Protecting Competition

Antitrust litigation is critical to safeguard against anticompetitive practices by dominant medtech firms.

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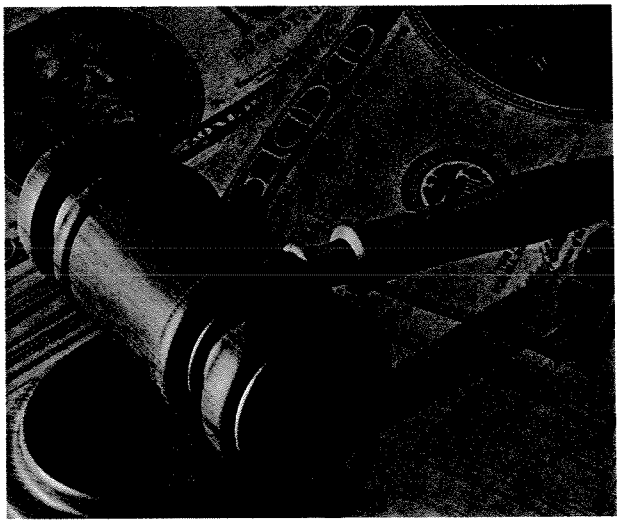

Few industries witness as much antitrust litigation as the medical device industry. In some respects, that is not surprising. Medtech industry players include many dominant firms that have a tradition of engaging in practices that raise barriers to market entry, expansion, and competition. These practices cross the line drawn by antitrust laws when they artificially restrain the competitive process.

Anticompetitive practices are particularly egregious in the medical device industry, in which competition is conducive to innovation and smaller fringe firms are often the source of technological breakthroughs.

Examples of innovation driven by fringe firms are evident in other industries as well. For example, in the soft drink industry, Royal Crown—not Coke or Pepsi—produced the first diet cola, the first caffeine-free soft drinks, and the first soft drinks in cans. During the 1970s, Japanese automakers Toyota and Nissan created higher-quality and lower-priced cars in a more dynamic fashion than industry giants General Motors, Ford, and Chrysler. The message is a simple one: nascent start-up competitors are essential to the robust competition and innovation necessary to spur industrial progress and growth.

In the medical device market, it is frequently the smaller fringe firms that create the disruptive innovations that move the market to a new generation of technological excellence. A dominant firm that holds the established technology may not welcome such innovations and may attempt to handcuff customers in order to delay acceptance of the innovation. When a dominant firm employs exclusionary contracting practices, competitors are discouraged from entering the market, and competition and innovation are hindered.

Antitrust laws, which serve to protect the competitive process and all forms of rivalry, play a crucial role in preventing anticompetitive practices in the medical device marketplace. Medtech executives should be aware of the potential implications of these practices, which can stifle innovation and competition in the market, delay medical and technological progress, and ultimately harm the patients who rely on the devices.

This article explores various exclusionary contracting practices that raise antitrust concerns and their implications for the medtech industry. It also illustrates how enforcement of antitrust laws can prevent dominant firms from using these practices to deter competition.

Case in Point

In the U.S. market, the dominant players in the manufacture and rental of specialty hospital beds are Kinetic Concepts Inc. (KCI; San Antonio, TX) and Hillenbrand Industries Inc. (Batesville, IN). In 1995, KCI sued Hillenbrand and several of its subsidiaries for antitrust violations.

KCI alleged that Hillenbrand bundled its specialty beds with its standard hospital beds and conditioned discounts for standard beds on a customer's commitment to deal exclusively with Hillenbrand for its

specialty bed rentals. After seven years of discovery, a 21-day trial, and the admission of more than 680 exhibits into evidence, a jury awarded KCI more than $173.6 million. Under federal antitrust laws, that amount was tripled to $521 million—one of the largest antitrust verdicts in the history of the United States.

Background. Most specialty beds are rented to acute-care hospitals that contract with KCI or Hillenbrand through agreements negotiated with group purchasing organizations (GPOs). These contracts are then accepted by the GPOs' member hospitals. They last for three years or longer but provide for termination upon 60 to 90 days' notice.

