Recent Medical Device Antitrust Cases

David A. Balto

I. Masimo Corp. v. Tyco Healthcare Group, L.P., No. 02-CV-4770 (C.D. Cal.)

In March 2005, after a four-week trial, a federal court jury found that Tyco Healthcare Group and Mallinckrodt, Inc. (collectively, Tyco) violated the antitrust laws through anticompetitive business practices related to the sale of Tyco's Nellcor pulse oximetry products. Masimo Corp. (Masimo), a manufacturer of pulse oximetry products, brought the action against Tyco alleging that it was foreclosed from the market for pulse oximetry systems due to Tyco's use of exclusive dealing arrangements and other anticompetitive agreements with hospital group purchasing organizations (GPOs), hospitals, Integrated Health Networks (IHNs) and original equipment manufacturers (OEMs) in violation of Sections 1 and 2 of the Sherman Antitrust Act, and Section 3 of the Clayton Act.

The jury found that Tyco unlawfully maintained monopoly power in the relevant market, and that Tyco's sole-source agreements, bundling of unrelated products, market-share based compliance contracts, and co-marketing agreements with OEMs were unlawful restraints of trade in violation of the antitrust laws. Each practice, standing alone, was found to violate Section 1 and Section 3. The jury awarded Masimo $140 million in damages or $420 million after trebling. Tyco appealed the jury verdict and Masimo is sought an injunction. On appeal, it was decided that Tyco pay $14.5 million in damages – $43.5 million after trebling – but the court denied Masimo's request for a permanent injunction. Both parties appealed this ruling in the 9th Circuit. In late October 2009, the 9th Circuit came back with a decision upholding the District Court decision that Tyco violated the antitrust laws through anticompetitive business practices related to the sale of Nellcor products. The Ninth Circuit also held that above-cost bundling discounts when combined with sole-source or market-share-based pricing can be anticompetitive when such practices involve a significant portion of the market, however because Masimo did not allege anticompetitive tying or pricing Tyco's bundled discounts could not, as a matter of law, violate Section 2.

A. Background

Pulse oximetry products are used by hospitals to monitor the blood oxygen levels of critically ill patients. They are a standard of care and an essential element of hospital operating rooms, intensive care units, and neonatal units, where they help to dramatically reduce the number of deaths and risk of

respiratory failure in patients. Masimo and Tyco are competitors in the marketing and manufacturing of pulse oximetry products sold to hospitals and other healthcare providers.

B. The Alleged Anticompetitive Conduct

Masimo claimed that Tyco foreclosed Masimo and other rivals from over 70% of the relevant market and that the "combined effect" of the following practices by Tyco violated Section 2 of the Sherman Act: (1) providing loyalty discounts to hospitals in exchange for their commitment to purchase not more than a specified percentage of their requirements for oximetry products from Masimo or other rivals; (2) entering into sole-source exclusive dealing arrangements with hospital GPOs and IHNs that prevented Masimo and other competitors from selling oximetry products to member hospitals; (3) offering bundled rebates in which discounts on oximetry products were linked to discounts on unrelated Tyco products; (4) entering into oximetry equipment financing programs that imposed financial penalties on hospitals that switched to rival products; and (5) entering into contracts with OEMs that effectively foreclosed rivals from the market. Additionally, Masimo alleged that Tyco's agreements with GPOs, IHNs, and OEMs created a de facto exclusivity that foreclosed Masimo from the market in violation of Section 3 of the Clayton Act and Section 1 of the Sherman Act.

Masimo argued that Tyco possessed market power because Tyco's market share averaged 80% at all relevant times and cited circumstantial proof such as Tyco's gross profit margins, alleged practices of price discrimination among different categories of purchasers, alleged power to exclude rivals, and alleged acts creating substantial entry barriers in the market. Masimo presented the following evidence of entry barriers: (1) significant up-front costs and lead times for research and development to obtain Food and Drug Administration (FDA) approval and achieve learning curve economies; (2) high capital costs to enter the market as compared to Tyco's "low cost manufacturing advantage"; (3) Tyco's brand recognition and brand loyalty produced by its long-standing dominance in sales and installed base; (4) the tendency of hospitals to standardize product choices in any given product category; (5) network effects that increase the minimum market share required to efficiently compete in the oximetry market; (6) Tyco's intellectual property rights protecting sensor sales in its installed base of Nellcor-compatible sockets; and (7) Tyco's exclusionary agreements with oximetry purchasers, GPOs, and IHNs.

The following sections provide a brief synopsis of the parties' arguments about Tyco's alleged anticompetitive practices.

C. Volume Share Discounts in Compliance-Based Agreements

Tyco's compliance-based contracts granted substantial discounts to Tyco customers in exchange for a contractual commitment: (1) to purchase no more than a small percentage (usually about 10%) of sensors from Tyco's rivals and the

remaining percentage (usually about 90%) from Tyco; and (2) to utilize Tyco monitors or Tyco-compatible monitors throughout 90% (or whatever the commitment level) of the hospital. Masimo argued "that a jury could reasonably find that these exclude Masimo from the oximtery market because they reflect pricing terms that are based on terms that operate to exclude competition rather than to reflect the supply and demand for Tyco's products on their own merits." Masimo argued that Tyco's compliance-based discounts, in conjunction with sole-source agreements, created a de facto exclusivity that substantially foreclosed Masimo from the market.

D. Sole-Source Contracts with GPOs and IHNs

Masimo argued that Tyco's sole-source contracts with GPOs created a "strong disincentive" for GPO members and IHNs to deal with Tyco's competitors, and excluded Masimo from a substantial portion of the oximetry market. Tyco argued that its sole-source agreements were not exclusionary because they allowed hospitals to purchase "off contract." Masimo, however, presented evidence that any attempts outside of a GPO contract were very difficult and usually not worth the time and effort for members.

