Medical Device Mergers: Practical Considerations That Can Help Minimize The Impact Of Regulatory Review

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Medical device companies contemplating mergers are often surprised to learn that even relatively small transactions can generate considerable interest at the Federal Trade Commission (FTC)[1] and a variety of foreign antitrust agencies[2] (collectively, the "agencies"). This interest can result in rigorous, sometimes prolonged, antitrust regulatory reviews. Too often, companies initiate merger plans under the misconception that seemingly insignificant deals face less intense regulatory scrutiny. Moreover, companies are often caught off guard by the number of jurisdictions whose premerger reporting requirements capture their deal, the sheer volume and type of detailed information demanded by the agencies, and the timetable that develops as the agencies execute their respective reviews and decide whether to clear or challenge the transaction.

This article examines a number of recent medical device mergers and other developments in multinational antitrust enforcement to identify some practical considerations that medical device companies should keep in mind when planning each stage of the merger process—from the initial contemplation of a merger through signing, antitrust clearance, and closing.

I. The Antitrust Agencies Scrutinize Deals of All Sizes

The antitrust agencies are not charged solely with reviewing and challenging large, high-profile mergers like Whole Foods Market, Inc.'s 2007 acquisition of Wild Oats Markets, Inc.[3] In reality, the agencies investigate and challenge deals of all sizes. Rather than focusing on the size of the proposed merger, or the profile of the entities involved, the agencies—in particular, the FTC—typically review deals with a focus on determining whether there is some unique potential, incipient, or longstanding competitive dynamic between the merging parties that will be lost as a result of their combination, even where one or both parties are relatively small or have little to no current competitive presence.

For instance, in October 2007, the FTC challenged the $220 million acquisition by Kyphon, Inc. ("Kyphon") of Disc-O-Tech Medical Technologies, Ltd., and Discotech Orthopedic Technologies, Inc. (collectively, "Disc-O-Tech").[4] In 2006, Disc-O-Tech had only $14 million in global revenues and a freshly introduced product in the United States—Confidence, a brand of minimally invasive vertebral compression fracture (MIVCF) treatment products.[5] In order to alleviate potential harm to the U.S. market for MIVCF treatment products, the FTC required the parties to divest all assets related to Disc-O-Tech's Confidence cement and delivery system.[6] The FTC explained that, in spite of Disc-O-Tech's small worldwide revenues and recent U.S. product introduction, the Confidence product was Kyphon's principal competitive threat and was poised to make significant inroads into Kyphon's near monopoly position.[7]

Even the acquisition of targets with no current competitive presence or market share in the United States can become the focus of FTC inquiry, particularly where such companies are in the midst of seeking FDA approval or are otherwise developing a product that may potentially compete in the United States at some point in the future. For example, in March 2006, the FTC challenged and entered into a consent order relating to the acquisition of Inamed Corporation by Allergan, Inc.[8] The FTC alleged that Allergan was the dominant supplier of cosmetic botulinum toxin in the United States and owner of Botox®, the only botulinum toxin type A product approved by the FDA for the treatment of facial wrinkles.[9]

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1 The FTC almost always reviews medical device mergers, although the Antitrust Division of the U.S. Department of Justice (DOJ) has on several occasions sought and obtained relief relating to mergers in medical device industries. *See, e.g.*, Complaint, *United States. v. Gen. Elec. Co. and Instrumentarium OYJ*, No. 1:03-cv-1923-RCL (D.D.C. Sept. 16, 2003) (seeking and ultimately obtaining relief in the markets for critical care monitors and orthopedic-vascular C-arms); Press Release, Dept. of Justice, Varian Medical Systems and IMPAC Medical Systems Abandon Merger Plans (Nov. 7, 2000), *available at* http://www.usdoj.gov/atr/public/press_releases/2000/6915.htm (announcing that Varian Medical Systems Inc. had abandoned its attempt to acquire IMPAC Medical Systems after DOJ announced its intent to block the transaction, which DOJ alleged would harm competition in the sale of radiation oncology management systems software and medical devices known as linear accelerators); *see also* Interview with Mark Botti, ANTITRUST HEALTH CARE CHRON., Mar. 2006, at 3 ("In medical products, the [Federal Trade] Commission tends to do more of that than we do, although there are certain areas of medical equipment where DOJ has expertise.").

