

Analyzing Medical Device Mergers

Scott Sher

Wilson Sonsini Goodrich & Rosati*



THIS YEAR, the Federal Trade Commission ("FTC") and European Commission ("EC") launched several high-profile medical device merger investigations, and already have issued several consents. In July 2006, the FTC required Hologic to divest prone stereotactic breast biopsy systems acquired from Fischer Imaging.¹ In March 2006, the FTC required Allergan to divest Inamed's under-development botulinum toxin product, prior to clearing the merger of those two companies.² In early 2006, both the FTC and European Commission completed their review of competing offers from Boston Scientific Corporation and Johnson & Johnson for Guidant Corporation, requiring the potential acquirers to divest multiple product lines before completing their acquisitions.³

Regulatory review of medical device mergers will only become more brisk in the future, as medical device mergers represent a

substantial percentage of today's M&A activity. According to a prominent health care research group, mergers involving medical device companies comprised approximately 60% of the dollar volume of all M&A activity in one recent month.⁴ And the trend toward consolidation will only accelerate. In 2005, there were nearly 1,000 deals in the health care industry (with pharmaceutical and medical device mergers making up the majority of that figure), representing \$158.7 billion of M&A activity.⁵

This drive toward consolidation is not surprising. The expenditures associated with bringing medical devices to market are high and the success rate is relatively low. In many medical device markets, it takes years to bring a product to market. New entrants must navigate thorny patent portfolios held by competitors; invest in costly and extensive distribution that often demands a specialized and trained sales force; and convince customers to switch from existing products with established track records to new and untested ones. Thus, acquisition is oftentimes the preferred exit strategy for

smaller medical device companies seeking to realize a return on their investment.

Despite the fact that companies in these industries have engaged in substantial M&A activity, the number of consent decrees from the antitrust agencies here and abroad involving medical device mergers remains limited. Neither the FTC nor the DOJ has had the opportunity to articulate a rubric by which to review medical device transactions, except in the most cursory manner through the very few conclusory analysis statements (i.e., DOJ competitive impact statements and FTC analyses to aid public comment) that have been issued in connection with several negotiated consents.

Nonetheless, counsel advising these clients are not left in a complete vacuum, since we can draw upon experience in the pharmaceutical industry for guidance when analyzing medical device mergers. The familiar and oft-deployed framework used by the FTC to review pharmaceutical mergers can easily be imported to the

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¹ See FTC Press Release, FTC Challenges Hologic/Fischer Imaging Deal (July 7, 2006), available at <http://www.ftc.gov/opa/2006/07/hologic.htm>; see also *In the Matter of Hologic, Inc. and Fischer Imaging Corporation*, Decision and Order, No. 051-0263 (July 7, 2006), available at <http://www.ftc.gov/os/caselist/0510263/0510263do.pdf>. This decision is significant for several reasons, including because it involved the challenge of a consummated deal that was not reportable under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (total deal value was \$32 million).

² See FTC Press Release, FTC Requires Divestiture Before Allowing Allergan's Acquisition of Inamed (Mar. 8, 2006), available at <http://www.ftc.gov/opa/2006/03/allergan.htm>; see also *In re Allergan and Inamed*, Decision and Order, No. C-4125 (Mar. 8, 2006), available at <http://www.ftc.gov/os/caselist/0610031/0610031AllerganInamedDecisionandOrderPublicRecordVersion.pdf>.

³ See FTC Press Release, FTC Requires Asset Divestitures Before Allowing Boston Scientific's \$27 Billion Acquisition of Guidant Corporation (Apr. 20, 2006), available at <http://www.ftc.gov/opa/2006/04/bostonsciGui.htm>; EC Press Release, Mergers: Commission clears, subject to conditions, takeovers of Guidant by Boston Scientific and of Guidant's vascular businesses by Abbott Laboratories (Apr. 11, 2006), available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/491>; see also FTC Press Release, FTC Requires Divestiture of Assets to Allow Johnson & Johnson's Purchase of Guidant Corp. (Nov. 2, 2005), available at <http://www.ftc.gov/opa/2005/11/jandj.htm>; EC Press Release, Mergers: Commission approves takeover of Guidant Corporation by Johnson & Johnson, subject to conditions (Aug. 25, 2005), available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/05/1065>.

⁴ "The month of April [2006] saw a surge of dealmaking in the Medical Device sector, with a total of 14 transactions announced. Based on revealed prices, the total amount spent to fund this activity was \$4.7 billion, or 59% of all M&A dollars spent during the month." Irving Levin Associates, *Medical Device Merger Mania*, *The Health Care M&A Monthly* (May 2006), available at <http://www.levinassociates.com/publications/mam/mamheadlines/06%20mamhead/605mamhead.htm>.

⁵ Irving Levin Associates, *The Year in Health Care M&A, 2005*, *THE HEALTH CARE M&A MONTHLY* (Jan. 2006), available at <http://www.levinassociates.com/publications/mam/mamheadlines/06%20mamhead/601mamhead.htm>.

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medical device industry.⁶ Some of the key issues—including the analysis of intellectual property, the impact of Food and Drug Administration (“FDA”) review, and complicated issues raised when structuring remedies—arise in both medical device and pharmaceutical merger cases.

In addition, we can look to the recent decision from the EC analyzing the proposed acquisition of Guidant by Johnson & Johnson for guidance in how to analyze some of the more significant issues involved when attempting to determine the competitive impact of mergers involving medical device companies.⁷ That decision set forth a very detailed framework for analyzing mergers in medical device industries.

