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Client Alert

Medical Device Lawsuit Watch - February 2008

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This summary of key lawsuits affecting medical devices is provided by the Health Care Law Group of Crowell & Moring LLP, in collaboration with the firm's Torts, Antitrust and Intellectual Property Law Groups.

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Southeast Missouri Hospital v. C.R. Bard, Inc.
No. 07-0031 TCM (E.D. Mo. 1/22/2008)

The United States District Court for the Eastern District of Missouri, interpreting the Supreme Court's decision in *Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1995 (2007) ("*Twombly*"), has denied C.R. Bard, Inc.'s ("Bard") motion to dismiss a class action complaint alleging that Bard conspired with Tyco International, Inc. ("Tyco") to preserve the two companies' market power in the urological catheter market. Tyco's motion to dismiss, however, was granted.

Plaintiff's first cause of action alleged that Bard and Tyco used their market power to enter into exclusive dealing agreements with group purchasing organizations ("GPOs") and integrated delivery networks ("IDNs") in violation of §1 of the Sherman Act. In considering Plaintiff's §1 claim, the district court applied *Twombly* and analyzed the complaint to determine whether Plaintiff's factual allegations raised "a suggestion of a preceding agreement,

not merely parallel conduct that could just as well be independent action." The district court first found that Plaintiff incorrectly treated the two companies as one competitor in order to aggregate their combined market share into "a more imposing figure", but had failed to establish that Bard and Tyco had an agreement to act as one.

The district court next determined whether Plaintiff adequately pled its claims against the companies as separate competitors. Plaintiff alleged Bard, with 75-90% of the urological catheter market, and Tyco, with a maximum market share of 20%, used their market power to enter into exclusive dealing and bundling arrangements in violation of §1 of the Sherman Act. Citing *Twombly*, The district court held that these allegations against Bard were sufficient to "nudge' [the] claim across the line from conceivable to plausible." The district court dismissed the claims against Tyco, however, because Tyco's alleged market share of 20% was too small to establish market power and Plaintiff could not "bootstrap its claims against Tyco by accumulating its market share" with Bard's.

Plaintiff's other claims, alleging violations of §2 of the Sherman Act, §3 of the Clayton Act, Missouri's antitrust law, and civil conspiracy, were similarly upheld as to Bard and dismissed as to Tyco.

Digene Corp. v. Third WaveTechnologies Inc.
No. 07-0022 (W.D. Wis. 1/11/08)

The Western District of Wisconsin recently granted summary judgment for Digene Corp. ("Digene"), rejecting the claims of Third Wave Technologies Inc. ("Third Wave") that Digene unlawfully used monopoly power to exclude Third Wave from the human papilloma virus ("HPV") testing market, via exclusive dealing and free equipment arrangements. Digene developed the first, and currently the only, FDA-approved commercial test for detecting certain types of high-risk human papilloma virus ("HPV") and captures over 95% of the sales in the HPV testing market. Third Wave sells raw materials and testing components that laboratories can use to create their own HPV tests. Third Wave's products do not require, and do not have, FDA approval.

Digene initially sued Third Wave for patent infringement; Third Wave counterclaimed with allegations that Digene used exclusive dealing contracts with long lock-in periods and cancellation penalties to exclude competitors from the market. On Digene's motion for summary judgment, the district court found that none of Digene's contracts prohibited customers from purchasing tests from other manufacturers, and that Third Wave had successfully and steadily increased its market share since coming into the market. In addition to competitive pressures imposed by Third Wave, the court also noted that Digene was further constrained from exercising monopoly power by the market power of its customers, and insurers and government programs who make reimbursements for diagnostic tests.

The court also dismissed Third Wave's claims that Digene's practice of providing customers with "free" equipment, which was necessary to perform Digene's tests, violated the Robinson-Patman Act. The court held that the price of the equipment was built into the unit price of the test kits, and Third Wave had therefore failed

to demonstrate that Digene engaged in predatory pricing. Additionally, Third Wave failed to establish that Digene was likely to recoup any losses resulting from the alleged predatory pricing, because it was not likely that Digene could maintain its monopoly long enough to do so.