2 Today, more than 80 countries have merger control laws, many of which include premerger notification requirements. *See* ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS 415 (6th ed. 2007).

3 *See* Press Release, Fed. Trade Comm'n, FTC Seeks to Block Whole Foods Market's Acquisition of Wild Oats Markets (June 5, 2007), *available at* http://www.ftc.gov/opa/2007/06/wholefoods.shtm; Press Release, Fed. Trade Comm'n, FTC Consent Order Settles Charges that Whole Foods' Acquisition of Rival Wild Oats Was Anticompetitive: Whole Foods Required to Sell 32 Wild Oats Stores, Intellectual Property, and Related Assets in 17 Markets (Mar. 6, 2009), *available at* http://www.ftc.gov/opa/2009/03/wholefoods.shtm.

4 *See* Complaint, *Kyphon Inc., Disc-O-Tech Med. Techs. and Discotech Orthopedic Techs.*, Docket No. C-4201 (Oct. 5, 2007), *available at* http://www.ftc.gov/os/caselist/0710101/071009complaint.pdf.

5 *See* Analysis of Agreement Containing Consent Orders to Aid Public Comment, *Kyphon Inc., Disc-O-Tech Med. Techs. and Discotech Orthopedic Techs*, Docket No. C-4201 (Oct. 9, 2007), at 1-2 [hereinafter *Kyphon* Analysis], *available at* http://www.ftc.gov/os/caselist/0710101/071009analysis.pdf.

6 *See id.* at 1.

7 *See id.* at 3.

8 *See* Analysis of Agreement Containing Consent Orders to Aid Public Comment, *Allergan, Inc. and Inamed Corp.*, Docket No. C-4156 (Mar. 8, 2006), at 1 [hereinafter *Allergan* Analysis], *available at* http://www.ftc.gov/os/caselist/0610031/0610031AllerganInamedAnalysis.pdf.

9 *See id.*

Inamed's botulinum toxin type A product was in Phase III clinical trials and was expected to be the first serious challenger to Botox® in the United States.[10] Because other firms' development programs lagged far behind Inamed's, the FTC maintained that the acquisition would eliminate the next most likely entrant in the market.[11] Thus, the FTC required the parties to grant certain development and distribution rights to a botulinum toxin type A product to a third party.[12]

The same cause for concern can exist in markets where large, incumbent players constitute the historical lion's share of the market. In these situations, the FTC may focus on a much narrower range of products where smaller players are beginning to blossom and steal share by offering more advanced "next generation" technologies and feature benefits that minimize the impact on patients, the time or cost of a procedure, etc. As an example, in the FTC's recent January 2009 consent order relating to the acquisition of Datascope Corp. by Getinge AB, the FTC limited the relevant product market to endoscopic vessel harvesting devices ("EVH"), rather than a larger, possibly more intuitive, market consisting of all vessel harvesting methods:

> The EVH device market is the relevant product market in which to analyze the competitive effects of the proposed acquisition. EVH devices are used in coronary artery bypass graft ("CABG") surgery, most often to remove the saphenous vein from the patient's leg, or sometimes the radial artery from the arm, for use as a conduit to bypass one or more blocked coronary arteries. Because it is a minimally-invasive procedure, EVH provides several benefits over the other two vessel harvesting methods (open and bridging) both of which are more invasive, cause more pain and scarring, and carry a greater risk of infection. As a result, neither of the other methods is considered a viable economic alternative for EVH devices. EVH devices, therefore, constitute a separate product market.[13]

Thus, even though some CABG procedures are performed using other vessel harvesting technologies—in this case, open and bridging methods—the FTC defined a market to include only "minimally invasive" EVH devices, due to the reduced impact such devices have on patients.