This article explores three significant questions that companies contemplating medical device mergers should consider:

1. What are the boundaries of the relevant product market?
2. Are the barriers to enter the market—including IP, distribution and regulatory hurdles—so high that new participants are not likely to enter?
3. What are appropriate and likely remedies?

Given the relative dearth of decisions in this area, it is critical for medical device companies to consider carefully whether and how the antitrust process will affect the timing and likelihood of successful consummation. To that end, this article examines the results of several recent medical device merger investigations and the framework set forth by competition authorities in their analyses and decisions clearing these transactions.

I. What is the Appropriate Market Definition in Medical Device Mergers?

In the absence of any contested merger reviews in either pharmaceutical or medical device industries, it is unclear as to how the agencies will define the contours of the relevant market. Agency-issued decisions “in these matters are not very detailed; they generally allege relevant product markets in a conclusory manner with little support.”⁸ Despite the lack of an extensive body of law, however, the antitrust agencies here and abroad have articulated several defining principles regarding the appropriate bounds of the relevant product and geographic market. For example:

- A. **GEOGRAPHIC MARKET:** We know with relative certainty that in the United States, because of the existence of country-specific intellectual property rights, and because of FDA regulatory requirements, only companies sanctioned to manufacture and distribute products in the U.S. market will be considered participants in the antitrust relevant market. EU geographic market definition is different: it depends upon country-specific procurement, regulatory, intellectual property, and reimbursement policies and processes. As discussed below, the fact that competition differs from market to market can be helpful in predicting the likely effects of transactions in some geographic markets.
- B. **PRODUCT MARKETS ARE TAILORED CAREFULLY, BUT MARKET DEFINITION IS NOT CONSISTENT:** The agencies’ analysis of market definition in pharmaceutical and medical device mergers is not transparent, and not always obviously consistent. For example, the FTC has excluded from

the relevant product market drugs that treat the same conditions if the two drugs differ in any of the following manners: (a) contraindications involved with drugs using different active ingredients; (b) length of time that the therapy lasted; (c) strength of dosage; (d) delivery method; and (e) adverse effects. The guiding principle, however, is that the FTC defines markets narrowly in pharmaceutical merger reviews. Although we do not have the same extensive body of merger consents to analyze in medical device markets, we can assume that the FTC and DOJ will look at such mergers similarly.

This article, explores these two critical issues in turn.

A. The Relevant Geographic Market

Companies contemplating mergers in medical device markets should presume that the U.S. antitrust agencies will look only to a national market definition, and will not consider participants outside of the United States as part of the relevant market. Regulatory barriers, IP barriers and distribution barriers make it unlikely that the antitrust authorities would contemplate a global market.⁹ For example, as explained by the Department of Justice in its negotiated consent involving the acquisition of Instrumentarium by General Electric (“GE”), a combination of two companies that manufactured sophisticated monitoring devices used in hospitals:

The Complaint alleges that the relevant geographic market for the sale of critical care monitors is the United States. Any company seeking to sell a critical care monitor in the United States must register with the Food and Drug Administration (“FDA”) and receive approval for its products.

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⁶ Although the DOJ has reviewed a few medical device deals in the recent past—both involving General Electric—some in the DOJ, in fact, recognize that the FTC is the likely destination for most medical device merger reviews in the future. See ABA Antitrust Section, *Interview With Mark Botti*, ANTITRUST HEALTH CARE CHRONICLE (Mar. 2006), available at <http://www.antitrustreview.com/files/2006/03/Spring%202006%20Chronicle.pdf>.

⁷ *In re Johnson & Johnson and Guidant*, Commission Decision, No. COMP/M.3687 (Aug. 25, 2005), available at http://ec.europa.eu/comm/competition/mergers/cases/decisions/m3687_20050825_20600_en.pdf.

⁸ M. Howard Morse, *Product Market Definition in the Pharmaceutical Industry*, 71 ANTITRUST L.J. 633, 643 (2003).

⁹ As discussed in greater detail below, non-U.S. participants will be considered “potential entrants” in many instances.

. . . Thus, in the face of a small but significant increase in the price of critical care monitors, purchasers in the United States cannot turn to any producer of critical care monitors that has not received FDA approval for its products. . . .¹⁰

In addition to country-specific IP rights and regulatory schemes, the need for a local sales and distribution presence likely affects geographic market definition analysis in medical device mergers. It is highly unlikely that a physician or hospital would purchase a device from a non-U.S.-based supplier if that supplier did not have a local presence to service, replace and provide training on the equipment. Oftentimes, medical devices are highly sophisticated pieces of equipment, and even in the face of a post-merger anticompetitive price increase, physician or hospital customers are unlikely to switch to a supplier who can not easily provide them with the necessary services for their product.

The European Commission likewise has contemplated that geographic markets in medical device industries are national—rather than EU-wide or global—due to unique conditions that exist from country to country. In *Johnson & Johnson / Guidant*, for example, the EC concluded that (1) regulatory processes differ from country to country; (2) reimbursement schemes vary by country; and (3) procurement processes differ widely between countries. As a result of these differences, the Commission

concluded that prices and market shares vary widely by country.¹¹

In its *Guidant* decision, the European Commission specifically looked to the likely effects of the merger in certain markets by analyzing pricing differentials in countries where there were more or fewer competitors, depending upon country-specific IP and regulatory barriers.¹²

Similarly, the existence of national markets can help guide the FTC's antitrust review of the likely competitive effects of medical device mergers in the United States. In particular, because foreign regulatory bodies responsible for the approval of medical devices are more lax than the U.S. FDA, companies often are able to launch their products earlier abroad than in the United States. Thus, the FTC may have a glimpse of future competition by looking to jurisdictions where multiple parties already have received clearance from the appropriate regulatory bodies.