E. Bundled Rebates

Masimo argued that Tyco's bundled discount programs with GPOs leveraged Tyco's dominant position in other product markets with its dominant position in the pulse oximetry market and that Masimo could not match Tyco's offer because it offered only oximetry products. Masimo contended that these rebates "created a powerful disincentive for hospitals to buy Masimo's oximetry products for reasons that ha[d] nothing to do with the relative merits of the competing oximetry systems." Tyco argued that the rebate programs were voluntary and that Masimo could seek hospitals' business by offering a better deal.

F. Equipment Financing Programs

Masimo claimed that Tyco used its equipment financing programs with GPOs and non-GPO hospitals to foreclose competition in the relevant market. Under these programs, hospitals signed written commitments to purchase a high percentage of their oximetry equipment from Tyco and received new monitoring equipment without paying cash at the outset, or Tyco would provide new monitors with no cash payment required to any hospital willing to trade in a rival's product. Hospitals participating in these programs were required to purchase Tyco sensors for their new and existing Tyco monitors.

G. Co-Marketing Agreements with OEMs

Masimo argued that Tyco's co-marketing agreements with OEMs prevented the OEMs from offering Masimo products and denied Masimo access to "vital" channels of the market. Masimo provided evidence that Tyco's standard form agreements required that "OEMS [is this how it's spelled in the original?] in their product manuals recommend only Tyco sensors for use with those modules,

and state that 'no other sensors should be used (including sensors not manufactured by [Tyco]).'' Tyco argued that the co-marketing agreements did not contain any exclusivity provisions, and provided evidence that Tyco's OEMs offered other vendors' products at the same time they offered Tyco products.

II. Kinetic Concepts, Inc. v. Hillenbrand Industries, Inc., No. 95-CV-0755 (W.D. Tex.)

In 1995, Kinetic Concepts, Inc. (KCI) sued Hillenbrand Industries and several of its subsidiaries (collectively, Hillenbrand) for antitrust violations involving the manufacture and rental of specialty hospital beds and surfaces designed to treat specific medical conditions such as burns, pressure sores, spinal injuries, and pneumonia. KCI and Hillenbrand are the two major competitors in the manufacture and rental of specialty hospital beds and surfaces. In its complaint, KCI alleged that Hillenbrand bundled its specialty beds with its standard hospital beds, and conditioned additional discounts on the standard beds to exclusive dealing commitments on its specialty bed rentals. After 7 years of discovery, a 21-day trial, and over 680 exhibits admitted into evidence, the case resulted in a plaintiff's jury verdict of nearly $174 million or $521 million after trebling, one of the largest antitrust verdicts in the nation. The case settled prior to the formal entry of this judgment.

A. Background

Most specialty beds are rented to acute care hospitals that contract with KCI or Hillenbrand through agreements negotiated with GPOs. These contracts are then accepted by GPOs' member hospitals, and usually last for 3 years or longer with termination upon 60- to 90-days notice. In addition to specialty beds, Hillenbrand manufactures and sells standard hospital beds used in nonintensive care unit rooms in hospitals, the majority of such sales also through GPO contracts. Hillenbrand had an approximately 90% or greater U.S. market share in standard hospital beds. Standard hospital beds and specialty beds constitute two separate markets, and in terms of revenue, the standard hospital bed market is more than twice the size of the specialty bed market.

B. The Alleged Anticompetitive Conduct

In the early 1990s, Hillenbrand started conditioning additional discounts on standard hospital beds on a customer's commitment to sole-source its rental of specialty beds from Hillenbrand. The contracts required a hospital to place at least 90% of its specialty bed rentals with Hillenbrand. Therefore, to obtain an additional discount on Hillenbrand's high market share standard hospital beds, a hospital was required to select Hillenbrand as its only source for specialty beds. This strategy is referred to as bundling and was the basis of KCI's claims.

At trial, KCI was required to prove harm to competition sufficient to meet legal standards and present evidence sufficient to convince a jury that consumer harm was present. KCI explained that, although it could match Hillenbrand's discounts in the specialty bed market, it could not match the additional

incremental discount on the standard hospital beds. KCI claimed that due to its few remaining GPO contracts and the few GPO contracts up for re-bid, consumers were denied choice and quality in their specialty bed selections. Hillenbrand offered little evidence of valid business or efficiency justifications and argued that its bundled arrangement helped consumers by lowering prices. However, KCI presented evidence that Hillenbrand could easily have lowered its prices without the bundling arrangements.

III. Retractable Technologies, Inc. v. Becton Dickinson & Co., No. 01-CV-036 (E.D. Tex.)

In January 2001, Retractable Technologies, Inc. (RTI), a manufacturer of safety syringes, sued the two largest manufacturers of standard and safety syringes and the two largest GPOs, alleging that they illegally conspired to prevent RTI from selling its retractable needle syringe products to hospitals and monopolized the needle and syringe market. RTI's lawsuit named as defendants Becton Dickinson & Co. (BD), Tyco International (US) Inc., Tyco Healthcare Group, L.P. (collectively, Tyco), and GPOs Novation L.L.C. and Premier Inc.

The procedural history of this case is quite interesting. RTI filed its First Amended Complaint in February 2001 and subsequently, the defendants moved to dismiss RTI's complaint for failure to state a claim. The court ordered RTI to replead all of its claims because its complaint made merely conclusory allegations of antitrust law violations.