In addition to specialty beds, Hillenbrand manufactures and sells standard hospital beds used in non-intensive-care units in hospitals. The majority of these sales are also made through GPO contracts. At trial, evidence established that standard hospital beds and specialty beds constitute two separate markets. In terms of revenue, the standard hospital bed market is more than twice the size of the specialty bed market. Hillenbrand had approximately 90% or more of the U.S. market share in standard hospital beds.

Exclusionary Conduct. In the early 1990s, Hillenbrand began conditioning additional discounts on standard hospital beds on a customer's commitment to use Hillenbrand as its sole source for specialty bed rentals. The contracts required a hospital to place at least 90% of its specialty bed rentals with Hillenbrand. Thus, 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, referred to as bundling, was the basis of KCI's claims.

At trial, KCI was required to demonstrate that Hillenbrand's practices harmed competition and consumers. KCI argued that it could match Hillenbrand's discounts in the specialty bed market; however, it could not match the additional incremental discount on the standard hospital beds. KCI claimed that consumers were denied choice and quality in their specialty bed selections, and the company presented evidence of such lack of choice through testimony from customers, who claimed Hillenbrand's offer of discounts on standard hospital beds could not be refused.

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Hillenbrand, offering little evidence in terms of valid business or efficiency justifications, argued that its bundled arrangement helped consumers by lowering prices. KCI rebutted by presenting evidence that Hillenbrand could easily lower prices without its bundling arrangements. Ultimately, KCI prevailed.

The GPO Debate

Over the past decade, the structure of the medical device industry has dramatically changed due to the growing presence of GPOs. However, whether this presence is beneficial to the healthcare market is an issue of great debate. Antitrust agencies, Congress, and state governments are paying close attention to the effects of GPO contracting arrangements.

GPOs negotiate contracts on behalf of their member hospitals. In return, they receive a percentage of the sale from a supplier as an administrative fee. GPOs also charge upfront marketing fees, private-label fees, and education fees. These fees are either retained by the GPO or returned as rebates to member hospitals.

The original expressed purpose of GPOs was to obtain better pricing on products than individual member hospitals could obtain on their own, as well as to provide value-added services. In recent years, some parties have started to debate whether these stated purposes have changed and whether consumers are actually receiving lower prices as a result of the activities of GPOs.

Although GPOs may reduce costs by giving hospitals greater bargaining power with suppliers, the growing consolidation and market power of GPOs has increased the exclusionary potential of certain GPO contracting practices. This is an antitrust concern.

Many small, start-up medical device manufacturers have claimed that contracting practices by GPOs have effectively foreclosed them from the market. Examples of alleged practices include sole-source contracts; bundling of products so hospitals must purchase the bulk of their supplies from a single vendor to qualify for a discount on any one product; and long-term contracts requiring significant commitment from hospitals in order to be eligible for GPO-negotiated discounts, known as market-share discounts.

Small manufacturers argue that incumbent suppliers, together with GPOs, use these practices to eliminate competition and preserve their market share. Thus, the activities of GPOs have frequently been an important element of antitrust disputes.

For instance, Retractable Technologies (RT; Little Elm, TX) developed the retractable VanishPoint

syringe, designed to improve safety by minimizing needlesticks. According to RT, its ability to market the syringe was impeded by exclusionary GPO agreements that favored other syringe manufacturers. RT claimed its prices were higher than conventional needles because it could not access enough of the hospital market to obtain the sales volume necessary to lower its per-unit costs. After a hard-fought antitrust suit, RT secured a settlement of more than $100 million on the eve of trial.[1]

Exclusionary Contracting

If a firm has little market power, arrangements such as bundling, market-share discounts, and sole-source contracts do not usually raise antitrust concerns. In fact, such practices can offer several efficiencies. They can give dealers incentives to devote themselves to the success of a brand. In turn, manufacturers have an incentive to support and invest in the success of their dealers because their sales will not be diluted by inter-brand free riding. The arrangements can also lower production costs and provide better tools for quality control and the protection of trade secrets and trademarks.[2]

However, when a dominant firm offers such arrangements, they can harm competition, leading to higher prices, lower quality, and less innovation. Exclusive contracting arrangements can facilitate collusion among competitors and help them maintain prices above competitive levels. Such practices can also facilitate exclusion. By denying competing firms access to the market share necessary to achieve their minimum efficient scale, exclusionary agreements can raise rivals' costs. This enables the firm with the exclusive contracting arrangement to raise prices. With competition diminished, the drive to innovate is dampened.