For example, in one recent non-public merger investigation involving medical devices, the FTC was able to determine the likely competitive impact of a merger between two medical device companies where only one was approved for sale in the United States (and the other was expecting eventual FDA approval), but in Canada both parties competed. Because prices were substantially lower in Canada where both parties already competed than in the United States where only one participated, the FTC reasonably could conclude that the combination of the two parties in the

United States likely would harm competition, as it would deprive U.S. customers of the benefit of pricing competition, as evidenced in Canada.

B. Narrowly Tailored Product Markets

Companies contemplating mergers in medical device industries must consider that the agencies will define markets narrowly. Sophisticated customers—including doctors, pharmacists, and hospitals—that explain their understanding of the market to the FTC and DOJ inevitably will have a substantial impact upon the agencies' ultimate determination of the contours of the relevant product market, and differentiate between alternative therapies depending upon the unique characteristics of each. In addition, in pharmaceutical and medical device mergers, these customer-physicians are far less likely to switch from their established and known product set to new and untested alternatives, which likely biases their definition of the market. As a result, in many such industries, the SSNIP test likely will yield narrow market definitions. As noted by Howard Morse in his article providing an extensive discussion of product market definition in pharmaceutical markets: "the FTC appears to start with a presumption of narrow markets" in contrast to the dictates of the 1992 Merger Guidelines which require the agencies to take a broader and more holistic approach to market definition.¹³

In past pharmaceutical cases, the agencies have looked to the following characteristics to determine the scope of the relevant

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¹⁰ *United States v. General Elec. Co. and InnoServ Tech. Inc.*, Competitive Impact Statement, No. 1:98cv01744 (July 14, 1998), available at <http://www.usdoj.gov/atr/cases/f1800/1843.pdf>; see also *In the Matter of Hologic, Inc. and Fischer Imaging Corp.*, Analysis of Agreement Containing Consent Order to Aid Public Comment (July 7, 2006), available at <http://www.ftc.gov/os/caselist/0510263/0510263analysis.pdf> ("The relevant geographic market . . . is the United States. Prone SBBs are medical devices, and thus cannot be marketed or sold in the United States without prior approval by the [FDA]. Further, a firm wishing to sell prone SBBs in the United States must establish a local sales and service organization and must not infringe any U.S. patents."); *In re Medtronic Inc. and Physio-Control Int'l Corp.*, Analysis of Proposed Consent Order to Aid Public Comment (Oct. 1, 1998), available at <http://www.ftc.gov/os/1998/10/9810324ana.htm> ("The relevant geographic market is the United States. Only companies that have received U.S. Food and Drug Administration approval to sell their devices in the United States may supply automated external defibrillators to U.S. customers.").

¹¹ In *Guidant*, the European Commission noted that even though prices differed widely by country, "virtually no customer has affirmed to source the products from abroad . . . [M]any have reported that sourcing from abroad is too risky in terms of inventory management and regular updates on products." *In re Johnson & Johnson and Guidant*, *supra* note 7, at 67-69.

¹² See generally *id.*

¹³ See Morse, *supra* note 8, 71 ANTITRUST L.J. at 643-44. In medical device mergers, the antitrust agencies usually consider the potential theory of harm to be unilateral rather than coordinated. Thus, the ultimate value of the market definition analysis may be minimal. Even with multiple participants in the "relevant market," the agencies worry about the effects of combining two close substitutes, and whether that combination will enable the merged entity to raise prices without the concern that customers will turn to another product in the "relevant market" because that other product is insufficiently similar to the merging parties' products. This issue goes beyond the scope of this article, but promises to be an important and ongoing debate in industries where the products are heterogeneous. See Marc Schildkraut, "Oracle and the Future of Unilateral Effects," ANTITRUST (May 2005).

product market, although they have not applied such criteria consistently:

- the disease or condition that the class of drugs treats;¹⁴
- the drug's chemical compound (i.e., active ingredient);¹⁵
- the dosage frequency and level required;¹⁶
- the drug's method of delivery; and¹⁷
- whether the drug is branded or generic.¹⁸

For example, in the recent consent decree involving Allergan and Inamed, the FTC defined a relevant product market to include only botulinum toxin, a product used to treat wrinkles caused by repetitive muscle movement.¹⁹ Even though "there are many products and procedures that can be used to treat facial wrinkles, such as dermal fillers, topical creams, lasers, chemical peels, and surgery, botulinum toxin therapy is sufficiently differentiated from these other products and procedures that they are not close economic substitutes."²⁰ Thus, even though there are many classes of devices used to treat wrinkles, the FTC limited the product market definition to a particular type of device—botulinum toxin—because of its unique product characteristics.

The FTC's analysis in the Allergan / Inamed merger likely was guided by sophisticated doctors, hospitals and "thought leaders" in the industry who were able to explain to the agency the differentiated nature of

the varying wrinkle treatments, and how some treatments were more appropriate and longer-lasting for certain patients than others, and that there were no adequate substitutes for botulinum toxin for certain treatments. Again, in medical device deals, customers are sophisticated and their reaction to the impact of transactions and parties' arguments regarding competitive effects are extraordinarily important in the agencies' ultimate determination of the appropriate bounds of the product market.