Thereafter, on January 18, 2002, RTI filed its Second Amended Complaint, and BD and Tyco subsequently filed motions to dismiss, both alleging that RTI again failed to assert any viable claims against the defendants. In July 2004, with only five days before the start of trial, RTI reached a settlement with BD in which BD agreed to pay RTI $100 million. RTI reached settlements with the other defendants in early 2003.

A. Background

RTI designs, develops, manufactures, and markets hypodermic products that have retractable needles for use in the health care industry. RTI's retractable needle products operate such that the needle automatically retracts back into the hypodermic barrel after use, thereby preventing sticks from needles that have been exposed to bodily fluids and could contain life-threatening diseases. Defendants BD and Tyco are the two largest manufacturers of standard and safety syringes. RTI described the GPOs as "middlemen" between medical device manufacturers and health care providers whose "true purpose was to funnel large market shares to medical device manufacturers in exchange for substantial fees." The GPOs were being sued not only as independent entities but also as agents for their member facilities.

B. The Alleged Anticompetitive Conduct

In its complaint, RTI alleged that the defendants conspired to eliminate or lessen competition and to acquire and maintain monopoly power among hospitals and healthcare providers. RTI claimed that BD and the other defendants obtained their dominant position in the market for hypodermic products by engaging in "a systematic and pervasive course of illegal conduct designed to unlawfully exclude and suppress competition." Until the end of 1999, BD controlled more than 70% of the U.S. market for all hypodermic products, and BD and Tyco together controlled 90% of the market. RTI alleged that BD and Tyco used their dominance of the hypodermic market to create leverage and exclude RTI and other competitors from other product markets, such as the market for RTI's retractable needle system.

RTI alleged that, with the assistance of defendant GPOs, BD and Tyco used anticompetitive practices such as tying and bundling and entered into exclusive dealing contracts with GPOs, hospitals, and healthcare providers to restrict their purchasing decisions only to BD and Tyco for hypodermic products. To acquire and maintain monopoly positions in the market, BD and Tyco allegedly tied their hypodermic products with a larger collection of products that hospitals and healthcare providers were required to purchase to receive discounts and avoid penalties.

In addition, RTI argued that sole-source suppler relationships between and among BD and Tyco, GPOs, hospitals, and other healthcare providers, allowed BD and Tyco to require hospitals and healthcare providers to purchase almost 90% and in some cases 100% of their medical devices through BD and Tyco. BD and Tyco also allegedly threatened GPOs, hospitals, and healthcare providers with sanctions to force them to give BD and Tyco exclusive availability to purchases [is there some language missing here?] and not enter into agreements with BD and Tyco's competitors. The results, RTI claimed, were substantial entry barriers for potential competitors and the elimination of competition in the market.

IV. Medtronic AVE Inc. v. Cordis Corp., No. 03-CV-212 (E.D. Tex.)

In June 2003, Medtronic AVE Inc., a subsidiary of Medtronic, Inc., filed suit against Cordis Corp., a subsidiary of Johnson & Johnson (J&J), alleging that Cordis misused its monopoly power in the drug-eluting stent (DES) market through tying and exclusive dealing arrangements and foreclosed competition in the market for other angioplasty products. Medtronic AVE and Cordis are competitors in the markets for coronary angioplasty products such as balloon angioplasty catheters, non-drug-eluting coronary stents (non-DES), and guide catheters. A motion to dismiss was granted on January 29, 2008 after nearly 400 filings by both parties. The parties each bore their own costs and fees from the dismissal.

A. Background

Balloon angioplasty is a procedure used to treat coronary artery disease. During the procedure, a catheter is threaded through the coronary artery system,

and a balloon tip on the end of the catheter is placed in the arterial blockage. A doctor fills the balloon with sterile fluid to enlarge the opening in the artery to allow improved blood flow. In coronary stenting, a stent is inserted in the artery in conjunction with balloon angioplasty to ensure that the artery remains open. The majority of stents used in patients in the United States are non-DES.

In 2003, the FDA approved Cordis's Cypher DES, making Cordis the only company with an FDA-approved DES product in the United States. Cordis allegedly began using anticompetitive tactics before FDA approval of the Cypher DES when it was clear that Cypher would be the first DES approved for use in the United States, thereby giving Cordis monopoly power in the DES market.

B. The Alleged Anticompetitive Conduct

Medtronic alleged that once Cordis achieved monopoly power in the DES market, it used unfair and unlawful sales and marketing practices to put Medtronic AVE's non-DES at a competitive disadvantage in the non-DES market. Moreover, Medtronic claimed that Cordis tied purchases of its Cypher DES to purchases of its non-DES and other angioplasty products through economic incentives, marketing practices, and threats.

J&J, Cordis's parent company, established the following marketing program in anticipation of Cypher's FDA approval: (1) Cordis offered a 5% discount on all Cordis products purchased in 2003, including Cypher DES, if customers increased their purchases of Cordis's angioplasty products in the third and fourth quarters of 2002; and (2) if customers bought Cordis's non-DES products before the release of Cypher DES, Cordis promised they could trade non-DES products for Cypher DES when it became available. Moreover, Medtronic claimed that Cordis threatened customers that they would not be given priority in the purchase of Cypher DES if they did not place substantial orders for Cordis's non-DES and other angioplasty products in 2002.

Medtronic argued that, through its anticompetitive arrangements, Cordis unlawfully leveraged its monopoly power in the DES market to gain an advantage and foreclose competition in markets for non-DES systems and other angioplasty products.

V. Rochester Medical Corp. v. C.R. Bard Inc., No. 5:04-CV-060 (E.D. Tex.)

In March 2004, Rochester Medical Corp. ("RMC"), manufacturer of urological and incontinence devices, filed suit against two large medical device companies and [how many?] GPOs claiming that, through anticompetitive practices, they foreclosed RMC from the market for urological products. The complaint alleged that C.R. Bard Inc. (Bard) and Tyco International (US) Inc. (Tyco), with the assistance of GPOs Novation L.L.C. and Premier Inc., used tying, bundling and other exclusionary leveraging tactics to force hospitals and clinics to buy catheter products inferior in quality to RMC's catheter products.

