Basic Concepts and Issues: A Primer on Distribution and Sales Representative Agreements in the Medical Device and Durable Medical Equipment Industries

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ABSTRACT: Counsel for a manufacturer of medical devices or durable medical equipment must have working knowledge of various legal disciplines to draft contracts with intermediaries (sales representatives and distributors) for the marketing and sale of the manufacturer’s products. If the manufacturer wishes to sell its products abroad, counsel must become familiar with the laws and business practices of the target country, and methods of gaining access to the foreign market. This Article gives readers an overview of the applicable legal principles, under U.S. and foreign laws, in the areas of agency, contracts, healthcare regulation, consumer protection, intellectual property protection, and dealer protection. To aid counsel in drafting intermediary agreements, specific contractual terms and issues are explored in depth, including: appointment clauses, performance provisions, provisions concerning pricing and payment, protective clauses (shielding the manufacturer from liability), term and termination provisions, independent contractor clauses, export control clauses, recordkeeping and audit provisions, choice of law clauses, and dispute resolution clauses.

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Without marketing and distribution, a superior medical device or article of durable medical equipment (DME) is just that, the latest great product which never made a commercial impact, never helped a patient, and never made a return for anyone. The history of small or start-up medical device and equipment companies is replete with promising products that never received significant marketing or distribution and thus did not perform well commercially. This Article aims to give counsel (in-house or outside), regulatory experts, or businesspeople who are not familiar with relevant legal issues an introduction to concepts that are basic to the law of marketing and distributing medical devices and DME.

Given the readership of this journal, a familiarity with healthcare law and regulatory practice, particularly in the United States, is assumed. The focus of this Article is on the issues that should be dealt with in the written agreement that the manufacturer will enter into with the third party who will actually call on customers and represent the device to the commercial world. What attributes characterize this third party? What are the different types of persons who can accomplish marketing or distribution for the device manufacturer? What are the “tricks of the trade” that experienced manufacturers address in their written agreements? In order to convey a better understanding of these issues, a short background on the mechanics of marketing and distributing in the medical device industry is warranted.

There are basically four methods of distribution for devices: directly employed sales-people, third-party distributors, sales representatives, and catalog sales. This Article concentrates on “indirect” marketing and distribution through third-party distributors and sales representatives. For convenience, this Article refers to these third parties as “intermediaries” and to the written agreement with them as the “intermediary agreement.” This choice of language is only for this Article, and only because it allows the authors to make certain legal and practical distinctions between distributors and sales representatives. Similarly,

and trauma markets. The company’s medical devices are used for the healing of complex fractures of the bones, stimulation of bone growth in the bone fracture and surgical fusion context, wound care and pain management as well as orthopedic bracing for the pre-and post-surgical and sports markets. Orthofix’s products are distributed in over 85 countries around the world through direct sales representatives employed by the company as well as third-party distributors and sales representatives. Mr. Kolls is a 1988 graduate of Georgetown University Law Center.
again solely for ease of reference, this Article refers to medical devices and DME as “medical devices” or “devices.”

Seasoned businesspeople and lawyers in this area know that the terms applied to these relationships are loose and fluid. For example, in the real world, the employee of a manufacturer whose job is the handling of product distribution functions may deal with an intermediary that the law might classify as a distributor, but might refer to the distributor’s employees as “our sales reps.” Similarly, a manufacturer might enter into a document entitled “manufacturer’s representative agreement between ABC, Inc and The XYZ, Company, Ltd.” That document could be a sales representative agreement or it might be a distributorship. The manufacturer might enter into several identically titled agreements with different parties, some of which might be distributorships, others sales representative contracts, and still others pure marketing contracts. While the language is variable, the nature of the relationship is usually judged on the substance of the contract and the parties’ operating practices under it. Indeed, this Article will commonly use, for example, the term “distribution” in its generic meaning of getting devices into the supply chain and on their way to end users.

In any event, for the small or start-up device company, a relationship with an experienced third-party distributor or sales representative has many advantages. These relationships can get the company’s product immediate commercial visibility. The right intermediary representing the right devices in the right territory may have invaluable relationships with local doctors and physician’s groups, ambulatory surgical centers or hospitals, or may have previously dealt with certain insurance plans. The intermediary might have a relationship with trade show or professional seminar organizers. In other words, the intermediary should bring an existing book of business or the ability to inject the device into the supply chain—expertise that small and start-up device companies sometimes lack. That is, the intermediary should possess experience in operating a compliant and effective distribution function.