Exclusionary contracting practices of dominant firms are of particular concern in the medical device industry due to its considerable economies of scale. For example, if exclusionary contracting arrangements prevent innovative firms from accessing a large share of the market, their costs may be significantly higher. In addition, exclusivity arrangements may restrict access to capital markets, which may be reluctant to invest in a firm vying with a dominant firm. More-affordable and improved products may be precluded from the market. Innovation is also hindered when agreements enable firms to drive up their rivals' costs.

The following are descriptions of common exclusionary arrangements and their potential anticompetitive effects on the marketplace. Although these practices have the potential to enhance competition in certain instances, their use by dominant firms in the medical device industry can create barriers to entry, stifle competition, and diminish innovation essential to modern healthcare.

Bundling. Bundling occurs when a seller offers two or more products as a package and sells it for a single price. For example, a seller may offer a lower price on one product if the buyer also purchases one or more of the seller's other products.

Bundling is very similar to tying. Under a tying arrangement, the seller of a product conditions the sale of one product on the buyer's agreement to purchase a second product. The first product is known as the tying product, and the second is known as the tied product. The concern raised by a tying claim is that a firm with power in the tying product's market can use that power to restrain competition in the tied product's market.[3] In cases where a bundle of products is priced such that a hospital cannot realistically purchase the products individually, an illegal de facto tie can result.

Bundling allows a firm to use its advantage in one market to gain an advantage in one or more related markets. Under antitrust laws, it is illegal for a monopolist to act to preserve its monopoly through exclusionary conduct. Thus, bundling is anticompetitive if it allows a firm to monopolize or attempt to monopolize other complementary product markets.

Small companies and new market entrants may find it particularly difficult to compete against a bundled offer. For example, if a dominant vendor has a 90% market share in the bundled product and is offering a 4% discount on that product plus a 6% discount on the competitive product, another vendor must offer not only the 6% discount on its competing product but also offer the value of the 4% discount on the 90% market share product. Obviously few rivals can compete with such a bundling arrangement.[3]

Market-Share Discounts. Market-share discounting occurs when a seller offers a lower price on a product, usually through a rebate, if the buyer increases its purchases of the seller's product expressed as a percentage of its total purchases. For example, a buyer might earn a 1% rebate if the seller's products represent 60% of the buyer's purchases. This might increase to a 2% rebate at a 70% level, and so on. Firms that use market-share discounts often penalize buyers if they purchase competitive products, and such penalties often require buyers to forego the rebates they would earn under the agreement. GPOs argue that market-share discounts produce consumer benefits. When used by dominant firms, however, these discounts can force hospitals to contract with preferred suppliers and deter market entry by competing suppliers.

Other Exclusionary Practices. Exclusive arrangements can also exist within various other contracting provisions. For example, Dentsply International Inc. (York, PA), the nation's largest manufacturer of dental equipment and supplies, designed an exclusivity policy that prohibited dealers from purchasing competitive tooth lines and deterred competitors from actively promoting their product lines.[4] Dentsply's policy provided that authorized dealers could "not add further tooth lines to their product offering." In light of this policy, the Department of Justice (DoJ) filed a civil antitrust action against Dentsply. In February 2005, the U.S. Court of Appeals for the Third Circuit Court ruled that Dentsply's exclusivity policy violated Section 2 of the Sherman Antitrust Act and granted the government's request for injunctive relief.