On August 2, 2007, a motion was granted which severed Rochester Medical's claims against Tyco to be heard at a hearing to be held in February of 2008. The next day a notice of settlement was filed and on August 6, 2007 the action was dismissed by reason of settlement.

A. Background

RMC manufactures catheter products such as Foley catheters, male external catheters, urethral catheters, and a catheter clinically proven to reduce infections, namely its Release-NF Catheter. Bard and Tyco also manufacture Foley catheters, infection control catheters, and other urological products. GPOs Novation and Premier contract with Bard and Tyco to supply products to member hospitals who choose to buy catheters under these contracts.

B. The Alleged Anticompetitive Conduct

In its complaint, RMC alleged that the defendants conspired to eliminate or lessen competition in the relevant market, and acquire and maintain monopoly power among hospitals and healthcare providers. RMC alleged that Bard controlled 75% of the relevant market for Foley and urethral catheters, and Bard and Tyco together controlled more than 90% of those markets. RMC claimed that Bard and Tyco used illegal and anticompetitive practices such as bundling, kickbacks, bribes and product disparagement to guarantee substantial business from GPOs. In addition, RMC claimed that the defendant GPOs required member hospitals to purchase up to 90% or more of Bard's and Tyco's products to receive cost savings and avoid penalties, thereby blocking entry by competitors. According to RMC, these practices decreased the quality of Foley catheter products; substantially foreclosed it and other competitors from entering and effectively competing in the market; unreasonably restricted choice and access to safer and higher quality products; increased prices; and harmed patients.

Specifically, RMC asserted that Bard and Tyco's sole-source contracts with GPOs required GPOs to purchase Foley catheters from Bard or Tyco to obtain substantial price reductions on Foley catheters and other products that RMC did not sell. Moreover, the contracts penalized member hospitals if they did not purchase either standard or infection-control Foley catheters from Bard or Tyco by requiring them to pay higher prices for other urological products. RMC claimed that the defendants' contracts allowed them to obtain and leverage their monopoly power in the standard Foley catheter market in order to gain monopoly power in the infection-control Foley catheter market. Moreover, Bard and Tyco allegedly threatened hospitals and other health care providers with expulsion from a GPO, withdrawal of product availability, and withdrawal of financial incentives and kickbacks.

VI. ConMed Corp. v. Johnson & Johnson, Inc., No. 03-CV-8800 (S.D.N.Y.)

In November 2003, ConMed Corp. (ConMed) sued Johnson & Johnson and several of its subsidiaries (collectively, J&J) alleging that J&J restricted competition in the endoscopy market, resulting in higher prices for consumers. Specifically, ConMed alleged that its ability to sell its surgical products was stifled by J&J's anticompetitive contracting practices, which included entering into exclusive contracts with hospitals, tying and bundling the price of products to a hospital's agreement to buy a high percentage of J&J products, and imposing financial penalties on hospitals that purchased competitive products such as those provided by ConMed. ConMed seeks damages of up to hundreds of millions of dollars and an injunction against J&J's sales practices. Trial was scheduled to begin in April 2007 in the U.S. District Court for the Southern District of New York. However, prior to trial the parties reached settlement of $11 million and the case was therefore dismissed on April 6, 2009 with prejudice.

A. Background

As a leading medical technology company, ConMed designs, develops, manufactures, and sells medical devices used in a broad range of surgical procedures, including endoscopic procedures and surgery such as laparoscopy. ConMed's endoscopy products account for approximately 10% of its total annual revenue. J&J also manufactures and sells these minimally invasive surgical products under its subsidiary Ethicon Endo-Surgery, Inc. (Ethicon).

B. The Alleged Anticompetitive Conduct

ConMed alleged that J&J and several of its subsidiaries, including Ethicon, engaged in illegal and anticompetitive conduct with respect to sales of products used in endoscopic surgery, resulting in higher prices to consumers and the exclusion of competition.

In its complaint, ConMed specifically alleged that J&J blocked ConMed's ability to sell endoscopic surgical products by entering into exclusive contracts with hospitals requiring them to purchase endoscopy products only from J&J; tying and bundling the price of sutures to a hospital's agreement to buy a high percentage of its endoscopy products from J&J; threatening and imposing financial penalties on hospitals if they purchased competitive endoscopy products; and giving hospitals inaccurate and misleading information as to their ability to deal with ConMed. The complaint also contends that J&J furthered this anticompetitive conduct through its contracts and other dealings with GPOs like Novation L.L.C. and Premier Inc. ConMed asserted that in the absence of J&J's illegal conduct, hospitals would have access to lower priced endoscopy products and would purchase a substantial portion of such products from ConMed.

VII. Applied Medical Resources Corp. v. Johnson & Johnson, Inc., No. 03-CV-1329 (C.D. Cal.)

In 2003, Applied Medical Resources Corp. (AMR), a manufacturer of medical devices used in minimally invasive surgery, sued Johnson & Johnson (J&J) and Novation L.L.C., a GPO,

for allegedly harming AMR's sales of medical products through exclusionary practices such as product bundling. AMR alleged that the defendants' anticompetitive practices were designed to acquire and maintain J&J's monopoly in the market. AMR's claims against Novation were dismissed following a 2004 settlement, and AMR and J&J are currently in litigation before the U.S. District Court for the Central District of California. J&J filed a motion for summary judgment on all claims. On February 2, 2006, Judge James V. Selna denied J&J's motion for summary judgment, except on the claims of contracts with carve-outs and on Section 3 of the Clayton Act.