Riegel v. Medtronic Inc.
No. 06-179 (S.C. 6/25/2007)

The U.S. Supreme Court will soon decide whether federal medical device law preempts state tort claims against manufacturers whose products pass the Food Drug and Administration's (FDA) pre-market approval (PMA) process. Under the Food Drug and Cosmetic Act, federal law bars the imposition of any state "requirements" that are "different from" or "in addition to" requirements established by FDA. The Supreme Court has previously held that this express preemption provision does not bar state law claims against makers of devices that have gone through FDA's 501(k) process, also known as "pre-market notification", because that process does not create device-specific federal requirements that trigger preemption. In *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996) the Supreme Court left unanswered the question of whether the PMA process—which is more rigorous that 510(k)—creates the kind of device-specific federal requirements that are needed to trigger preemption.

Petitioner Donna Riegel has argued that claims arising out of her husband's injuries caused by the bursting of a balloon catheter during angioplasty should be allowed to go forward, even though the Evergreen Balloon Catheter used in surgery received PMA approval. Petitioner argues that the express preemption language governing medical devices was intended to preempt state regulatory activity, not litigation. Medtronic has argued that although FDA does not mandate design specifications pursuant to the PMA process, it can direct a manufacturer to make changes or to consider something different. Moreover, Medtronic argues, it is the FDA, not a lay jury, that is the designated agency with expertise to balance reasonable effectiveness and safety with medical device availability.

The case was dismissed on preemption grounds in federal district court, and that decision was affirmed by a divided Court of Appeals for the Second Circuit. The Second Circuit decision aligns with those in the majority. The Supreme Court heard oral arguments in the case on December 4, 2007.

Acumed LLC v. Stryker Corp.

Case No. 04-CV-513 (D. Or.)

Acumed LLC began this litigation in April 2004 accusing Stryker Corporation, Stryker Sales Corporation, Stryker Orthopaedics, and Howmedica Osteonics Corporation (collectively "Defendants") of infringing the '444 patent with their T2 Proximal Humeral Nail (T2 PHN).

On September 20, 2005 a jury found that Defendants had willfully infringed the '444 patent. On February 22, 2006, the Court granted Acumed's motion for a permanent injunction and denied Defendants' motion for stay of injunctive relief pending appeal. Defendants' appealed the District Court's rulings to the Federal Circuit. On April 12, 2007 the Federal Circuit affirmed the finding of willful infringement but vacated the permanent injunction in light of the Supreme Court's intervening decision in *eBay Inc. v. MercExchange, LLC*, 126 S. Ct. 1837 (2006). Defendants' then appealed to the Supreme Court, which on November 13, 2007 denied Defendants' Petition for Certiorari.

Acumed's Motion for Permanent Injunction was granted by the District Court on November 20, 2007 and Defendants promptly filed a motion to stay the injunction pending yet another appeal to the Federal Circuit. Defendants' argued that they would be irreparably harmed if the permanent injunction was not stayed and that the public interest would best be served by the stay. With respect to the public interest, Defendants argued that their product was superior to Acumed's because it did not expose patients to the risks associated with screw back out. The motion to stay was denied on November 28.

In denying the motion to stay, the district court concluded that, contrary to Defendants' assertions, there was not sufficient objective evidence of any public-health issue with respect to Acumed's product to establish that the public interest would be served by staying the permanent injunction. In addition, the Court noted that Acumed established that it continues to lose sales and market share as a result of Defendants' sales and would be substantially harmed by a stay of the permanent injunction.

Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.
Case No. 03-0597 (D. Az.)

On December 11, 2007 a jury awarded Bard Peripheral Vascular, Inc. and Dr. David Goldfarb $185 million in damages. The jury found that W.L. Gore & Associates, Inc. willfully infringed U.S. Patent No. 6,436,135. The products found to infringe included W.L. Gore's standard grafts and stretch grafts, including grafts sold under the trade names Propaten, Intering, Acuseal, Viabahn, Excluder, Tag, and Viatorr. The jury also rejected Gore's allegations that the patent was invalid.

DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.
Case No. 01-10165-EFH (D. Mass.)

On December 11, 2007, a Federal District Judge in Massachusetts entered a final order against Medtronic in the amount of $226.3 million for infringement of U.S. Patent No. 5,207,678 (the "'678 patent"), relating to a pedicle screw for stabilization of spinal column segments. In doing so, the Court rejected Medtronic's ensnarement defense.

Based on the doctrine of ensnarement, Medtronic unsuccessfully argued that DePuy could not have patented a hypothetical claim covering the accused products because such a claim would have been anticipated or rendered obvious by the prior art. The Court rejected this argument.