The exclusive nature of contracts can also be exacerbated by their duration and by policies that require renewal prior to expiration. Even an exclusive contract of a short duration or that is terminable at will can have anticompetitive effects. For example, in response to DoJ's suit, Dentsply moved for summary judgment. The company argued that its practices could have few anticompetitive effects in light of the short-term nature of its agreements. However, DoJ successfully argued that the agreements were anticompetitive partly because they were self-perpetuating. DoJ provided evidence that the effect of Dentsply's agreement was to allow it to raise prices, restrict output, and reduce quality by preventing the distribution of superior artificial teeth.

When used by a dominant firm, practices such as bundling, market-share discounts, and other exclusive contracting arrangements discourage rivals from developing new and innovative products that may challenge a dominant firm's presence in the market. The economic costs of entering, expanding, and competing in the market are significantly increased. As a result, innovation and the development of next-generation products are inhibited. In an industry like medical devices, where there is rapid technological growth and high costs associated with switching technologies, these practices can have a significant anticompetitive impact.

Analyzing Exclusive Dealing Claims

A contract need not be 100% exclusive to be deemed anticompetitive when its incentives are strong enough to amount to de facto exclusive dealing. For example, many GPO sole-source contracts with suppliers require that a member hospital use a particular supplier for 90% of its needs, allowing the remaining 10% to be obtained elsewhere. Members can also choose not to accept the GPO contract and negotiate separate agreements with other vendors. However,

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a 90% compliance requirement can still be anticompetitive and result in de facto exclusivity. The Sherman Antitrust Act does not require literal exclusivity but rather prohibits conduct that unreasonably restrains competition. Moreover, the Supreme Court has emphasized the significance of examining the economic realities of a situation rather than formalistic definitions.[5]

For example, suppose a supplier has a contract with a GPO stating that it will provide 90% of the GPO's member hospitals' requirements for a medical device. If the contract requires membership compliance and if a rival cannot achieve minimum viable scale by serving 10% of the marketplace or paying a premium for some other distribution, then the contract will have the same anticompetitive effect as 100% exclusivity. Furthermore, even if other competitors can achieve scale, they may have high marginal costs. Thus, the dominant supplier can still achieve sufficient market power and maintain higher prices.[2]

Sometimes dominant firms suggest that any pricing is legal so long as it is above cost. Although there are some predatory pricing cases that support such a view, the better view is that even above-cost pricing can be anticompetitive.[6] For example, in the bundling cases described above, the exclusionary effect does not depend on any price below cost but on the economic benefits of the bundled purchase. For example, in *Kinetic Concepts,* Hillenbrand argued that to prevail with any of its claims, KCI had to prove that Hillenbrand's bundled prices were predatory and that there was substantial market foreclosure. However, the facts presented by KCI were sufficient to convince the jury of the coercive, exclusionary nature of the bundle.

Similarly, in *LePage's Inc.* v. *3M,* an en banc panel of the Third Circuit affirmed a jury verdict that found the use of bundled rebates by a dominant manufacturer could be an act of illegal monopolization.[7] 3M's bundled rebate programs involved discounts offered to certain customers conditioned on the purchase of six of 3M's product lines. The size of the rebate was connected to the number of product lines in which customers met specific growth targets. If the customer failed to meet the target in one product line,

it lost the rebate across all lines.

The court found that the precedent set in the predatory pricing claims did not apply to structured rebates that lowered prices. The court explained that the principal anticompetitive effect of such arrangements "is that when offered by a monopolist they may foreclose portions of the market to a potential competitor who does not manufacture an equally diverse group of products and who therefore cannot make a comparable offer." Thus, exclusionary arrangements present more than a simple pricing issue to be determined by a predatory pricing analysis. The competitive effects of such arrangements must be carefully analyzed, even when resulting prices are above cost.

Conclusion

Antitrust laws are designed to protect competition—not to punish successful firms that generate efficiencies and provide benefits to consumers. However, antitrust laws will condemn practices that restrict competition and harm consumers. In numerous sectors of the medical device market, innovation and competition has been harmed by the exclusionary practices of dominant firms. Antitrust litigation will increasingly play an important role in attacking these practices and protecting the role of innovative start-up firms in the market.

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