J&J's motion for summary judgment asserted that there was no harm to competition, therefore each of the claims must fail; that its bundling practices do not fall within any well-recognized exclusionary or predatory practices under Section 2 of the Sherman Act; that a Sherman Act Section 1claim must fail if its practices are not exclusionary under Section 2; and that its exclusive dealings claim under Section 3 of the Clayton Act must fail because its bundled offerings are based on percentage purchase requirements and are not exclusive.

Summary judgment was denied on the Section 2 claim on the grounds that J&J used its market power in the sutures market to protect its position in trocars. And there was evidence that bundling had an adverse effect on prices and limited market penetration by AMR. On the Section 1 claim, summary judgment was denied as it was noted that it does not necessarily follow that conduct which is lawful under Section 2 is also lawful under Section 1.

Summary judgment was granted to J&J on the claim that contracts with carve-outs hindered AMR's ability to compete on the grounds that after late 2003 GPOs could purchase AMR's trocars without penalty; and that AMR, after this date, had the ability to compete on those key factors where there were contractual carve-outs. J&J was also granted summary judgment on the Clayton Act claim on the grounds that the contracts with tiered purchasing requirements allowed outside purchases. And where the contracts were in fact exclusive, the GPOs merely provided services not controlled by Section 3.

After a trial by jury, on September 26, 2006, it was "ordered and adjudged that plaintiff Applied Medical Resources Corporation ('Applied') take nothing, that action be dismissed with prejudice on the merits, and that defendants Ethicon Inc., Ethicon Endo-Surgery Inc. and Johnson and Johnson Health Care Systems Inc. recover of the plaintiff their costs of the action." However, by this time multiple parties had intervened. On September 9, 2007, a motion to grant an order to enforce a final settlement was filed by Applied and granted shortly thereafter.

A. Background

AMR manufactures a line of trocars and clip appliers, medical devices placed in the abdomen of a patient in surgery to aide the entry of medical instruments into the body cavity during minimally invasive "keyhole" surgery. J&J manufactures trocars as well, but has a much broader product line. J&J also manufactures "endo" devices, used in minimally invasive surgery, as well as sutures. As of late 2003, an estimated $285 million worth of trocars are sold in the United States every year.

B. The Alleged Anticompetitive Conduct

AMR alleged, in its First Amended Complaint filed December 8, 2003, that J&J used its monopoly power in the sutures market to maintain its monopoly in the trocars and clip appliers market. In doing so, it entered into exclusivity contracts with GPOs in which they offered hospitals significant discounts through product bundling. AMR claimed that it could not compete and a substantial part of the market competition was foreclosed to them due to J&J's exclusive dealing contracts.

AMR specifically alleged that J&J had a direct, substantial, and adverse effect on competition by its monopolization of the trocar and clip appliers market, artificially creating barriers to entry in the relevant markets, foreclosing competition, and stifling innovation and that it was directly injured by J&J's unlawful conduct depriving AMR of past profits, future profits, and the value of invested capital due to fruitless efforts to enter the relevant markets and sums spent to mitigate damages. AMR contended that it was proximately damaged by J&J due to the fact that its market share is much higher in areas less affected by J&J's GPO contracts and that it has achieved much greater market penetration in Europe, where government-owned hospitals often insist on unbundled bids.

VIII. Genicon, Inc. v. Ethicon, Inc., No. 04-CV-00229 (E.D. Texas)

In October 2004, Genicon, Inc. (Genicon), a manufacturer of medical devices used in minimally invasive, gynecologic, urologic and pediatric laparoscopic surgery, filed suit against J&J, its subsidiary Ethicon, Tyco and a number of GPOs to recover damages and to gain access to the laparoscopic products and hospital markets. J&J and Tyco are manufacturers of products that compete with Genicon's products. The remaining defendants are GPOs that effectively decide what products their member hospitals will purchase. The suit alleges that the defendants engaged in anticompetitive practices and product disparagement to prevent Genicon's entry into those markets. The suit is pending in the United States District Court for the Eastern District of Texas. The case went through discovery and after March 2006, the defendants filed a counterclaim against Genico. Ultimately, on January 21st, 2007, the court granted a joint motion to dismiss filed by Genico, Inc., Johnson & Johnson, and Ethicon, Inc., et al.

A. Background

Genicon designs, develops, manufactures, and markets disposable endomechanical products that are utilized during minimally invasive "keyhole" surgery. Such products include trocar cannula systems, scissors, graspers, and dissectors. The FDA approved Genicon's products for use in 1998, with international approvalcoming in 1999. Genicon sells its products in nearly 50 countries, and the innovativeness of Genicon's

products has been recognized with the award of numerous patents. J&J and Tyco through their subsidiaries Ethicon and United States Surgical Corporation, respectively, also manufacture and sell competitive medical devices that are used in keyhole surgery.

B. The Alleged Anticompetitive Conduct

Genicon alleged that two competing manufacturers, J&J and Tyco, violated unspecified federal and state antitrust laws by entering into exclusive or near-exclusive contracts with four GPOs, Novation L.L.C., Premier Inc., Broadlane, and Healthtrust Purchasing Group, representing a substantial share of the market for disposable endo-mechanical products and various submarkets.

Specifically, Genicon alleged that its ability to sell its endo-mechanical products was stifled by defendants' anticompetitive contracting practices, which included exclusive contracts between defendant-manufacturers and GPOs, tying and bundling by linking the price of products to a GPO-member's agreement to buy a high percentage of defendants' products, including both J&J's endo-mechanical products and sutures, in which markets it allegedly possesses market power, and imposing financial penalties on GPO members if they purchased competitive products such as those provided by Genicon.