This “on the street” experience often (but not always) means the intermediary can be expected to know the ins and outs of written intermediary agreements as he, she, or it has likely signed such agreements in the past. In order to level the playing field, this Article surveys the basic concepts of intermediary agreements by describing their basic provisions. Starting with the appointment clause and ending with the more important
of the miscellaneous boilerplate provisions, the authors describe the practical and legal issues that these provisions are designed to address both in the United States and overseas. More importantly, the Article details the manner in which the manufacturer typically wants to negotiate the provision (and why) in the hopes that small or start-up companies might be able to negotiate better intermediary agreements. Nonetheless, experienced practitioners may find the review useful as well.

I. Sales Representatives and Distributors

The most common types of third-party intermediaries are independent sales representatives and distributors. As a first step, the manufacturer must decide whether it wishes to engage a sales representative or a distributor. While sales representatives and distributors share many features, there are also fundamental differences.

A. Sales Representatives

A sales representative\(^1\) markets medical devices as an agent of the manufacturer. While the scope of the sales representative’s authority may be broader or narrower as desired by the parties, the sales representative always acts as a true intermediary between the manufacturer and the purchaser. That is, the sales representative does not acquire title or ownership rights to the devices it markets on behalf of the manufacturer. Privity of contract runs directly between the manufacturer and the purchaser of the device, and the sales representative has, in theory, no contractual liability to the purchaser. In consideration for the sales representative’s marketing efforts, the manufacturer typically pays the sales representative a commission, which is in most cases a percentage of the purchase price of the device.

B. Distributors

A distributor\(^2\) purchases the medical devices from the manufacturer for resale to end users or other distributors. As a result, while the parties typically enter into a written distribution agreement, each order and purchase of medical devices thereunder constitutes a separate sales contract or transaction.

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1 Sales representatives are often also referred to as commercial agents or sales agents. For the purposes of this Article, these terms will be treated interchangeably.

2 Distributors are also referred to as buy-sell distributors or resellers. For the purposes of this Article, these terms are treated synonymously.
Therefore, unlike the agreement with a sales representative, the distribution agreement should be drafted to establish the terms and conditions governing each of the individual sales contracts. Since the distributor purchases and resells medical devices, it has independent contractual obligations and liabilities to its customers. There is generally no privity of contract between the manufacturer and the distributor’s customers that gives rise to contractual claims by the customer against the manufacturer. Notable exceptions to this general principle, however, are the warranties and representations made by the manufacturer for its medical device. Those warranties and representations typically accompany the device in the form of express warranties or other claims about the device’s performance that may be set forth on packaging or other written materials.\(^3\)

C. What is the appropriate Intermediary?

There is no one appropriate type of intermediary. Instead, the decision of appointing either a sales representative or a distributor should be made by considering all of the surrounding circumstances. An important factor for medical device manufacturers is retention of control over billing and payment. Payment for most medical devices is made either by health insurance providers or government medical programs. These payors require accurate and timely completion of payment documentation, such as prescription forms (using particular identifying coding), assignments of benefits, certificates or letters of medical necessity, and (for Medicare coverage) advanced beneficiary notices. Incomplete, inaccurate, or improper completion of the forms, or the use of inappropriate, unethical, or illegal means in obtaining payment affects the ability to receive payment. More importantly, false statements or violation of healthcare regulatory provisions upon, or in connection with,

\(^3\) If the warranty is directly made by the manufacturer to any end user, as will typically be the case, the manufacturer is directly liable to the end user under contract law. If not, the end user may be a third-party beneficiary under the sales contract between the manufacturer and the distributor. Under § 2-318 of the Uniform Commercial Code (UCC), a seller’s express or implied warranty for goods “extends to any person who may reasonably be expected to use, consume or be affected by the goods and who is injured by breach of the warranty.” U.C.C. § 2-318(C) (2002). Section 2-318 provides for three alternative versions, with a state selecting one of the options when enacting the UCC. Id. § 2-318(A)–(C). The versions differ mainly in the scope of the third-party beneficiaries protected thereunder, ranging from “any natural person who is in the family or household of [the] buyer” (Alternative A), to “any natural person” (Alternative B’), to “any person,” which could include companies (Alternative C). Id. The manufacturer should verify which option or variation thereof the state whose law governs the warranty has enacted.
Distribution Contracts

payment documentation can subject the manufacturer, even in a distributor situation, to investigations by and liability to private or government payors.