In short, medical device companies contemplating mergers must recognize that the FTC's modus operandi is to identify narrow bands of competition between the parties, often to the astonishment of companies that perceive themselves to be competing in a much broader competitive context against larger, more established players.

II. Multiple Regulatory Jurisdictions Can Play a Significant Role

When a proposed merger falls within the purview of multiple regulatory jurisdictions, any one of them can delay closing. A typical scenario might be an acquisition involving a U.S.-based company that has designed a new medical device and has received European marketing approval, but is still actively seeking U.S. FDA approval. Such a company could find itself required to file multiple premerger notifications—in the United States, across Europe, and elsewhere, depending on the company's and its merger partner's presence. Given this multitude of potential regulatory filings, and the need to gather the numerous and distinct sets of materials and information required by each, companies face myriad administrative, tactical, and substantive issues that can bog down the closing of their deals for days, weeks, and even months.

Determining whether a premerger notification is actually required in any given jurisdiction often requires engaging local counsel, who will likely also be involved in drafting and submitting any necessary filings. Moreover, these filings often require the submission of much different information across jurisdictions, all of which add another layer of complexity to formulating and implementing an overall antitrust strategy, in addition to consuming additional time, resources, and attention.

The U.S. Hart-Scott-Rodino (HSR) premerger notification process requires the identification of the areas of overlap of the merging parties by North American Industry Classification System ("NAICS") industry code, as well as the submission of copies of certain acquisition-related documents (known as "4(c)" documents).[14] Typically, 4(c) documents can include board minutes summarizing meetings at which the transaction was discussed, banker's books prepared by the seller, and letters to shareholders, customers, and employees explaining the benefits of the deal. These 4(c) documents are often the cornerstone of the filing, providing the basis for the U.S. agencies' first impressions of the merging parties' markets and the competitive landscape.[15] While a thorough 4(c) search and review can take several days and even weeks to conduct, a company's failure to do so, even in transactions that are ultimately deemed to pose no threat to competition whatsoever, can subject it to civil penalties and, possibly more importantly, require it to recertify its HSR submission and begin a new 30-day waiting period.[16]

In the medical device context, 4(c) documents often take on added importance. For a medical device company that has received approval to market in Europe, but not yet in the United States, 4(c) documents will often memorialize or summarize the extent to which nascent products are making inroads against incumbents in Europe. Thus, 4(c) documents provide the FTC a significant means to analyze and predict the impact that such a product might have upon its

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[10] *See id.* at 1-2.

[11] *See id.* at 2.

[12] *See id.*

[13] *See* Analysis of Agreement Containing Consent Order to Aid Public Comment, *Getinge AB and Datascope Corp.*, Docket No. C-4251 (Jan. 29, 2009), at 2 [hereinafter *Getinge* Analysis], *available at* http://www.ftc.gov/os/caselist/0910000/090129getingeanal.pdf.

[14] More specifically, HSR Item 4(c) requires the submission of "all studies, surveys, analyses and reports which were prepared by or for any officer(s) or director(s) . . . for the purpose of evaluating or analyzing the acquisition with respect to market shares, competition, competitors, markets, [and] potential for sales growth or expansion into product or geographic markets . . . ." *See* Antitrust Improvements Act Notification and Report Form for Certain Mergers and Acquisitions, Instructions to FTC Form C4, at V, *available at* http://www.ftc.gov/bc/hsr/hsrform.shtm.

[15] *See* 1 STEPHEN M. AXINN ET AL., ACQUISITIONS UNDER THE HART-SCOTT-RODINO ANTITRUST IMPROVEMENTS ACT § 8.05[16] (3d ed. 2009) ("This portion of Item 4 which calls for the production of documents directly relating to the question of the proposed acquisition's impact on competition is probably the most important section of the [HSR] Form.").