IX. Daniels Sharpsmart, Inc. v. Tyco International, US Inc., 5:05-cv-00169-DF (E.D. Texas)

Daniels Sharpsmart brought suit in August 2005 against Becton Dickinson, Tyco International and others alleging a conspiracy to monopolize the market for hypodermic syringe disposal containers. Becton filed a motion to dismiss arguing that the plaintiff failed to show substantial foreclosure of competition and that the claims were time barred, among other things. In denying Becton's motion to dismiss in October 2006, Judge David Folsom said Daniels Sharpsmart had met its burden at the pleading stage and that the allegations were of ongoing wrongful conduct, which prevents a statute of limitations bar.

In October 2007 Becton settled this suit. Subsequently attorneys for the companies filed a dismissal stipulation with the U.S. District Court for the Eastern District of Texas arguing the claims should be dismissed pursuant to a settlement agreement and release in the case. This dismissal stipulation was denied and trial was scheduled to commence in January 2009. However, prior to trial a private settlement was reached and a judgment dismissing the action by reason of settlement was entered on December 30, 2008.

A. Background

Daniels Sharpsmart makes containers used to dispose of sharps and syringes. Domestic sales for sharps containers amount to $250 to $300 million annually.

B. The Alleged Anticompetitive Conduct

The suit alleged that even though the sharps container products of Tyco and Becton Dickinson were more expensive and less safe, those companies managed to control the market through group purchasing organizations, whereby member hospitals had to pay penalties if they failed to commit to getting the majority of their sharps containers through the makers.

It was alleged that Becton Dickinson entered into contracts with group-purchasing agents and forced them to receive hypodermic products only from Becton. The company also bid for contracts by offering to bundle its products, often including substantial financial incentives to hospitals and other customers that agree to purchase the vast majority of the products they need from those bundles, according to the suits.

X. **Louisiana Wholesale Drug Co. v. Becton Dickinson Co., 2:05-cv-01602-JLL-CCC (D. N.J.)**

In August 2007 a class action antitrust Complaint passed the new, stricter "plausibility" pleading standard the Supreme Court established in 2007 in Bell Atlantic Corp. v. Twombly, 127 S.Ct. 1955; (No. 05-1126) 2007 U.S. LEXIS 5901 (2007). In re Hypodermic Products Antitrust Litigation, No. 05-CV-1602 (JLL/CCC) (D. N.J. June 29, 2007). In three separate, unpublished opinions, a New Jersey district court overruled defendant medical device manufacturer Becton Dickinson & Company (Becton)'s motion to dismiss Section 1, Sherman Act and Section 3, Clayton Act claims because the three Complaints provided plausible grounds to infer that Becton and group purchasing organizations (GPOs) entered into unreasonably anticompetitive agreements.

A. The Complaint

Healthcare organizations, pharmacies and wholesalers sued Becton separately. Plaintiffs' Amended Complaint states causes of action for exclusive dealing and exclusionary practices in violation of Section 1 of the Sherman Act and Section 3 of the Clayton Act; unlawful maintenance of monopoly power and attempted monopolization in violation of Section 2 of the Sherman Act; state antitrust law violations; and unjust enrichment. The Complaint alleges that that Becton has been a leading U.S. hypodermic syringe manufacturer since the 1950's and that Becton has a dominant share in four relevant product markets collectively called the disposable hypodermic product market. The Complaint contends that Becton entered into anticompetitive arrangements with GPOs, which serve as negotiating agents for hospitals, where Becton would pay a GPO million dollar cash payments and offer "equity positions" with the expectation that the GPO "would favor Becton's products, regardless of price, over those of Becton's competitors". Kickbacks like these were illegal until 1986, when Congress

amended the Social Security Act's "anti-kickback" provisions to create exceptions for vendors' payments to GPOs. For example, in 1999, the Complaint alleges, Becton awarded one GPO, Novation, with a $1 million payment and high administration fees for a four year "sole-source" contract, whereby Becton would be the only vendor approved by Novation to sell disposable hypodermic products to Novation members. In 1998, the Complaint also alleges, Becton and another GPO, Premier, entered into a 7.5 year sole-source contract. Further, the Complaint alleges that when Becton faced competition in the 1970's from Terumo, a Japanese corporation, Becton engaged in a program called "Block Terumo". The program entailed "the use of an aggressive strategy" including "bundled pricing and contracting strategies and other similar exclusionary and predatory tactics". Becton allegedly used similar strategies to limit competition from another competitor, Retractable Technologies, in the late 1990s. The Complaint alleges that Becton's agreements and practices foreclosed competition and thus caused purchasers of Becton's disposable hypodermic products to pay higher prices.

B. Standard for Review

Becton's motions to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure contended the Complaint is deficient in alleging unlawful exclusionary conduct, anticompetitive effects, the relevant markets, antitrust injury, and standing. The Court addressed the standing issue in a separate opinion. Before considering each ground for dismissal, the court set out the applicable standard of review. The court first observed that in the Third Circuit, antitrust Complaints should be liberally construed, citing Commonwealth of Pa. ex rel. Zimmerman v. PepsiCo, Inc., 836 F.2d 173, 179 (3d Cir. 1988). The court then referred to Twombly, where the Supreme Court held that to avoid dismissal, an antitrust Complaint need not provide detailed factual allegations but must plead "enough facts to state a claim to relief that is plausible on its face." 127 S. Ct. at 1964, 1974. The court followed Twombly and found that the Complaint's Section 1 and Section 3 causes of action alleged facts that provided plausible grounds to infer that Becton and certain GPOs and manufacturers had entered into anticompetitive, illegal agreements.