Yanovich v. Zimmer Austin, Inc.
No. 07-3058 (6th Cir. 11/21/07)

The Court of Appeals for the Sixth Circuit upheld the district court's grant of summary judgment in favor of Zimmer Austin for a products liability manufacturing and defect claim concerning an artificial knee. Yanovich's lawsuit alleged that Zimmer Austin defectively designed and manufactured the Intermedics Natural Knee II ("NK II") System with defective patella button pegs, in violation of the Ohio Products Liability Act ("OPLA").

Yanovich sued Zimmer Austin, Inc ("Zimmer") after discovering that the pegs of her implanted patella button had fractured. In support of her products liability claim, Yanovich relied on one expert witness – a professor specialized in polymer engineering – who argued that Zimmer's choice of plastic and hardening occasionally resulted in insufficiently strong products and defective patellas. The Northern District of Ohio District Court granted Zimmer's motion for summary judgment, finding that Yanovich failed to introduce evidence to support a jury verdict in her favor.

On appeal, the Sixth Circuit affirmed the district court holding of summary judgment, reasoning that Yanovich introduced insufficient evidence that Zimmer's NKII system was defective and caused a tortious injury under OPLA. The Sixth Circuit determined that Yanovich's manufacturing defect claim failed because the expert witness failed to raise a genuine issue of material fact that the extracted patellas materially deviated from the sample patellas as required under OPLA. The Sixth Circuit also found that Yanovich's design defect claim failed because the expert witness failed to inquire about the foreseeable risks associated with the design or formulation of the patellas, and failed to examine the benefits associated with the design or formulation of the patellas under Ohio law.

Miller v. DePuy Spine Inc.
No. A551017 (District Court, Clark County, Nevada 11/14/07)
[Complaint]

Plaintiff filed suit in Nevada state court against defendants DePuy Spine, Inc. and Johnson & Johnson, Inc., alleging various tort theories related to alleged defects of an artificial intervertebral disc implant Plaintiff received. Plaintiff alleged defendants breached FDA requirements through the defective design and manufacture of the implant, which constituted negligence per se. Defendants contend that the FDA has exclusive or primary jurisdiction over the matters asserted in the complaint. Plaintiff sought general damages, special damages, and exemplary damages each in excess of $10,000, as well as reasonable attorney's fees.

Defendants removed the case to the U.S. District Court for the District of Nevada, asserting complete diversity among the parties and that the amount in controversy exceeds $75,000. Although Plaintiff did not specifically request damages in excess of $75,000, Defendants posited that because Plaintiff alleged a "progressively worsening" condition and "substantial pain, disability, and medical expense" that will require "more [i]nvasive medical treatment," the compensatory and special damages alone would more likely than not exceed $75,000.

Defendants further asserted that Plaintiff's claim for past and future loss of earnings should be sufficient to meet the jurisdictional amount in controversy, despite the fact that Plaintiff had not submitted any regarding his salary while he was employed, on the assumption that Plaintiff earned at least the median income in Clark County, Nevada.

Medical Supply Chain, Inc. v. Neoforma, Inc.
No. 06-3331 (10th Cir. 11/16/07)

Medical Supply Chain, Inc. filed a 115-page complaint in federal district court against a number of companies for an alleged conspiracy to shut out competition in the hospital supply market. The complaint alleged 16 causes of action, ranging from violations of the Sherman Act to prima facie tort.

Sifting through the claims, the district court issued an order on March 7, 2006 dismissing the case and explaining that "although plaintiff asserts many conspiracy theories, it does not allege any facts that support its allegations." Further, the court warned the plaintiff and the attorneys that neither the district court nor the Tenth Circuit would tolerate frivolous claims. On March 16, 2006, Medical Supply filed several motions, including a motion for reconsideration. Later in March, it filed several other unrelated motions. The district court entered a final judgment as to the March 7, 2006 order on August 4, 2006. On August 7, 2006, the district court denied Medical Supply's other motions and struck its motion for reconsideration.

On September 8, 2006, Medical Supply filed its notice of appeal to the Tenth Circuit, appealing the district court's denial of its motion for reconsideration. The Tenth Circuit held that the August 7, 2006 order striking

Medical Supply's motion for reconsideration disposed of that motion. Under Federal Rule of Appellate Procedure 4(a)(1)(A) a party must file a notice of appeal "within 30 days after the judgment or order appealed from is entered." Thus, Medical Supply filed its notice of appeal two days late, and the Tenth Circuit lacked jurisdiction to hear the case.