[16] *See, e.g.*, Press Release, Dept. of Justice, Iconix Brand Group to Pay $550,000 Civil Penalty for Violating Antitrust Pre-Merger Notification Requirements (Oct. 15, 2007), *available at* http://www.usdoj.gov/atr/public/press_releases/2007/226778.htm ("Iconix submitted no [4(c)] documents, despite the fact that such documents existed, including a formal presentation made to its Board of Directors about the transaction and a less formal e-mail among officers and directors.").

introduction in the United States. Depending on the facts, the FTC might develop concerns over the loss of potential competition as a result of that product being acquired by a competitor. For example, in its review of Allergan's acquisition of Inamed, the FTC drew upon the established competitive landscape in Europe to inform its assessment of how Inamed's product, if approved by the FDA, might impact the U.S. market, as well as to gauge and remedy the acquisition's potential anticompetitive effects:

> In 2002, Inamed acquired the U.S. rights to a rival botulinum toxin type A, Reloxin, from Ipsen. Reloxin currently is in Phase III of clinical trials with the FDA and is best-positioned to next enter the market in the United States. . . . The consent order remedies the anticompetitive impact of Allergan's proposed acquisition of Inamed by requiring the companies to return the development and distribution rights to Reloxin, including the ongoing clinical trials and related intellectual property, to Ipsen. The Commission believes that Ipsen is well-suited to take over the development of Reloxin in the United States and replicate Inamed's competitive position in the relevant market. Ipsen has been manufacturing and marketing Reloxin in Europe for years under the brand name Dysport and is intimately acquainted with the development and regulatory program for Reloxin in the United States.[17]

In contrast, other jurisdictions take a different approach to building their initial picture of the market. For instance, there is no 4(c) document analog in the German notification. Rather, the German notification normally requires—in addition to basic information about the parties and the agreement—sales information on a country, EU, and worldwide level, as well as German market share estimates and narrative descriptions of the markets and products involved.[18] Thus, Germany's antitrust agency, the Bundeskartellamt or Federal Cartel Office (FCO), places significant emphasis on market shares in assessing the potential anticompetitive impact of a proposed transaction.

It should be noted that foreign antitrust agencies do, although rarely, challenge or otherwise decide not to approve deals that U.S. agencies ultimately clear, as happened with Coherent, Inc.'s attempted acquisition of Excel Technology, Inc. in 2006. There, DOJ approved the proposed acquisition in May 2006, but the FCO issued a prohibition order disapproving the deal in October 2006.[19] In the medical device context, where companies typically pursue and obtain European marketing approval prior to obtaining U.S. FDA approval, there is an even greater chance of diverging opinions between jurisdictions, since competition concerns may be more robust or tangible in Europe, where the products might be further along in development or are possibly already competing in the marketplace.

From a tactical perspective, multiple filings present a number of issues beyond simply where merging parties must file. For instance, the parties may be required to file in a jurisdiction that has less strict antitrust enforcement policies as compared to other jurisdictions. It may make sense to file first in the more lenient jurisdiction, in order to position that jurisdiction as the lead agency, give it a chance to frame the antitrust analysis, and thereby set the tone for the remaining jurisdictions. Moreover, depending on the presence and degree of competitive issues and substantive differences across jurisdictions, consistency of arguments across filings is critical. Increasingly, jurisdictions are working in concert to analyze the potential effects of mergers, often sharing information and documents submitted by the parties. As such, it never behooves the parties to present inconsistent arguments that deflate their credibility and create fact questions that need resolution.[20]

In addition, there may be voluntary premerger notification regimes where a filing should be considered, even if not required. That is, some jurisdictions allow voluntary notifications (for example, in the United Kingdom) and local counsel can help assess whether it makes sense to make such a filing prior to close in order to give the parties some measure of certainty, rather than wait and see if their deal will be investigated, challenged, or unwound after the closing.

Failure to adequately prepare for the possibilities associated with today's multitude of domestic and foreign antitrust filings can delay consummation and distract corporate focus. Such delays, even by a matter of days, can cost the parties valuable time—time that could have been spent integrating the merging companies.