Thus, the recent trend in device distribution within the United States has been for manufacturers to structure their indirect marketing so that they have control over the payment process, especially the submission of the payment documentation. For this reason, while only eight to ten years ago manufacturers typically marketed their medical devices through distributorships, manufacturers now predominantly opt for sales representative relationships. In a sales representative relationship, the manufacturer sells directly to the customer and is responsible for, and has control over, the submission of payment documentation and collecting payment. The manufacturer thus has the ability to prevent the risks associated with distributorships, in which the distributor purchases and resells the medical devices and thus is responsible for submitting payment documentation to obtain payment. The intermediary agreement should provide, of course, that the sales representative is obligated to assist the manufacturer as necessary with the completion and submission of payment documentation and the collection of payment, at the direction and control of the manufacturer. Since the sales representative has the direct contact with physicians who must complete some of the paperwork, the manufacturer may need the intervention of the sales representative in dealing with the physician or addressing any problems with the payment documentation.

International marketing is different. Unless the manufacturer has a subsidiary or business establishment in another country, the manufacturer may not have the detailed expertise and control in connection with completing and submitting payment claims to foreign health insurance or government medical plans. In this situation, it may be preferable that the intermediary be given the responsibility for submitting payment claims and collecting payment. In some countries, local law or practice may make it difficult for manufacturers to directly sell and collect payment. In addition, manufacturers may not

4 In Turkey, for example, healthcare is controlled by the government. Sellers of medical devices are required to obtain a certain “protocol” permitting them to sell to the centralized government healthcare procurement agency. However, the few protocols that are available are granted to local individuals or entities. See generally Public Procurement Law, No. 4734 (Apr. 1, 2002) (Turk.) (setting forth the procedures for public procurement of good and services), available at www.oecd.org/dataoecd/33/50/35016773.htm; ACCESS E. MEDITERRANEAN PROGRAM, U.S. COMMERCIAL SERV., MARKET BRIEF FOR TURKEY (2005), at www.buyusa.
wish to have the burden of enforcing payment obligations in a jurisdiction with a significantly different legal system, culture, and language. Therefore, in the international market, distributorships are generally the dominant form of indirect marketing. In such situations, the manufacturer is paid by the distributor and leaves the responsibility on the distributor to obtain payment from the local health insurance or government program upon the distributor’s resale.

D. International Intermediaries

International intermediaries raise particular issues that require special diligence and care. Before marketing and selling medical devices outside the United States, the manufacturer should, if at all possible, have a local attorney review the applicable legal requirements in the target country. These laws may be substantially different from U.S. law. The items discussed below, while not exhaustive, provide examples of the legal issues that may arise under foreign law.

1. Regulatory Requirements

Foreign regulation of medical devices as well as their marketing and sales follow different rules and principles than in the United States. Approval by the U.S. Food and Drug Administration (FDA) is no guarantee of regulatory approval abroad. Even though the FDA has entered into reciprocity agreements (“memoranda of understanding”) or an exchange of letters with various countries, the ability to market and sell FDA

5 It is equally important to study the business and cultural environment of the target country, which may be very different from the U.S. environment.


[T]he Secretary [of Health and Human Services] may enter into agreements with foreign countries to facilitate commerce in devices between the United States and such countries consistent with the requirements of this chapter. In such agreements, the Secretary shall encourage the mutual recognition of— (1) good manufacturing practice regulations promulgated under section 360j(f) of this title, and (2) other regulations and testing protocols as the Secretary determines to be appropriate.

Id.

7 An exchange of letters is “used in lieu of a formal agreement when the actions contemplated require only a limited resource expenditure and do not rise to the significance of a formal agreement.” OFF. OF REGULATORY AFF., U.S. FOOD & DRUG ADMIN. (FDA), COMPLIANCE POLICY GUIDES MANUAL, INTERNATIONAL MEMORANDA OF UNDERSTANDING § 100.900 (2005), 2005 WL 1284680.
approved devices is not guaranteed.\(^8\) Thus, before appointing an intermediary to market its medical devices in another country, the manufacturer must verify its ability to do so in that country, including any required licenses, approvals, or registrations, and the conditions for obtaining them. Certain countries may require that licenses to market and sell medical devices be held by local individuals or entities, resulting in a barrier to entry for the U.S. manufacturer. If the manufacturer terminates the intermediary holding the license, it may be prevented from continuing to market and sell its devices. An experienced intermediary will use this disadvantage to improve its bargaining position during the negotiation of the intermediary agreement. In addition, in many countries, it is impractical for the manufacturer to obtain necessary local licenses or regulatory approvals, and the manufacturer will look to the intermediary to do so. The intermediary agreement should contain a provision that obligates the intermediary to use its best efforts (or at least commercially reasonable efforts) to obtain necessary regulatory approvals within a certain time or as soon as possible. The manufacturer should also attempt to negotiate a provision requiring the intermediary to transfer any local license or registration to the manufacturer upon demand, to the extent permitted under local law.