C. Unlawful Exclusionary Conduct

The court set out the elements to the Complaint's' first count against Becton, unlawful exclusive dealing in violation of Section 1 of the Sherman Act and Section 3 of the Clayton Act. Section 1 requires: (1) concerted action by defendants; (2) that produced anti-competitive effects with the relevant market; (3) that the concerted action was illegal; and (4) that the plaintiff was inured as a proximate result of the concerted action. The crucial question, the court noted, is whether the challenged anticompetitive conduct arises from independent decision or from an agreement, tacit or express. Twombly, 127 S.Ct at 1964. Recovery under Section 3 of the Clayton Act generally requires, the court said, (1) an exclusive dealing arrangement; and (2) the probable effect of exclusion must be to substantially lessen competition in the market". Citing Tampa Elec. Co. v.

Nashville Coal Co., 365 U.S. 320, 327 (1961). In analyzing the sufficiency of these claims, the court applied Twombly which requires that a Complaint allege "enough facts to state a claim to relief that is plausible on its face." The court held the Complaint satisfied this standard.

The court first pointed out the Complaint's allegations about Becton's kickbacks to Premier and Novation and Becton's four and 7.5 year exclusive dealing contracts with these GPOs. The Complaint also cites a February 1997 article that reports that as a result of a deal between Becton and Premier, Premier would receive warrants for Becton stock, so that the more Premier purchased from Becton, the more Premier's warrants would be worth. The Complaint additionally alleges that Becton entered into agreements with GPOs, certain hospitals and other customers which included exclusivity clauses and bundled financial incentives. If a member desired to purchase disposable hypodermic products from another manufacturer, the Complaint alleges, the class member risked losing numerous financial incentives. These agreements foreclosed competition in a substantial portion of the market, the Complaint alleges. Finally, the Complaint alleges antitrust injury in contending that plaintiffs were injured by Becton's exclusive arrangements to the extent they were forced to pay higher prices for disposable hypodermic products than they would have paid in the absence of the agreements. The court thus concluded that the Complaint satisfied Twombly because it alleged enough facts to raise a reasonable expectation that discovery will lead to evidence of illegal agreement.

D. The Alleged Anticompetitive Conduct

Becton also argued, unsuccessfully, that plaintiffs' action should be dismissed because the Complaint contains no particularized allegations about competition in any specific market. Becton cited no legal authority, the court pointed out, that indicated that such particularized allegations are a pleading requirement. To the contrary, the court said, "Federal Rule of Procedure 8(a)(2) requires only a short and plaint statement of the claim showing that the pleader is entitled to relief in order to give the defendant fair notice of what the … claim is and the grounds upon which it rests", quoting Twombly, 127 S.Ct. at 1964 (citations omitted). In any event, the court continued, the Complaint provides examples of the types of exclusionary practices Becton utilized. Unlike in Twombly, where the Complaint sought to demonstrate anticompetitive agreements based on parallel conduct through inference, the Complaint in this instance alleges specific anticompetitive agreements between Becton and certain manufacturers (and GPOs). This gives Becton, the court found, sufficient notice of the particular grounds of plaintiffs' claims, particularly given the fact that plaintiffs have not yet had the benefit of discovery. For additional support, the court quoted Hosp. Bldg. Co. v. Trs. of Rex Hosp., 425 U.S. 738, 745-57 (1976), where the Supreme Court said that "dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly."

XI. Natchitoches Parish Hosp. Service Dist. v. Tyco International et al., No. 05-cv-12024-PBS (D.Mass)

Natchitoches Parish Hospital Service District filed a class action suit against Tyco and subsidiary companies in October 2005 to recover overcharges that members of a class paid for sharps containers. The complaint alleges that defendants used its monopoly power to improperly impair and exclude competition from less expensive and potentially superior forms of sharps containers. The anticompetitive conduct alleged includes imposing market share purchase requirements, bundling for exclusionary purposes, GPO agreements for exclusionary purposes, and conspiracy with other manufacturers to impose rebate penalties. After four years of motions practice and discovery, on December 7, 2009, this case went to trial before Federal Judge Patti B. Saris. Day 10 of trial ended December 18, 2009, and the Court is in recess until January 4, 2010.

A. Background

Sharps containers are products that are used for the disposal of needle-inclusive bio-hazard medical products, including syringes, blood collection devises and IVs. Healthcare providers and hospital practice of sharps disposals is regulated by the federal government to ensure safe disposal of medical waste. Use of sharps containers increased in the mid-1990s as hospitals and federal regulations placed greater emphasis on preventing accidental needle-stick injuries. Tyco has dominated the market for sharps containers selling over 70% of the sharps containers in the U.S., with revenue for domestic sales at roughly $200 million annually. The sharps containers market is approximately $250-300 million annually in the United States.

B. The Alleged Anticompetitive Activity

Natchitoches alleges a number of anticompetitive practices that have acted to prevent competitors from gaining market share, achieving economies of scale and scope, and driving down the prices charged by both Tyco and its competitors in the market. Specifically, Natchitoches alleges that Tyco imposed on purchasers market share purchase requirements tied to maintaining Tyco's dominant market share; bundled its goods to purchaser for the purpose of excluding other competitors; made agreements with GPOs to impose exclusionary contracts; and conspired with other manufacturers to impose rebate penalties on purchasers relating to a bundle of products. Tyco used its dominant position to threaten healthcare entities with financial penalties on all sharps containers and other Tyco products unless the healthcare entity bought nearly all of its sharps containers from Tyco. Plaintiff alleges that absent Tyco's anticompetitive activity, class members would have enjoyed lower costs and unfettered competition for the sharps containers purchased.