Fry v. Guidant Corp.
No. 3:03-0842 (M.D. Tenn. 11/30/2007)

The United States District Court for the Middle District of Tennessee granted relator Fry's motion to compel medical device manufacturer Guidant to produce documents sought by Fry in discovery requests that expanded the scope of the discovery in a False Claims Act *qui tam* action. The complaint alleged that Guidant engaged in a fraudulent scheme to conceal available refund credits from hospitals.

Fry's motion sought to expand the scope of discovery to ten years prior to the date the complaint was filed, to include discovery regarding replacement of recalled devices, to expand discovery nationwide, and to include the production of business and training documents relating to product recalls. Fry also sought discovery sanctions against Guidant.

The district court granted Fry's motion to compel Guidant to produce responsive documents, and denied Fry's request for sanctions. The court first ordered production of documents ten years prior to the filing of the complaint, disagreeing with Guidant that the ten-year statute of limitations only applied to cases in which the government intervened. Second, the court ordered discovery relating to devices replaced as a result of recalls, because the complaint made numerous references to such devices. Third, the court granted nationwide discovery on the grounds that the complaint asserted nationwide claims. Finally, the court ordered that Guidant produce general and training documents relating to product recalls. Fry's request for discovery sanctions was denied.

Klein v. DePuy
No. 07-1493 (7th Cir. 10/25/2007)

On October 25, 2007, the Seventh Circuit affirmed dismissal of a lawsuit filed by a patient with a hip implant, holding that his claims were barred by North Carolina's six-year statute of repose. Plaintiff, who underwent surgery in September 1998, filed suit in federal district court in Indiana against DePuy and Johnson & Johnson, alleging that a defective prosthesis caused him to develop osteolysis. Plaintiff's surgeon believed that the hylamer cup liner used in the hip replacement wore at a faster rate than predicted, causing debris to spread into the nearby femur area.

The district court dismissed the lawsuit, applying North Carolina's statute of repose rather than Indiana's 10-year statute of repose, over plaintiffs' objection. The North Carolina statute prohibits the commencement of an "action for the recovery of damages for personal injury . . . based upon or arising out of any alleged defect or any failure in relation to a product . . .more than six years after the date of initial purchase for use or consumption." On appeal, the Seventh Circuit affirmed, finding that the injury and physical harm occurred in North Carolina and that Indiana had few contacts in the case, although DePuy is headquartered there. Moreover, because Indiana did not have a general interest in the case, application of North Carolina's law would not offend the public policy of Indiana. The Seventh Circuit also rejected plaintiff's argument that the North Carolina Supreme Court would find an exception to the state's statute of repose in this case, concluding that the plain language and history of the statute indicates that the statute does not allow for exceptions.

Masimo Corp. v. Tyco Health Care Group, L.P.
C.D. Cal. (No. CV02-4770MRP 3/22/2006)

In 2002, Masimo Corporation filed suit against Tyco Health Care Group, L.P. and Mallinckrodt, Inc. (collectively, Tyco), for alleged anti-competitive business practices by Tyco in connection with its Nellcor pulse oximetry brand. Pulse oximetry products, the sales of which exceed $500 million in the United States, are used by hospitals to monitor blood oxygen levels of critically ill patients.

Masimo contended the Tyco shut it out of over 90% of the market for pulse oximetry sensors and patient cables in the United States. It argued that Tyco did so by engaging in a series of illegal exclusionary and anti-competitive acts designed to maintain its monopoly power, including entering into exclusive dealing contracts with purchasers, and in particular, Group Purchasing Organizations (GPOs), which negotiate contracts on behalf of their member hospitals.

After a four-week trial in 2005, the jury found that Tyco violated the antitrust laws by (1) providing market share discounts to hospitals, (2) entering into sole source contracts, (3) offering bundled rebates for its oximetry and other unrelated products, and (4) entering into co-marketing agreements with manufacturers. The jury found that Masimo was due $140 million in damages.

Tyco filed a motion for judgment as a matter or law and, in the alternative, a motion for a new trial. Considering that motion in March of 2006, the district court sustained the jury's liability verdict based on the market share discounts and sole source contracts, but vacated the jury's finding based on the other alleged anticompetitive practices. The district court also vacated the damages award as not "ly[ing] within the range sustainable by the proof." In June, 2007, the district court separately considered the issue of damages and reduced Masimo's total damages award to $14.5 million.

Tyco filed its notice of appeal to the Ninth Circuit shortly thereafter. The parties are currently briefing the issues on appeal.

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