Since the violation of local law could result in a withdrawal or suspension of the license, the manufacturer must ensure that the intermediary is trustworthy and reliable. A particular concern is corruption or bribery. For example, the intermediary may want, or be expected, to pay “grease money” to accomplish the issuance of any licenses. While such conduct is almost always a violation of local law, it is common in some countries.\(^9\) Use of

\(^8\) The purpose of such agreements is not avoid national approval requirements but to “provide for the mutual assessment of the comparability of specific FDA programs or activities with those of a foreign regulatory authority” and “enable each country to consider reducing the rate of inspection or sampling of imports from the other country that would otherwise be necessary.” \textit{Id.}

corruption and bribery is not only a concern under local law. The Foreign Corrupt Practices Act (FCPA)\(^\text{10}\) prohibits the paying, offering, promising, or giving of any money or other thing of value to any foreign official, party, or person to influence the official’s, party’s or person’s decisions or acts.\(^\text{11}\) An exception


\(^{11}\) Id. §§ 78dd-1(a), -2(a), -3(a). While these three provisions of the FCPA pertain to different types of U.S. persons, the core prohibition in each provision reads as follows:

It shall be unlawful . . . to make use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value to—

1. any foreign official for purposes of—
   (A) (i) influencing any act or decision of such foreign official in his official capacity, (ii) inducing such foreign official to do or omit to do any act in violation of the lawful duty of such official, or (iii) securing any improper advantage; or
   (B) inducing such foreign official to use his influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality,
   in order to assist such person in obtaining or retaining business for or with, or directing business to, any person;

2. any foreign political party or official thereof or any candidate for foreign political office for purposes of—
   (A) (i) influencing any act or decision of such party, official, or candidate in its or his official capacity, (ii) inducing such party, official, or candidate to do or omit to do an act in violation of the lawful duty of such party, official, or candidate, or (iii) securing any improper advantage; or
   (B) inducing such party, official, or candidate to use its or his influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality.
   in order to assist such person in obtaining or retaining business for or with, or directing business to, any person; or

3. any person, while knowing that all or a portion of such money or thing of value will be offered, given, or promised, directly or indirectly, to any foreign official, to any foreign political party or official thereof, or to any candidate for foreign political office, for purposes of—
   (A) (i) influencing any act or decision of such foreign official, political party, party official, or candidate in his or its official capacity, (ii) inducing such foreign official, political party, party official, or candidate to do or omit to do any act in violation of the lawful duty of such foreign official, political party, party official, or candidate, or (iii) securing any improper advantage; or
Distribution Contracts

exists for facilitating or expediting payment for the purpose of expediting or securing the performance of a routine governmental action, such as the payment of application or license fees. Furthermore, it is an affirmative defense if the payment of gift was either lawful under the local country’s laws or was a reasonable and bona fide expenditure, such as travel and lodging expenses, incurred by or on behalf of a foreign official, party, party official, or candidate and was directly related to—(A) the promotion, demonstration, or explanation of products or services; or (B) the execution or performance of a contract with a foreign government or agency thereof.

Penalties for violations of the FCPA can be severe. Thus, while the intermediary agreement should contain a covenant or warranty by the intermediary to comply with all applicable law, the manufacturer should continuously monitor the intermediary to detect potential problems early and take remedial action. In addition, a provision specifically identifying the FCPA and requiring the intermediary to observe its terms should be included. The manufacturer may even wish to consider including a penalty or liquidated damages provision in the intermediary agreement where such provisions are legal and enforceable. A penalty provision typically provides for a contractual

(B) inducing such foreign official, political party, party official, or candidate to use his or its influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality, in order to assist such person in obtaining or retaining business for or with, or directing business to, any person.