In its decision to unwind the Hologic / Fischer Imaging merger, the FTC defined the relevant product market to include only prone stereotactic breast biopsy systems ("SBBS"), which allow physicians to "conduct a highly precise, minimally-invasive breast biopsy using x-ray guidance."²¹ Not only were alternative minimally-invasive biopsy systems excluded from the product market (i.e., ultrasound and magnetic resonance systems), but also were "upright" (as opposed to prone) SBBSs. Ultrasound and magnetic resonance systems were excluded from the relevant product market because they were not suited to remove microcalcifications (small lesions) and were more "cumbersome and time consuming compared to" prone SBBSs.²² Upright SBBSs—which are used for the same types of minimally-invasive breast biopsies as prone SBBSs—were excluded from the market because they caused more discomfort for patients during the biopsy procedure and their usage required additional equipment that could otherwise

be deployed by breast centers to perform mammographies, thus lowering the number of mammographies that could be performed by the breast center each day. Even though they were "much less expensive" than prone SBBSs, they were not considered part of the relevant market.

In its analysis of the Boston Scientific / Guidant merger, the FTC likewise defined markets narrowly. The merger combined two companies that manufactured drug eluting stents ("DES") (among other products).²³ The FTC narrowed one product market definition to a subset of DES devices, including within the relevant product market only one method by which the DES was deployed to the coronary artery. According to the FTC's analysis to aid public comment: "The two most common types of delivery systems in the United States are over-the-wire and Rapid Exchange ("RX"). Over-the-wire delivery systems employ a long guidewire and require two operators to implant the DES. In contrast, RX delivery systems employ a shorter guidewire that can be handled by a single operator."²⁴ The FTC concluded that DES providers without the capability to use RX delivery could not act as competitive constraints on the parties.

Moreover, the FTC, in its merger analyses of drug consolidations, often presumes that patients that rely on particular therapies are "locked in" and will not switch to therapies using different active ingredients, presumably because it could be dangerous—or at a minimum ill-advised—for a patient to

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¹⁴ See FTC Press Release, Pfizer, Pharmacia Will Divest Assets to Settle FTC Charges (Apr. 14, 2003) (treatments for erectile dysfunction), available at <http://www.ftc.gov/opa/2003/04/pfizer.htm>.

¹⁵ See FTC Press Release, FTC Requires Divestitures in Connection with Baxter's Purchase of Wyeth's Generic Injectable Drug Business (Dec. 20, 2002), available at http://www.ftc.gov/opa/2002/12/baxter_wyeth.htm.

¹⁶ See FTC Press Release, Consent Order Resolves Charges that Biovail and Elan Agreement Unreasonably Restrained Competition in Market for Generic Hypertension Drug (June 27, 2002), available at <http://www.ftc.gov/opa/2002/06/biovailelan.htm>.

¹⁷ See FTC Press Release, Resolving Anticompetitive Concerns, FTC Clears \$16 Billion Acquisition of Immunex Corp. By Amgen Inc. (July 12, 2002) (merger investigation where the FTC defined the relevant markets by the mechanism of action), available at <http://www.ftc.gov/opa/2002/07/amgen.htm>.

¹⁸ See FTC Press Release, Preserving Competition, FTC Requires Divestitures Before Allowing Teva's \$7.4 Billion Acquisition of IVAX (Jan. 23, 2006), available at <http://www.ftc.gov/opa/2006/01/tevaivax.htm>.

¹⁹ See, e.g., *In re Allergan Inc. and Inamed Corp.*, Analysis of Agreement Containing Consent Orders to Aid Public Comment, No. C-4156 (Mar. 8, 2006), available at <http://www.ftc.gov/os/caselist/0610031/0610031AllerganInamedAnalysis.pdf>.

²⁰ *Id.*

²¹ *In the Matter of Hologic, Inc. and Fischer Imaging Corp.*, Analysis of Agreement Containing Consent Order to Aid Public Comment, *supra* note 10, at 3.

²² *Id.*

²³ See *supra* note 3.

²⁴ *In re Boston Scientific Corp and Guidant Corp.*, Analysis of Agreement Containing Consent Order to Aid Public Comment, No. 061-0046 (Apr. 20, 2006), available at <http://www.ftc.gov/os/caselist/0610046/0610046analysis060420.pdf>.

switch. Such lock-in concerns lead the agencies to define markets narrowly. The FTC also presumes that once a particular patient has begun a course of treatment with a drug that relies upon one active ingredient, the patient will not switch to a drug using a different active ingredient, even in the face of an anticompetitive price increase.²⁵ The FTC is wary of presupposing that patients' demands are price-elastic—after all, once a doctor has chosen a drug regimen for a life-threatening condition, for example, no plausible price increase would cause the marginal customer to switch therapies and risk compromising treatment.²⁶

The same is true for many medical devices. For example, in the European Commission's analysis of the Johnson & Johnson / Guidant transaction, the EC noted that—in its analysis of the effect of the merger on the carotid stenting market—that “carotid angioplasty is a complex procedure, with potential life-threatening consequences. As errors can be fatal, physicians are more reluctant to switch between brands unless there is very clear evidence of clinical superiority.”²⁷

II. Entry Barriers

The medical device industry, like the pharmaceutical industry, is characterized by high entry barriers, in the form of high capital costs to enter, rigorous IP protection, and demanding regulatory approval requirements.

A. Capital Investments

In its pharmaceutical and medical device cases, the FTC sets forth in its Complaints the extensive entry costs associated with successful participation in these markets.

