] For instance, under the Quality System Regulations and Current Good Manufacturing Practices[36] adopted by the FDA, all manufacturers must "establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality."[37] Such a requirement is not device specific and will not appear in a defendant's premarket approval application, but if a manufacturer allows its medical device to become contaminated resulting in harm to a patient this is a violation of federal law for which state tort law should and does provide a remedy.

While the court's primary holding was on the preemption issue, the opinion also soundly rejected a number of alternative theories in support of dismissal which defendants have commonly raised in medical device cases. For instance, the defendants claimed that Bausch's complaint failed to plead sufficient facts about how her Trident System failed to comply with federal law in order to state a "plausible" claim under the new and stricter federal pleading standards established by the Supreme Court in *Ashcroft v. Iqbal*[38] and *Bell Atlantic Corp. v. Twombly*.[39]

The seventh circuit rejected this argument, noting that a defendant's premarket approval application is not a public record and it would be impossible for a plaintiff to plead with specificity how her medical device deviated from the requirements contained within the application before having a chance to obtain it in discovery.[40] According to the court, "If plaintiffs must allege that the defendant violated a particular FDA-approved specification before discovery, then it is difficult to appreciate how any plaintiff will ever be able to defeat a Rule 12(b)(6) motion."[41]

Indeed, prior to *Bausch*, many claims against medical device manufacturers had been dismissed for precisely this reason. Fortunately, the seventh circuit in *Bausch* recognized the principle that "a plaintiff's pleading burden should be commensurate with the amount of information available to them."[42]

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Applying *Bausch* to Your Case

Bausch protects the rights of plaintiffs within the seventh circuit's jurisdiction to bring claims for damages under state tort law where they have been harmed by a medical device that received premarket approval from the FDA but was manufactured out of compliance with federal law. Plaintiff's attorneys bringing such claims should explicitly state in the complaint that the claims are solely based on defendant's violations of federal law in order to nullify any argument that the claims are "different from or in addition to" federal requirements.

While proving a medical device was built in violation of federal law may at first blush seem like a difficult standard, the Quality System Regulations and Current Good Manufacturing Practices are very broad and proving a violation of these regulations should not be much harder than proving a violation of common law state tort duties. Moreover, where the medical device at issue has been recalled, it is highly likely you will be able to discover a violation of federal law, as a recall by definition means the medical device is considered by the FDA to be in violation of federal law.[43]

While *Bausch* allows manufacturing defect claims to survive preemption, it should be noted that many design defect and failure to warn claims will continue to be preempted. The FDA considers the design of a medical device during the premarket approval process, and an FDA approved design is immune from liability. Thus, design defect claims may proceed only if a manufacturer designs a device differently than the design approved by the FDA. Additionally, failure to warn claims are preempted unless the warning was specifically required (as opposed to merely permitted) by federal law.

Finally, *Bausch* significantly lowers the pleading standard in medical device cases in recognition of the principle that "a plaintiff's pleading burden should be commensurate with the amount of information available to them." However, before filing a complaint, you should attempt to obtain as much information as possible about the device at issue and how it was built in violation of federal law through your client's medical records and by scouring the FDA's website. That way if a defendant tries to claim you have not pleaded sufficient facts to state a "plausible claim," you can credibly tell the court that you have pleaded as specifically as possible based on the information available to you.

Conclusion

Bausch represents a major victory for plaintiffs in medical device cases. It protects the right of plaintiffs to bring claims for damages if they have been harmed by a medical device that received premarket approval from the FDA, and it lowers the pleading standard for surviving a motion to dismiss. As a result, many claims involving dangerous medical devices that cause harm

which district courts have routinely been dismissing since the Supreme Court's decision in *Riegel* will now be allowed to go forward.

Endnotes

[1] *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

[2] *See, e.g., In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation*, 592 F.Supp.2d 1147, 1152 (D. Minn. 2009)(dismissing class action arising out of allegedly defective leads attached to cardiac defibrillators); *Ilarraza v. Medtronic, Inc.*, 677 F.Supp.2d 582 (E.D.N.Y. 2009)(dismissing claims arising out of allegedly defective implanted medication pump); *Heisner v. Genzyme Corp.*, 2010 U.S. Dist. LEXIS 21339 (N.D. Ill. 2010)(dismissing claims arising out of allegedly defective Seprafilm barrier); *Parker v. Stryker Corp.*, 584 F.Supp.2d 1298, 1301 (D. Colo. 2008)(dismissing claims arising out of allegedly defective hip replacement system); *Lewkut v. Stryker Corp.*, 724 FSupp.2d 648 (S.D. Tex. 2010)(same); *Anthony v. Stryker Corp.*, 2010 U.S. Dist. LEXIS 31031 (N.D. Ohio Mar. 18, 2010)(same); *Lemelle v. Stryker Orthopaedics*, 698 F.Supp.2d 668 (W.D. La. 2010)(same).

[3] *Bausch v. Stryker Corp.*, 2010 U.S. App. LEXIS 26094 (7th Cir. 2010).

[4] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008).

[5] *Id.*

[6] *Id.*

[7] *Id.* at 316-17.

[8] *Id.* at 317.

[9] 21 U.S.C. § 360c(a)(1)(C) (2011)

[10] *Riegel*, 552 U.S. at 317.

[11] 21 U.S.C. § 360c(f) (2011).

[12] 21 U.S.C. § 360e (2011).

[13] *Id.*; *Riegel*, 552 U.S. at 317-20.

[14] 21 U.S.C. § 360e(d)(6)(A)(i) (2011).

[15] *Riegel v. Medtronic*, Inc., 552 U.S. 312, 316 (2008).

[16] 21 U.S.C. §§ 301-399a (2011)

[17] 21 U.S.C. § 360k (2011).

[18] *Id.* at 321-23.

[19] *Id.*

[20] *Id.*

[21] *Id.* at 323-25, 330.

[22] *Id.* at 324-24.

[23] *Id.* at 326.

[24] See Endnote 2 for examples of the many cases dismissing such claims.

[25] *Bausch v. Stryker Corp.*, 2008 U.S. Dist. LEXIS 99118 (N.D. Ill. 2008).

[26] *Id.*; *Bausch v. Stryker Corp.*, 2010 U.S. App. LEXIS 26094 (7th Cir. 2010).

[27] *Id.*

[28] *Bausch v. Stryker Corp.*, 2008 U.S. Dist. LEXIS 99118 (N.D. Ill. 2008).

[29] *Id.* at 17.

[30] *Bausch v. Stryker Corp.*, 2010 U.S. App. LEXIS 26094, *3-4 (7th Cir. 2010).

[31] *Id.* at 8-11.

[32] *Id.* at 11.

[33] *Id.* at 43.

[34] *Id.* at 19-24.

[35] *Id.* at 20-21.

[36] 21 C.F.R. § 820 (2011).

[37] 21 C.F.R. § 820.70(e) (2011).

[38] *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009).

[39] *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

[40] *Bausch v. Stryker Corp.*, 2010 U.S. App. LEXIS 26094, *35-38 (7th Cir. 2010).

[41] *Id.* at 38 (citations omitted).

[42] *Id.*

[43] 21 C.F.R. § 7.3(g) (2011): "Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure."

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