Id. § 78dd-3(a).
12 Id. §§ 78dd-1(b), -2(b), -3(b).
13 Id. §§ 78dd-1(c), -2(c), -3(c).
14 Some violations are punishable by up to a $5 million fine and/or 20 years imprisonment for individuals and up to a $25 million fine for corporations. 15 U.S.C. § 78ff(a) (2005).
15 See infra Part II.B.3., notes 53-63 and accompanying text.
16 Many civil law jurisdictions, such as countries in Latin America and continental Europe, enforce contractual penalties. On the other hand, countries with a common law system, such as the Australia, Canada, Ireland, New Zealand, the United Kingdom, and the United States, rarely enforce contractual penalties but recognize and enforce reasonable liquidated damages clauses. See Ugo Mattei, The Comparative Law and Economics of Penalty Clauses in Contracts, 43 AM. J. COMP. L. 427, 433-38 (1995).
penalty by the intermediary if it violates certain provisions of the intermediary agreement, such as the obligation to comply with all applicable law. Liquidated damages are essentially standardized damages for a breach of contract if the amount of damages resulting from the breach is difficult to determine. While a liquidated damages clause is not enforceable as a legal penalty, its practical effect on the intermediary may sometimes be the same. Thus, the penalty or liquidated damages provision can be a significant motivator for the intermediary to comply with applicable law.

2. Different Healthcare Systems

The variety of healthcare delivery and payment systems outside the U.S. can affect the manufacturer’s ability to market and sell its medical devices profitably. Some countries have a government-operated healthcare system. Other countries have a mandatory government health insurance program requiring the enrollment of all or most individuals, while in other systems the government may own or operate most hospitals. In some of these countries, purchase and payment for medical devices occurs, directly or indirectly, through government agencies. The manufacturer may thus be subject to government procurement regulations, price controls, and local content preferences. Often, the regulatory and procurement requirements will affect the decision whether to market and sell medical devices in a particular country. One of the great advantages of a local intermediary is its familiarity with the foreign environment. This can also be one of the intermediary’s great dangers if the intermediary is not trustworthy. Accordingly, the manufacturer should become at least reasonably familiar with the healthcare system and the regulatory and procurement environment before it decides to market and sell in a particular

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18 Id. § 65:1.
20 In Germany, for example, employees with earnings below a certain threshold are enrolled in the government health insurance program. FED. MINISTRY OF HEALTH AND SOC. SECURITY, WELCOME TO THE MINISTRY: HEALTH INSURANCE, at www. bmgs.bund.de/eng/gra/index.php (last visited Sept. 17, 2005).
21 See INT’L HEALTH COMPARISONS, supra note 19, at 8.
country. In addition, in many areas of the world, the manufacturer can engage independent agents with knowledge of the local market and the identities and reputations of dependable intermediaries. These agents serve as middlemen brokering the arrangement between the manufacturer and the intermediary. They can be of great value to the manufacturer in preparing to enter an unknown market.

3. Consumer Protection Laws

The manufacturer should also consider the target country’s consumer protection laws, many of which are stricter than in the United States. For example, while it is standard for a manufacturer to limit its warranties and liabilities in the United States, other countries restrict the manufacturer’s ability to disclaim warranties or limit liability.22 Thus, the typical disclaimer of implied warranties or the limitation of the end user’s remedies in the event of a defect may not be enforceable. Non-U.S. consumer protection laws typically are not waivable in advance and apply even if the warranty or sales contract chooses the law of another jurisdiction.

4. Intellectual Property Protection

Before entering a foreign market, the manufacturer should take steps to protect its intellectual property (IP) rights. IP rights are the intangible assets that protect the manufacturer’s market position. A device or technology patent permits the manufacturer to exclude others from marketing, selling, distributing, or using the device or technology.23 A copyright in a work, such as the documentation for a product or marketing materials, grants the manufacturer exclusive rights to reproduce, distribute, and publicly display such work.24 Trademark and service mark rights

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22 Consider, for example, Germany. German law generally does not permit the exclusion of liability for willful conduct. Bürgerliches Gesetzbuch [BGB] [Civil Code], newly promulgated with effect of Jan. 1, 2002, BGBl. I 42, 2909, as amended, § 276(3), translated in German Law Archive: Civil Law Statutes (Geoffrey Thomas & Gerhard Dannemann eds., 2003), at www.iuscomp.org/gla/ (last visited Sept. 18, 2005). A disclaimer of warranty or liability therefore is ineffective if the manufacturer fraudulently omitted to disclose the defect or issued an express guarantee or warranty. Id. § 444. If the exclusion is a standard business term (defined as a contractual term pre-established for a multitude of contracts which one party presents to the other party), an exclusion for gross negligence or a restriction on certain types of remedies for product defects, such as repair of the defective product, are invalid. Id. § 309(7)(b), (8)(b). The manufacturer’s standard product warranties would likely also qualify as standard business terms.