III. Antitrust Review Can Greatly Impact Timing and Ability to Close

There are a number of factors that can impact closing, even with respect to deals that are ultimately not found to be problematic from an antitrust standpoint. Factors that can affect closing include:

- *Antitrust waiting periods.* As necessary, merger partners must abide by any applicable waiting periods before closing, including the 30-day waiting period in the United States, as well as any applicable non-U.S. waiting periods (e.g., one month in Germany, 30 working days in Portugal, etc.).
- *Problematic or incendiary 4(c) and other documents.* Party documents are often a primary source of information, particularly in the United States in light of the 4(c) filing requirement. As such, documents that refer to the deal as a means to eliminate current or potential competition or to prevent price wars, that espouse the expected dominance of the combined firm after close, or, more subtly, that paint a picture of narrow markets with limited competition from nonmerger partners, can raise red flags at the FTC

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[17] *See* Press Release, Fed. Trade Comm'n, Preserving Competition, FTC Requires Divestiture Before Allowing Allergan's Acquisition of Inamed (Mar. 8, 2009), *available at* http://www.ftc.gov/opa/2006/03/allergan.shtm.

[18] *See* Gesetz gegen Wettbewerbsbeschränkungen [GWB] [Act Against Restraints of Competition] § 39(3) ("Obligation to Notify"); BUNDESKARTELLAMT, COMPETITION POLICY DIVISION, INFORMATION LEAFLET ON THE GERMAN CONTROL OF CONCENTRATIONS 9-10 (July 2005), *available at* http://www.bundeskartellamt.de/wDeutsch/download/pdf/Merkblaetter/Merkblaetter_englisch/06MerkblattzurDeutschenFusionskontrolle_e.pdf.

[19] *See* Hassaun A. Jones-Bey, *Coherent CEO Speaks Out on Blocked Acquisition*, LASERFOCUSWORLD (Dec. 1, 2006), *available at* http://www.laserfocusworld.com/display_article/279862/12/none/none/ colum/Coherent-CEO-speaks-out-on-blocked-acquisition ("U.S. Department of Justice approval was announced in May. But in July the FCO notified Coherent that it had decided to extend its investigation into the acquisition of Excel, relating to certain low-power CO_2 laser products. Despite the fact that the merger was between two U.S. firms, FCO approval was required because Coherent is also one of the largest employers in the German photonics industry.").

[20] *See, e.g.,* Press Release, Bundeskartellamt, Clearance of General Electric/InVision Merger in Close Cooperation with U.S. Competition Authority (Aug. 19, 2004), *available at* http://www.bundeskartellamt.de/wEnglisch/News/Archiv/ArchivNews2004/2004_08_19.php ("The Bundeskartellamt in Bonn has cleared the planned acquisition of InVision Technologies, Inc., Newark (USA) by the General Electric Company, Fairfield (USA) subject to conditions. The project was also examined by other competition authorities in Europe and America and was dealt with by the Bundeskartellamt in close cooperation with the US Federal Trade Commission (FTC) in particular.").

and potentially increase the time it takes to review, resolve concerns, and clear a transaction.[21]

- *High combined market shares.* High combined market shares virtually always spark interest and in many cases support a *prima facie* legal case against a merger. The key here is recognizing that the agencies, particularly the FTC, typically focus on a narrow set of products and technologies, which usually amplifies the parties' market shares.[22]
- *One party has relatively high market shares.* High market shares, even for only one party to the deal, are often the most important criterion considered by some agencies in deciding to open and pursue an antitrust investigation. For instance, under German antitrust law—even in cases where there is little or no horizontal overlap between the merging parties' products—if one party to the merger has sufficiently high market shares, the FCO may be compelled to investigate the extent to which the merger potentially strengthens that firm's dominant position (for example, by providing it with additional financial strength). Moreover, in Germany, a dominant market position is presumed where a single firm has a share of at least one third of the market.[23]
- *Negative customer reactions.* Depending on the facts, the agencies are likely to contact the parties' customers and question them about the impact a given deal could have on the products they purchase and the prices they pay. Even one customer complaint in a sea of neutral or favorable opinions can provide an antitrust agency with a sufficient springboard to escalate to the next phase of an investigation.[24]
- *Extended investigations.* In the event that any one agency escalates its investigation (i.e., the issuance of a second request in the United States[25] or the initiation of a second-phase investigation in Germany[26]), even if just to resolve minor lingering issues, closing can be delayed by a matter of months.