Customer Goodwill. In many medical device markets, a supplier must build a strong relationship with the customer, and must have a solid brand reputation. In medical device industries, competition often takes place at the quality—rather than pricing—level of the competing products. In that regard, established players in these markets—companies with long operating histories and a diversity of successful products—are often considered more reliable. Without strong brand recognition, competitors will not survive. As the FTC noted in an earlier medical device merger, the combination of SNIA S.p.A. and COBE Cardiovascular (two heart-lung machine manufacturers):

*A new entrant into this market would need to undertake the difficult and time-consuming process of . . . establishing a nationwide service and sales network and gaining customer acceptance. This is a very difficult process for new entrants because manufacturers are reluctant to establish a nationwide service and sales network until they have gained customer acceptance and have an established customer base, and customers are reluctant to purchase from a supplier unless it has an established service and sales network. As a result, a new entrant often finds itself in a “Catch 22” problem. For these reasons, new entry into the market would not be timely, likely or sufficient[.]*²⁸

Sales Force / Distribution. Medical devices are not software. They are not easy to sell, and developing a qualified direct sales force, credible after-sales service, and training capability for physicians is a difficult task.

For example, in the review of the Johnson & Johnson / Guidant proposed merger, the European Commission noted:

*[E]stablishing a new direct sales force, the key determinant of market success, would require the recruitment of sales people. . . . Sales representatives in the vascular business are the main point of contact between the suppliers and the physicians: their role is not only to introduce the products in the operating theatre, but also to disseminate the results of scientific studies and clinical trials and to be able to respond to requests of assistance from the doctors. Sales representatives have often worked within the hospital (as specialized nurses, for example) before joining a supplier's sales force.*²⁹

Distribution cannot be understated as a potential barrier to entry in medical device markets. Even more so than in pharmaceutical cases—where the quality of sales representatives is less critical—a credible sales force is difficult to develop. Sales representatives in medical device industries often have significant technical training in selling the product, and often act not only as company representative, but also, often as a technical assistant to the physician purchasing the product. In some industries, for example, sales representatives teach the physician how to operate the device being purchased, and provide after-sales technical support.

Product Range. Although such consideration is anathema to the principles guiding U.S. antitrust law, the European Commission continues to consider product range (or “portfolio”) as an entry barrier in

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²⁵ See, e.g., Hoechst Marion Roussel, Inc. & Andrx Corp., FTC Docket No. 9293 (Mar. 16, 2000) (Complaint ¶ 12), available at <http://www.ftc.gov/os/2000/03/hoechstandrxycomplaint.htm>.

²⁶ *Id.*

²⁷ *In re Johnson & Johnson and Guidant*, *supra* note 7, at 213.

²⁸ *In re SNIA S.p.A. and COBE Cardiovascular*, Analysis of Proposed Consent Order to Aid Public Comment, No. C-3889 (May 14, 1999), available at <http://www.ftc.gov/os/1999/05/sniaanai.htm>. Likewise, in requiring the parties to divest the target's endotracheal tubes, the FTC noted in its analysis of the merger of Tyco and Mallinckrodt, Inc., that “[e]ntry is further hampered by the fact that endotracheal tubes are critically important to customers, though relatively inexpensive, so customers would be reluctant to consider new, unproven products even in the face of higher prices.” *In re Tyco Int'l Inc. and Mallinckrodt, Inc.*, Analysis of Consent Order to Aid Public Comment, No. C-3985 (Oct. 17, 2000), available at <http://www.ftc.gov/os/2000/10/tycoanalysis.htm>.

²⁹ *In re Johnson & Johnson and Guidant*, *supra* note 7, at 53. In addition, oftentimes, medical devices are expensive durable goods that are not replaced often, or purchased in bulk quantity. Thus, potential new entrants are faced with the further difficulty of not having many sales opportunities to gain new customers and a foothold in the market. As the FTC noted in *Tyco*: “new entry into the endotracheal tube market is made more unlikely because of long-term hospital group purchasing organization contracts that may reduce the amount of sales opportunities available to new entrants.” *In re Tyco*, Analysis of Consent Order to Aid Public Comment, *supra* note 28.

merger analysis. In its *Guidant* decision, the EC noted that "product range is an asset in this business." Suppliers indicated during the market investigation that having a broad product portfolio is a successful factor in the peripheral business.³⁰ The EC concluded that it was relevant in the merger analysis to determine whether the combination would provide Johnson & Johnson with a leading position in several medical device markets. Although companies contemplating mergers in medical device industries need not worry that the U.S. antitrust agencies will consider product range a barrier to entry, in the EC's analysis, product portfolio is still a significant factor to consider.

B. Intellectual Property

One of the most significant entry barriers in medical device mergers is the existence of IP rights. In its *Guidant* decision, for example, the European Commission closely examined the patent portfolio of each of the parties in the affected markets on a national, EU-wide, and global basis to determine whether the transaction would effectively block competitors from entering the market.

Because IP rights are country-specific, it is critical to analyze the IP portfolio of all identified potential competitors to determine whether entry into the U.S. market is characterized by different hurdles than elsewhere. In *Guidant*, the EC determined that in Europe, the patent landscape was such that the parties' combined patent portfolio would not adversely affect competition in the drug eluting stent market, whereas in the U.S., the situation was far different.³¹

In the United States, patents had been granted on rapid exchange ("RX") technology to only several parties. In Europe, however, RX technology was not patentable, and as a

result, entry was far easier.³² Thus, whereas in the United States, potential competitors such as Medtronic were foreclosed because of IP litigation from entering into the RX DES market, in Europe they were not.³³ As a result, the European Commission concluded that it was "reasonably expected that the concentration will not significantly impede effective competition in the Common market" because "new entrants, primarily Medtronic and Abbott . . . are likely to compensate for the loss of competition resulting from *Guidant's* exit from the marketplace."³⁴ The EC reasoned that:

*The patent landscape in Europe is very different from the US for a number of reasons: first the patent coverage of these devices is much narrower [in Europe] than in the US, for example some primary patents on RX technology have never been granted in Europe; second, many interventional cardiology device patents have earlier expiry dates in Europe; third, European courts tend to be less interventionist than their US counterparts and more sensitive to public interest arguments. . . . Finally in the USA an injunction under a US patent in any federal court is effective throughout the USA whereas to achieve the same effect in the EU one would need to initiate country by country infringement actions.*³⁵

In addition, in medical device merger analysis, the agencies likely will be interested not only in the existing individual IP rights of each of the parties, but also whether, for example:

- the proposed merger would result in an intellectual property portfolio that is "blocking," meaning that potential

competitors could not enter the market because there is no legitimate work-around of the parties' IP rights as the IP portfolio of the merging parties occupied the entire field.³⁶ In fact, the doctrine of innovation competition probably is strongest in medical device and pharmaceutical mergers. Competition in these industries revolves around the ability to innovate and is predicated upon research and development efforts. "In industries where the main focus of competition is the development of new technologies rather than price competition, antitrust principles will apply, and competitive rivalry must be protected. If an entity acquires the ability to innovate in a relevant market, and substitutes are lacking, competition may suffer."³⁷

- the parties have asserted their collective IP rights against competitors, or have contemplated doing so. The FTC maintains that if the parties have asserted IP rights against competitors and the infringement litigation against those competitors is pending, absent a very strong showing to the contrary, that the third parties against whom the IP rights have been asserted are not likely to represent competition to the merging parties on a going-forward basis. The FTC reasons that it is not in a position to successfully engage in its own assessment of the strength of each party's position in IP litigation; instead, the FTC will presume that the merging parties' litigation is meritorious, and will be able to exclude the third-parties that they have sued.

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³⁰ *In re Johnson & Johnson and Guidant*, supra note 7, at 56.

³¹ *Id.* at 148.

³² *Id.* at 41.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.* at 38.

³⁶ See, e.g., *In the Matter of Hologic, Inc. and Fischer Imaging Corp.*, Analysis of Agreement Containing Consent Order to Aid Public Comment, supra note 10, at 4 (noting that Hologic could compete with Fischer "only by virtue of a license to the Fischer patents that Hologic acquired as part of the settlement of patent infringement litigation"); *In the Matter of Boston Scientific Corp. and Guidant Corp.*, Analysis of Agreement Containing Consent Order to Aid Public Comment, File No. 061 0046, supra note 3.

³⁷ David A. Balto and James F. Mongoven, *Antitrust Enforcement in Pharmaceutical Industry Mergers*, 54 FOOD & DRUG L.J. 255, 267 (1999). The Merger Guidelines specifically recognize that a transaction may lessen competition in such non-price attributes as "product quality, service, or innovation." DEP'T OF JUSTICE AND FEDERAL TRADE COMM'N, 1992 HORIZONTAL MERGER GUIDELINES ["1992 Merger Guidelines"] § 0.1, n.6 (revised Apr. 8, 1997), available at http://www.usdoj.gov/atr/public/guidelines/horiz_book/toc.html.

■ the parties have contemplated bringing IP enforcement litigation against third parties. If parties believe that they could assert patent rights post-merger, but simply have voluntarily refrained from doing so up until the time of the merger, the FTC will consider that fact relevant in analyzing whether such "threatened" third parties represent valid competitive threats going forward, or whether the merging parties believe that they could force them to exit with future patent infringement litigation.

IP rights have been at the forefront of several medical device merger reviews. For example, in the FTC's review of the merger between Boston Scientific and Cardiovascular Imaging Systems, Inc. ("CVIS"), the parties were engaged in an early-stage patent litigation.³⁸ Boston Scientific argued "the acquisition should be allowed because . . . it would resolve ongoing patent disputes between the companies."³⁹ The FTC disagreed, concluding that because "the patent litigation was in its early stages and the ultimate outcome was far from certain . . . and there was no reason that the litigation must end in an adjudicated decision that would require [one party] to exit the market."⁴⁰

The FTC further reasoned that in the patent litigation, Boston Scientific argued that CVIS' patent claims were weak and that it

would not be required to exit the market; on the other hand, in the antitrust case, Boston Scientific contended that the merger would settle a patent case that would eliminate the uncertainty created by CVIS' strong patent position.⁴¹ It appears that absent an overwhelming showing that the patent case would result in the exit of one of the parties, and only where the patent case has proceeded through advanced stages of litigation, will the FTC consider it significant in the merger analysis. Otherwise, the FTC likely will simply conclude that the litigation has little bearing on the determination of the effect of the merger.

The role of intellectual property must not be minimized.⁴² Any company contemplating a merger in the medical device field must not only consider whether it has the ability to block its competitors, but also whether the synergy of the parties' portfolios is such that combined, the parties can block competitors from entering the market, and whether the other party has contemplated—even if it has not yet brought—an IP case against other firms in the market.

C. Regulatory Approval

In no other industry is it as easy to identify likely entrants into a market. All medical devices are subject to a rigorous review process by the Food & Drug Administration ("FDA"). The FDA process can be long and arduous, and in almost all circumstances,

an "uncommitted entrant"—in other words, a party who has not begun the FDA approval process—cannot possibly be considered a likely entrant for purposes of merger analysis because such a party unquestionably must wait more than two years for FDA approval—the outer bounds of time for a party to be considered a possible entrant for entry analysis under the 1992 Merger Guidelines.⁴³

In addition, the FDA process makes it possible to track the stage of development and likelihood of entry of a potential FDA-pipeline candidate. Medical devices are subject to the Federal Food Drug & Cosmetic Act ("FFDCA"), which outlines the baseline requirements that apply to all medical devices necessary for marketing, proper labeling and monitoring performance once the device is on the market.⁴⁴ The process involves first determining whether the device at issue meets the definition of a medical device as defined by the FFDCA. The next step is classification of the medical device to determine the level of regulatory control that is necessary to assure the safety and effectiveness of the device. Following that, data and information must be developed in order to submit a marketing application and to obtain FDA clearance to market. Often clinical performance data is required to obtain clearance, and the trial must be conducted in accord with FDA's

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³⁸ See Scott A. Sher, *The Settlement of IP Disputes Through Merger and The Thicket of Probabilistic Competition*, THE THRESHOLD, at 11 (Summer 2005); M. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 GEO. MASON L. REV. 359, 375 (Spring 2002).