24 Id. § 4:2.
in the manufacturer’s mark enable the manufacturer to establish a brand or recognized symbol for marketing its products to customers.\textsuperscript{25} Trade secrets are proprietary information and know-how that, when kept secret and confidential, can provide an advantage in developing and improving its products.\textsuperscript{26} The most important IP rights will typically be patents and patent applications for the medical devices, the manufacturer’s name and marks, and any confidential information and trade secrets to which the intermediary may have access.

The loss of IP rights can seriously affect the manufacturer’s business. Therefore, the manufacturer should conduct thorough IP due diligence before expanding its operations into a foreign country. The following are the most important issues to be covered by the due diligence.

\textbf{a. Are the medical devices protected by a patent?}

Since patent law is principally national law, a U.S. patent will not provide any protection in a foreign country. Thus, to obtain patent protection in a foreign country, the manufacturer must file a patent application in that country. The burden is alleviated by the Patent Cooperation Treaty (PCT).\textsuperscript{27} After filing a U.S. patent application, the manufacturer can file a PCT application for such patent application designating any of the PCT member countries.\textsuperscript{28} While the PCT application does not result in a single international patent, because each designated country examines the patent application independently under its patent law, filing for international patents is simplified by having to file only one application. In addition, if the PCT application is filed within one year from the filing of the underlying U.S. patent application, the manufacturer can claim priority to the date of the U.S. application.

When prosecuting patent applications outside the U.S., the manufacturer must be aware of the differences in foreign patent law. While a patent application for a device may be filed in the United States within one year after the device has been sold or used in public,\textsuperscript{29} in most countries, any public use or public

\textsuperscript{25} Id. § 3:1.
\textsuperscript{26} Id. § 2:1.
\textsuperscript{28} Id. at 980 art. 8. Currently, in addition to the United States, 127 countries have signed or acceded to the PCT. WORLD INTELLECTUAL PROPERTY ORG., TREATIES DATABASE: CONTRACTING PARTIES—PCT, available at www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=6 (last visited Sept. 18, 2005).
\textsuperscript{29} 35 U.S.C. § 102(b) (2005).
sales will bar the patentability of a device.\textsuperscript{30} Therefore, sales of the device in the United States may prevent the manufacturer from patenting the device abroad. As a general matter, the manufacturer should devise and implement a policy that provides an internal system for the acquisition and protection of the manufacturer’s IP. An important part of such a policy is a proactive patenting strategy, which will consider patenting in important or potentially important foreign countries simultaneously with filing for patent protection in the United States.

b. Do the foreign country’s patent laws and enforcement practices provide sufficient protection?

A patent in a foreign country is only as strong as its patent laws and enforcement practices. All member countries of the World Trade Organization (WTO) are subject to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs),\textsuperscript{31} which requires WTO member countries to ensure that enforcement procedures as specified in this Part are available under their national laws so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements.\textsuperscript{32}

Despite this, large-scale infringement and the suspension of patent rights by foreign countries for national interests has become an increasing concern.\textsuperscript{33} Currently, governmental patent suspension seems to be largely concentrated on patents for pharmaceuticals, such as in India or Brazil in connection

\textsuperscript{30} See, e.g., European Patent Convention art. 54(1)–(2) (2005), available at www.european-patent-office.org/legal/epc/e/ar54.html#A54 (last visited Oct. 6, 2005) (defining an invention as new if it does not form part of the state of the art, which is comprised of everything made available to the public).

\textsuperscript{31} Agreement on Trade-Related Aspects of Intellectual Property Rights art. 1, Apr. 15, 1994, 33 I.L.M. 81, 84–85.

\textsuperscript{32} Id. at 99 art. 41(1). However, TRIP’s permits members to “exclude from patentability . . . diagnostic, therapeutic and surgical methods for the treatment of humans or animals.” Id. at 94 art. 27(3)(a). The manufacturer should therefore determine whether its medical device and process is excluded from patent protection in a particular country.

\textsuperscript{33} Id. at 95–96 art. 31 (If certain conditions are observed, “the law of a [WTO] Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government.”).
with antiretroviral drugs. If a medical device plays an important role in combating a national health emergency or crisis, however, those laws could also be used with regard to medical device patents.