In practice, even the review of a completely nonproblematic medical device merger can exhaust most or all of the initial waiting period. Or, as shown in the chart below, which presents various data points on a number of recent FTC medical device merger enforcement actions, final clearance, approvals, and closing can take anywhere from a few months to a year in cases where more significant antitrust issues exist.

Merger/ Acquisition	Date Deal Signed	Final Closing or Approval Date	Deal Size	Revenue/ Market Share		Relief Obtained
Getinge AB's acquisition of Datascope Corp.[27]	Signed Sept. 15, 2008	Closed Jan. 30, 2009,[28] after agreeing to divestiture on Jan. 29, 2009	$865M	Getinge: $2.2B world-wide in 2007	Datascope: $230.9M world-wide in FY2008	Required to divest endoscopic vessel harvesting product line
Kyphon Inc.'s acquisition of Disc-O-Tech Medical Technologies Ltd.[29]	Signed Dec. 20, 2006	FTC final approval on Dec. 21, 2007,[30] after agreeing to divestiture on Oct. 9, 2007	$220M	Kyphon: $408M world-wide in 2006	Disc-O-Tech: $14M world-wide in 2006	Required to divest Disc-O-Tech's Confidence cement and delivery system for the treatment of vertebral compression fractures

21 Consider, for example, comments made by Whole Foods CEO John Mackey in connection with its acquisition of Wild Oats, which were presented by the FTC in its case against the merger: "The FTC had shown the judge e-mails that Mackey sent to the Whole Foods board of directors in which he said the deal would prevent a price war between the two organic grocers. In one message, Mackey said eliminating Wild Oats would head off new competition 'forever, or almost forever.'" Peter Kaplan, *Judge Unmoved by Whole Foods CEO's Merger Comments*, REUTERS (Aug. 21, 2007), *available at* http://www.reuters.com/article/consumerproducts-SP/idUSN2139570420070822.

22 *See, e.g.,* United States v. Oracle Corp., 331 F. Supp. 2d 1098, 1110 (N.D. Cal. 2004) ("[A] post-merger market share of 30 percent or higher unquestionably gives rise to the presumption of illegality.") (citation omitted).

23 *See* Gesetz gegen Wettbewerbsbeschränkungen [GWB] [Act Against Restraints of Competition] § 19(3) ("Abuse of a Dominant Position"); *see also id.* § 36(1) ("Principles for the Appraisal of Concentrations") ("A concentration which is expected to create or strengthen a dominant position shall be prohibited by the Bundeskartellamt unless the undertakings concerned prove that the concentration will also lead to improvements of the conditions of competition and that these improvements will outweigh the disadvantages of dominance.").

24 For instance, while customer opinions on the whole were positive, the German FCO's continued investigation and ultimate disapproval of Coherent's attempt to acquire Excel was due at least in part to a handful of negative customer opinions:

> [T]he FCO received input from 22 customers, all but two of which were located within Germany, [Coherent CEO John] Ambroseo said. 'Of those surveyed, 17 were supportive to neutral on the transaction and five expressed concerns. One of the opposing parties had mistaken Coherent for one of our German competitors since the customer identified products that were not part of our portfolio.' He described the four remaining dissenting customers as predominantly providers of cutting and engraving equipment that accounted for less than $10,000 in combined annual CO_2 sales for Coherent and Excel, compared to combined annual revenues of Coherent and Excel in excess of $700,000.

Jones-Bey, *supra* note 19.