³⁹ *FTC v. Boston Scientific Corp.*, No. 95-00198, Memorandum of Points and Authorities in Support of the Federal Trade Commission's Motion for Preliminary Injunction, at 40 (D.D.C. Jan 27, 1995).

⁴⁰ *Id.*

⁴¹ See Sher, *supra* note 38; Morse, *supra* note 38, 10 GEO. MASON L. REV. at 375-76.

⁴² Of course, in some instances, the IP analysis is relatively straight forward, and does not require substantial analysis. If there have been no recent entrants into a market, and the likely participants state that they did not enter because of blocking IP rights by one of the incumbent suppliers, that itself likely ends the IP analysis, as it is obvious to the market that IP is an insurmountable barrier. If others have entered, notwithstanding the existence of the patent portfolio, that is evidence that IP is not a barrier to entry.

⁴³ This article focuses on medical devices subject to the IDE process, which as discussed below is time consuming and expensive. There are a whole host of medical devices, including scissors, band-aids and rubber gloves, for example, that do not require substantial FDA investigation prior to approval. These devices are approved via the 510(k) process—a premarket notification to the FDA that explains that the device belongs to a category already sanctioned by the FDA for manufacture and sale—which takes substantially less than two years, and requires a relatively small capital investment. In these product markets, the regulatory process is not likely an entry barrier. See U.S. Food & Drug Administration, 510(k) Overview, available at <http://www.fda.gov/cdrh/510k.html>.

⁴⁴ See *Getting to Market with a Medical Device*, U.S. Food and Drug Administration Center for Devices and Radiological Health, available at <http://www.fda.gov/cdrh/devadvice/3122.html>.

Investigational Device Exemption ("IDE") regulation. Generally, clinical trials are conducted in three phases, and many times take far longer than two years.⁴⁵

The FDA regulatory scheme governing medical devices is burdensome, making entry difficult, expensive and time-consuming. As noted by the FTC in its consent approving the acquisition of Guidant by Boston Scientific:

*Developing and receiving FDA approval for a DES is difficult, time-consuming and expensive. It can take hundreds of millions of dollars of research and development, significant funding for clinical trials, and an extensive amount of time to reach even the stage of seeking FDA approval. The regulatory process itself can also be time-consuming because the FDA reviews the volumes of materials and data a company submits in support of its application for approval. Considering all these factors, entry into the manufacture and sale of DESs is impossible to achieve within two years.*⁴⁶

The FDA regulatory process is thus significant for two primary reasons. First, it provides a schedule for the FTC to consult to assess the likelihood and timing of entry for potential entrants.⁴⁷ A device company not far along in trials is not likely to meet the criteria for entry required under the 1992 *Merger Guidelines*. Additionally, the process provides a good proxy for the time and cost of entry, and in almost all circumstances, a company not far along in the FDA process is not a good candidate for a timely entrant (within two years) or a likely one (due to high failure rates).

III. Likely Remedies

Divestiture is the preferred remedy in most merger cases, and the same holds true in medical device merger review. The FTC and DOJ have in almost all instances required divestiture to solve competitive problems, and where they have not required divestiture, they have encountered substantial post-closing concerns.⁴⁸

For example, in 1994 Boston Scientific agreed to acquire Cardiovascular Imaging Systems, Inc. ("CVIS") and SCIMED Life Systems, Inc. The three companies manufactured

and sold intravascular ultrasound ("IVUS") catheters.⁴⁹ The FTC settled with the parties, and rather than demand divestiture, the FTC instead required Boston Scientific to license its IVUS patents to Hewlett Packard and undertake other obligations to ensure that HP had access to BSC improvements in the technology.

In October 2000, the government was forced to bring suit against Boston Scientific to enforce the terms of the settlement. The FTC alleged that Boston Scientific effectively circumvented its obligations under the terms of the settlement. The continuing relationship, according to the Complaint, led to significant problems as Boston Scientific failed to license necessary technology and improvements to HP in a timely manner—or in some instances, at all. The FTC concluded that the licensing remedy had failed, as Boston Scientific had the ability and incentive to ensure that its competitor—HP—did not have the tools to succeed in the market.⁵⁰ The Court agreed.⁵¹

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⁴⁵ See Carol Rados, *Inside Clinical Trials: Testing Medical Products in People*, FDA Consumer Magazine (Sept./Oct. 2003), available at http://www.fda.gov/fdac/features/2003/503_trial.html ("Phase 1 trials try to determine dosing, document how a drug is metabolized and excreted, and identify acute side effects. Usually, a small number of healthy volunteers (between 20 and 80) are used in Phase I trials. Phase 2 trials include more participants (about 100-300) who have the disease or condition that the product potentially could treat. . . . In Phase 3 trials, the drug is studied in a larger number of people with the disease (approximately 1,000-3,000).").