The manufacturer should also consider the country’s history in the protection of patents and other IP rights. In some countries, enforcement is so weak or cumbersome that the practical protection offered by a patent is greatly diminished. In its due diligence, the manufacturer should also consider the target country’s enforcement against illegal imports and the risk posed by illegal activity in countries bordering the target country, especially if a neighboring country is known for illegal exports of infringing devices into the target country.

c. Is the medical device already protected in the target country by a third-party patent?

In some cases, the market for a specific medical device may be crowded. In such case, the manufacturer should consider a review of potentially relevant patents in the target country, especially of the most important competitors. In the absence of such review, sometimes referred to as a “freedom to operate” or “freedom to maneuver” analysis, the manufacturer may become subject to a patent infringement action in the foreign country.

d. Has the manufacturer protected all relevant marks and names before entering the foreign country?

Since the manufacturer’s marks are the source identifier for its medical devices, it is important to protect them before entering a foreign market by filing trademark or service mark applications in the foreign country. Without such protection, local competitors may adopt the manufacturer’s name and mark, potentially causing serious harm to the manufacturer’s business. For example, use of the manufacturer’s marks can create consumer confusion and thus undermine the marketing of the manufacturer’s devices. Even more seriously, disreputable competitors may sell substandard devices and severely injure the reputation of the manufacturer and its devices to such

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34 See Andrew Downie, Brazil Pushes for Cheaper Drugs and Free AIDS Diagnosis, CHRISTIAN SCI. MONITOR (Boston), Aug. 23, 2005 at 4; Sabin Russell, AIDS Relief at a Fraction of the U.S. Price; Indian Drugmaker Sidesteps Patents with U.N. Blessing, S.F. CHRON., July 7, 2004, at A8. While India has recently passed new patent legislation, there is still some debate regarding whether this bill will or should slow the production of generic AIDS drugs. See Robert Radtke, India Must Steer a Middle Path on Generic Drugs, FINANCIAL TIMES (London), Mar. 24, 2005, at 13.
Distribution Contracts

an extent that it cannot be salvaged even by a skillful public relations campaign. Since every potential intermediary is also a potential competitor, it is generally recommended that the manufacturer file the trademark or service mark applications before approaching the intermediary.

After considering these and other relevant factors, the manufacturer may well conclude in some cases that it is too risky to market and sell its medical devices in particular countries. Sometimes, the decision not to expand into a particular market may seem to be a lost business opportunity. Nevertheless, if the manufacturer has serious doubts after conducting the due diligence, the protection of its IP will typically outweigh the lost business opportunity.

5. Dealer Protection Laws

Dealer protection laws are laws providing extra-contractual rights and remedies to protect qualified dealers, including sales representatives and distributors. While many countries have repealed dealer protection laws, they still exist in some countries, mostly in Latin America and the Middle East, but also in Belgium. Coverage differs among the dealer legislation. In the United States, Puerto Rico enacted dealer legislation in 1964 that covers sales representatives as well as distributors. Typically, dealer protection laws restrict the principal’s right to terminate a dealer or obligate the principal to pay the dealer severance indemnities upon termination.

35 Examples are Guatemala, Ecuador, and Nicaragua. See Press Release, Office of the U.S. Trade Representative, Dep’t of State, U.S. and Central American Countries Conclude Historic Free Trade Agreement (2003), available at www.state.gov/p/wha/rls/prsrl/27492.htm. The laws were typically repealed without retroactive effect so that existing dealer agreements continued to be governed by the dealer protection laws.

36 For example, Belgium’s dealer protection law applies to exclusive distributors that have been appointed without a fixed term. Brazil’s statute covers sales representatives, but there are indications that courts may also apply it to distributors. Similar uncertainty exists in Colombia. Costa Rica’s dealer protection laws cover both sales representatives and distributors as long as the principal is non-Costa Rican. The dealer protection laws of Haiti, the Dominican Republic, El Salvador, Honduras, and Paraguay apply to sales representatives as well as distributors.


38 For example, under Puerto Rico’s dealer legislation, a principal will be liable for damages for terminating or refusing to renew a dealer agreement without “just cause.” Id. § 278b.

39 For example, Belgium’s dealer protection law requires the payment of “good-will indemnity” as well as cost reimbursement. Joost Everaert, Termination of
While not a strict dealer protection law, a system implemented by the member countries of the European Union (EU) merits special mention. In 1986, the Council of the European Communities issued Directive 86/653/EEC relating to self-employed commercial agents (the Agency Directive). The Agency Directive contains minimum requirements to be implemented by the EU member countries regarding remuneration, termination, and restraint of trade clauses following termination (i.e., post-termination covenants not to compete). Because the Agency Directive establishes only minimum requirements, the laws of the individual member countries may provide greater protections for sales representatives. On its face, the Agency Directive applies only to sales representatives, not distributors. In some countries, however, courts have begun to apply some of the protections of sales representatives by analogy to distributors if certain requirements are met. In short, before terminating any intermediary, the manufacturer should inquire whether a termination indemnity is due and what notice must be given.