25 *See* 15 U.S.C. § 18a(e)(1)(A) (prior to the expiration of the 30-day waiting period, FTC or DOJ may "require the submission of additional information or documentary material relevant to the proposed acquisition").

26 *See* Gesetz gegen Wettbewerbsbeschränkungen [GWB] [Act Against Restraints of Competition] § 40(1) ("Procedure of Control of Concentrations").

27 *See Getinge* Analysis, *supra* note 13.

28 *See* Press Release, Getinge AB, Getinge AB Announces Successful Completion of Cash Tender Offer for Datascope Corp. (Jan. 30, 2009), *available at* http://www.getingegroup.com/getinge.asp?ID=206&latest=1.

29 *See Kyphon* Analysis, *supra* note 5.

30 *See* Press Release, Fed. Trade Comm'n, Commission Approves Proposed Divestiture in Matter of Kyphon, Inc. (Dec. 21, 2007), *available at* http://www.ftc.gov/opa/2007/12/fyi07268.shtm.

Merger/ Acquisition	Date Deal Signed	Final Closing or Approval Date	Deal Size	Revenue/ Market Share		Relief Obtained
Boston Scientific Corp.'s acquisition of Guidant Corp.[31]	Signed Jan. 25, 2006	Closed on Apr. 21, 2006,[32] after agreeing to divestiture and other terms on April 20, 2006	$27B	Boston Scientific: $6.3B world-wide in 2005	Guidant: $3.6B world-wide in 2005	Required to divest all assets related to Guidant's vascular business
Allergan, Inc.'s acquisition of Inamed Corp.[33]	Signed Dec. 20, 2005	Closed March 23, 2006,[34] after agreeing to divestiture on March 8, 2006[35]	$3.2B	Allergan was the dominant supplier and only company to have a product approved by the U.S. FDA	Inamed's cosmetic botulinum product was expected to be the first serious challenger in the U.S.	Required to return the development of the Reloxin botulinum toxin type A product to its manufacturer, Ipsen Ltd.
Hologic, Inc.'s acquisition of certain assets of Fischer Imaging Corp.[36]	Signed June 22, 2005 (the FTC challenged the acquisition after the parties closed on Sept. 29, 2005)	FTC final approval on Aug. 9, 2006,[37] after agreeing to divestiture on July 7, 2006	$32M	Hologic: $288M world-wide in 2005	Fischer: $39M world-wide in 2005	Required to divest all assets acquired from Fischer relating to Fischer's prone stereotactic breast biopsy system business

IV. Practical Considerations

By adhering to a few guidelines and best practices, medical device companies contemplating and undertaking mergers can maximize their chances of closing as quickly as possible:

- *Engage antitrust counsel early.* Even where one or both parties' competitive presence, market share, or revenues appear to be so small as to be unworthy of agency attention, it is important to recognize that the acquisition of small companies with little actual presence in the market, or, for that matter, products still in the development pipeline, can be subject to extended antitrust scrutiny. In particular, many of the agencies have significant experience in these markets and are able to focus quickly on the issue of whether the merging companies compete, or will potentially compete, in some narrow product market. Moreover, competitors may take issue, and while the arguments they bring to the agencies' attention may be viewed with a somewhat jaundiced eye, such complaints may be sufficient to generate questions and create concerns that need to be resolved.
- *Dedicate internal personnel to antitrust.* It is important to appoint at least one key employee with sufficient substantive knowledge of the relevant products and market (in-house counsel, CFO, etc.) to work with outside counsel to gather the necessary information and provide sufficient breadth of detail to allow outside counsel to understand fully the landscape in which the merging companies compete. In particular, it is critical to encourage and entertain the dialogue that is necessary to adequately determine whether there are narrow, albeit possibly less intuitive, markets in which the companies might be seen to compete, and whether such markets might be defined by an antitrust agency as the relevant context in which to view a particular transaction.
- *Determine, as early as possible, the relevant premerger notification jurisdictions and corresponding waiting periods.* While this may sound like nothing more than routine practice, in reality the question of whether filings are necessary in certain jurisdictions is sometimes tabled as a secondary consideration. Moreover, local counsel is often required to make final determinations on sometimes difficult reportability questions and to identify whether there are jurisdiction-specific antitrust concerns that might risk delaying close. Bringing counsel to the table early and determining with finality where to file is one of the best ways to reduce the likelihood and impact of non-strategic, staggered waiting periods that delay closing. Having a firm understanding for the miscellaneous waiting periods early in the process is the best way to sensitize the various stakeholders (management, board, shareholders, etc.) and set expectations regarding the array of antitrust regimes that can come to bear on the parties' efforts to consummate the deal.