⁴⁶ One could look to the pharmaceutical industry, by analogy. For example, in a recent article by Ilene Gotts and Richard Rapp, the authors described how pharmaceutical merger review has evolved to include potential competition in existing and future goods. Ilene Knable Gotts & Richard T. Rapp, *Antitrust Treatment of Mergers Involving Future Goods*, Antitrust, at 100 (Fall 2004). The authors note that the average time a successful drug spends in Phases I through III is greater than 8 years. *Id.* at 102. They also point to data indicating that a new drug's probability of failure in Phase I is 81%, which declines to 57% in Phases II and III. Ultimately, the overall success rate for such drugs is 26%. *Id.* Thus, the authors concluded that only companies with products in sufficiently late stages of development represented true competitive threats worthy of consideration by the antitrust agencies in their merger analysis. Products that were not well into Phase III were considered too remote and insufficiently likely to succeed in the market to be considered viable competitive threats. The same is true for the medical device industry, where although the regulatory scheme is different, it nonetheless results in a substantial number of products never reaching market, and takes a considerable amount of time to complete.

⁴⁷ As noted by David Balto, "[t]he pharmaceutical industry . . . is uniquely suited for potential competition analysis. Because the required FDA approval process for new drugs takes several years to complete, is transparent, and fairly predictable, the FTC often is able to determine which firms are likely to enter a relevant market during a specific time period." David A. Balto & James F. Mongoven, *Antitrust Enforcement in Pharmaceutical Industry Mergers*, 54 FOOD & DRUG L.J. 255, 265-66 (1999). Thus, because "competition from a new product can be predicted . . . its competitive potential can be assessed." *Id.* at 266.

⁴⁸ See U.S. Dep't of Justice, Antitrust Division, Antitrust Division Policy Guide to Merger Remedies (Oct. 2004), available at <http://www.usdoj.gov/atr/public/guidelines/205108.htm> ("Structural remedies are preferred to conduct remedies in merger cases because they are relatively clean and certain, and generally avoid costly government entanglement in the market.").

⁴⁹ See FTC Press Release, FTC Will Ask Court to Block Boston Scientific Acquisition of Cardiovascular Catheter Company (Jan. 19, 1995), available at <http://www.ftc.gov/opa/1995/01/boston-sci.htm>.

⁵⁰ See FTC Press Release, Department of Justice Sues Boston Scientific Corp. Seeking Civil Penalties and Other Relief for Violations of 1995 FTC Order (Jan. 19, 1995), available at <http://www.ftc.gov/opa/2000/10/bscfinal.htm>.

⁵¹ *United States v. Boston Scientific Corp.*, 167 F. Supp. 2d 424 (D. Mass. 2001).

As noted in the FTC's 1999 Divestiture Study, and as reinforced in guidelines subsequent, absent compelling circumstances that make divestiture impossible, or would cause a diminution in realized efficiencies of the merger, it is most likely that the agencies will require divestiture to resolve competitive concerns in medical device industries.⁵²

That does not end the story. Any divestiture must also include assets necessary to continue the viability of the product line, including any relevant IP, confidential information, employees necessary to continue R&D and development, and other relevant assets.⁵³ For example, in its consent in the Allergan / Inamed merger, the FTC required the divestiture not only of Inamed's in-development botulinum toxin product, but also: "development and distribution rights, including the ongoing clinical trials and [] intellectual property . . . ; confidential business information . . . and [provide the opportunity to the acquirer] to enter into employment contracts with certain key individuals who have experience" with the product under development.⁵⁴

Likewise, in its consent in the Boston Scientific / Guidant merger, the FTC required Boston Scientific to divest "four existing manufacturing facilities and one currently under construction To minimize the possibility of supply disruptions and to prevent information exchanges between Abbott and Boston Scientific during the transition period, the Consent Agreement requires Abbott and Boston Scientific to enter into interim transitional service and confidentiality agreements."⁵⁵

Medical device companies contemplating a merger that will likely require remediation from the antitrust agencies must ask themselves—early in the process—whether it is possible (1) to divest a business unit, including the necessary licensing of IP, transfer of know-how and employees, without disturbing other business units; (2) to avoid a situation where the acquirer must rely upon the parties for their future success; and (3) most fundamentally, whether there is a suitable purchaser for the divested assets—meaning whether there is a buyer who can maintain the competitive

viability of the assets acquired. Without all three, the agencies are likely to conclude that a remedy is not possible, and will be more likely to challenge the transaction.

The issues raised in medical device mergers are unique and the question of the appropriate framework to review such transactions remains unsettled. As the number of such mergers increase, it will become increasingly important for the antitrust agencies here and abroad to more carefully consider issues surrounding market definition, entry barriers and appropriate remedies. With the merger mania in these markets continuing, the FTC and other agencies will have ample opportunity to publish statements, consents, and papers regarding transactions in these markets, and one day soon, there likely will be a merger challenge which will force the parties, government and the courts to more carefully contemplate and set forth the appropriate Section 7 analysis. ■

⁵² See Federal Trade Commission Bureau of Competition Staff, A Study of the Commission's Divestiture Process (1999) ("FTC Divestiture Study"), available at <http://www.ftc.gov/os/1999/08/divestiture.pdf>.

⁵³ *The Hologic / Fischer* decision and order requires Hologic to divest assets, license patents, provide past and present customer lists, supplier contract information, FDA information related to the divested assets, and all sales and service contracts. See *In the Matter of Hologic, Inc.*, Agreement Containing Consent Order, File No. 051-0263 (July 7, 2006), available at <http://www.ftc.gov/os/caselist/0510263/0510263agreement.pdf>.

⁵⁴ See *supra* note 2.

⁵⁵ See *supra* note 3.