XII. **UltiMed, Inc. v. Becton Dickinson Co, No. 06-cv-02266 (D.Minn.)**

In June 2006, UltiMed filed an antitrust suit against Becton Dickinson accusing its larger rival of barring competition in the market for home-use insulin syringes. The suit alleged that Becton had monopoly power in the home-use insulin syringe market and it unlawfully maintained that monopoly power through exclusive and anti-competitive contracts with third-parties. This suit was similar to and came on the heels of the 2004 settlement between RTI and Becton (see above). After almost three years of pending litigation, in January 2009, Becton and UltiMed agreed to settle with Becton paying to Ultimed $750,000. A joint stipulation of dismissal with prejudice was filed with the Court in January 2009.

A. Background

Ultimed designs and manufactures home-use insulin syringes for sale to the public and hospitals through pharmacies and GPOs. Becton and Ultimed, along with a few other medical device-manufacturing companies, are competitors in the home-use insulin syringe market. Becton however, maintains approximately a 90% market share in this $500-million market.

B. The Alleged Anticompetitive Conduct

Ultimed alleged that Becton bundled rebated and entered into exclusionary and anticompetitive contracts with pharmacy benefit managers (PBM), pharmacies and other medical suppliers to suppress competition in the insulin syringe market. UltiMed alleged that Becton used anticompetitive exclusive contracts with PBMs and pharmacies that included high market share requirements and required BD syringes to receive preferential placement on certain tiers of drug formularies and be listed as "plan preferred."

XIII. **I.C. Medical Inc. v. ConMed Corp., No. 2:09-cv-2124 (D. AZ)**

On October 9, 2009 I.C. medical filed a patent infringement suit against ConMed Corp. for infringing on two patents for a surgical smoke evacuation pencil, which ConMed sells under the trademarked name Goldvac. Additionally, the suit charged ConMed with using its large market share and agreements with GPOs to "predatorily" underprice the smaller electo-surgical equipment manufacturer. I.C. Medical seeks declaratory relief, preliminary and permanent injunctions, compensatory, treble and punitive damages, as well attorney's fees and costs.

ConMed answered the compliant on November 19, 2009, raising a counterclaim that the two patents I.C. Medical claims were infringed upon are invalid and should therefore be canceled. The Court has scheduled the Rule 16 Case Management conference for January 6, 2010.

A. Background

I.C. Medical competes with ConMed Corp in the small electo-surgery equipment market. I.C. Medical manufactures smoke evacuator systems to held doctors using electro-surgery and laser surgery devises. The firm developed its integrated telescopic smoke evacuation electro-surgical pencil in 1999. Such devices suction smoke created by the electronic and laser devises during surgery and removes it from the surgical site while also removing particulates (toxins and viruses) from the smoke.

B. The Alleged Anticompetitive Activity

I.C. Medical claims, in addition to the patent infringement, that ConMed is using its product market share to exclude I.C. Medical from winning supply agreements with group purchasing organizations and other medical supply groups. I.C. Medical claims that such agreements make it difficult for a smaller company with a smaller product line to sell its products to GPO members, even at a lower price point. Specifically, I.C. Medical argues that the ConMed is using its pencil product, Goldvac, "as a loss leader", selling them to GPOs and predatory low prices in order to exclude I.C. Medical from competing in the market.

IX. Freedom Medical v. Premier Purchasing Partners, L.P. et al, No. 5:09-cv-00152-DF (E.D. Texas)

On October 19, 2009, Freedom Medical filed suit against Premier Purchasing Partners, Premier Inc., Novation, Universal Hospital Services, Inc. (UHS), and Hill-Rom Company Inc. to recover damages and enjoin the parties from monopolizing and continuing to conspire to exclude Freedom from biomedical device rentals market. Hill-Rom and UHS compete with Freedom in the biomedical equipment rental market, and Premier, Premier Purchasing Partners and Novation are group- purchasing organizations which broker deals between health care providers and these rental companies. Defendants have until January 15, 2010 to file answers to Freedom's complaint.

A. Background

Freedom Medical, Hill-Rom and UHS each rent biomedical equipment to health care providers when their needs are unanticipated or greater than normal in the long- or short-term. Such equipment consists of defibrillators, ventilators, breathing pumps, and cardiac monitors. The total market for biomedical equipment rentals is estimated at over $450 million annually. Each of these companies also provides other services related to biomedical equipment.

UHS and Hill-Rom hold about 90% of the biomedical equipment rental market.

B. Alleged Anticompetitive Conduct

Freedom charges that the defendants entered into agreements in restraint of trade, conditioned on not dealing with competitors, and that they engaged in monopolization-related causes of action, tortuous interference with business relationship, business disparagement, and common law conspiracy.

Specifically, Freedom charges that UHS has entered into sole-source contracts with various GPOs, including Premier and Novation and that Hill-Rom and UHS have entered into dual-source contracts with these GPOs. Further, Freedom alleges that both Freedom and UHS penalize GPOs which do not agree to this exclusive contracts with them by paying them less in administrative fees or other revenue than they otherwise would. Further, both Hill-Rom and UHS have entered into commitment contracts with GPOs, which require the GPO's member hospitals to rent biomedical equipment from that supplier.

Freedom alleges that UHS and Hill-Rom's practice of market power has effectively excluded Freedom from access to GPO brokerage service at many GPOs. In addition, Freedom charges that Premier denied Freedom contracts despite the fact that Freedom offered the lowest rental prices among the bidders, and effectively barred them from the market.

DAVID BALTO
LAW OFFICES OF DAVID BALTO
1350 I ST NW SUITE 850
WASHINGTON, DC 20005
202-789-5424