[31] *See* Analysis of Agreement Containing Consent Order to Aid Public Comment, *Boston Scientific Corp. and Guidant Corp.*, Docket No. C-4164 (April 20, 2006), *available at* http://www.ftc.gov/os/caselist/0610046/0610046analysis060420.pdf.

[32] *See* Press Release, Boston Scientific Corp., Boston Scientific Completes Combination with Guidant (Apr. 21, 2006), *available at* http://bostonscientific.mediaroom.com/index.php?s=43&item=513.

[33] *See Allergan* Analysis, *supra* note 8.

[34] *See* Press Release, Allergan, Inc., Allergan Announces Completion of Inamed Acquisition (Mar. 23, 2006), *available at* http://agn.client.shareholder.com/releasedetail.cfm?ReleaseID=191073.

[35] *See* Press Release, Fed. Trade Comm'n, Preserving Competition, FTC Requires Divestiture Before Allowing Allergan's Acquisition of Inamed (Mar. 8, 2006), *available at* http://www.ftc.gov/opa/2006/03/allergan.shtm.

[36] *See* Complaint, *Hologic, Inc.*, Docket No. C-4165 (July 7, 2006), *available at* http://www.ftc.gov/os/caselist/0510263/0510263complaint.pdf; *see also* Analysis of Agreement Containing Consent Order to Aid Public Comment, *Hologic, Inc.*, Docket No. C-4165 (July 7, 2006), *available at* http://www.ftc.gov/os/caselist/0510263/0510263analysis.pdf.

[37] *See* Press Release, Fed. Trade Comm'n, Commission Approves Final Consent Order in Matter of Hologic/Fischer Imaging Corporation (Aug. 9, 2006), *available at* http://www.ftc.gov/opa/2006/08/fyi0653.shtm.

- *Get 4(c) and other business documents into counsel's hands early.* Doing so not only accelerates the time-consuming process of preparing and submitting, for example, the U.S. filing (and thus starting the waiting period), but also helps outside counsel cobble together a more realistic picture of the markets in which the firms participate, assess whether there are any substantive antitrust issues that will need to be addressed, and predict whether, as viewed in a vacuum, such documents could create misperceptions at the agencies that might need to be corrected or resolved.
- *Prepare to answer agency questions before they are raised.* Considering that it can be a matter of days, and sometimes even weeks, after the filing is submitted before it wends its way through the administrative clearance process and into the hands of the people who will conduct the substantive agency review, questions and issues that arise in a typical 30-day waiting period need to be addressed quickly, so that the agencies have time to digest and road test the parties' arguments and responses. Otherwise, the merging parties run the risk of the agency not having sufficient time to answer lingering issues during the initial waiting period, possibly forcing an escalation to the next investigatory phase.
- *Reach out to customers (before the antitrust agencies do).* As the agencies are highly likely to question customers, it is critical to have a communications plan in place prior to signing that involves contacting customers en masse or, better yet, individually if possible. It is simply not enough to assume that customers will understand the parties' rationale for merging, that they will clearly see how the transaction could benefit them, and that they will not have even minor fears over how they may be impacted (fears that could translate into agency concern). The best approach is almost always to reach out to them, inform them of the planned merger, and describe why the parties are doing so and how the combination will benefit them.