6. Use of the Prospective Intermediary during the Due Diligence

In many cases, the prospective intermediary may be a good source of information regarding local marketing, regulatory, business, and cultural conditions, especially if the intermediary has extensive experience assisting foreign manufacturers. In the end, however, medical device manufacturers should not rely on the representations and conclusions of the intermediary. The

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41 Id. at arts. 6–12. Remuneration refers to commissions, but may include other payments or value. Article 6 states that “[a]ny part of the remuneration which varies with the number or value of business transactions shall be deemed to be commission.” Id. at art. 6(2).

42 Id. at arts. 14–19. See infra notes 130-138 and accompanying text.


44 For further discussion of post-termination covenants not to compete, see infra note 92 and accompanying text.

45 A “commercial agent” is a “a self-employed intermediary who has continuing authority to negotiate the sale or the purchase of goods on behalf of another person, hereinafter called the ‘principal,’ or to negotiate and conclude such transactions on behalf of and in the name of that principal.” Id. at art. 1(2).

46 See infra note 139 and accompanying text.
intermediary will have its own agenda and may not always be objective about the risks and dangers of entering the country. Independent brokering agents, as mentioned above, may provide more objective assistance to the manufacturer and can be valuable in assessing claims made by the intermediary during negotiations. In addition, intermediaries are typically not legal professionals and, while having business knowledge or experience, may not be familiar with legal details. Thus, the manufacturers should seek independent counsel from a legal professional admitted to practice in the foreign country. While engaging local counsel may be costly, it is often cheaper to identify and address legal issues at the outset rather than having to deal with their consequences at a later time. In short, a manufacturer that wants to do business outside the United States should make the investment to do so correctly.

II. Specific Issues and Terms of the Intermediary Agreement

Written intermediary agreements typically establish continuing, often long-term, rights and obligations. As such, they should be carefully negotiated. More than once, the authors have seen problems caused by agreements that were negotiated and prepared carelessly, driven by the desire to “quickly close the deal.” Of course, optimal preparation time must be balanced against commercial realities, such as the need to act swiftly in the face of competition. Accordingly, the authors recommend the development of form agreements that can be quickly adapted to various circumstances. As a word of caution, however, such form agreements should not be considered “fill-in-the-blank” agreements. Each transaction will have its own facts and circumstances that require a careful adaptation and review by in-house or outside counsel. The written intermediary agreement should contain many, if not all, of the provisions discussed below.

A. Appointment

At the heart of the intermediary agreement is the appointment clause, pursuant to which the intermediary is appointed as a distributor or sales representative. This clause determines the extent of the marketing and sales activities; specifically, it identifies the medical devices to be marketed, the geographic territory and customer groups, and any rights of exclusivity for the intermediary. Before agreeing with the intermediary on these points, the manufacturer should verify that no other agree-
ments exist that may conflict with the appointment, such as an exclusive distributorship with regard to the territory for which the intermediary will be appointed. This type of overlapping distribution arrangement is known as “channel conflict” and can result in competition between intermediaries that sell the same medical devices in the same territory. If the manufacturer contemplates the appointment of other intermediaries in the future, even if it does not yet have concrete plans for other appointments, then a non-exclusive appointment is preferable. Exclusive versus non-exclusive appointments are discussed in more detail below.

1. Identification of the Medical Devices

The identification of the medical devices to be marketed can be broad or narrow. The broadest scope would be “all products that are offered by the manufacturer for general commercial distribution or sale in the Territory.” A narrower appointment would focus on specifically identified medical devices. Whether broad or narrow, since the manufacturer’s line of medical devices may change, the manufacturer should reserve the unilateral right to add or delete individual devices from the products to be marketed as well as the ability to change or alter any of such products. If the intermediary is appointed for only a specific group or type of medical devices, they should be identified with specificity to avoid any ambiguity. For reasons of clarity, it is also desirable to identify any medical devices that the manufacturer does not wish the intermediary to market; for example, devices marketed exclusively by another intermediary. The intermediary agreement should also specify whether next generation devices or replacement products are covered. The manufacturer may be particularly interested in covering next generation devices if it envisions a long-term relationship with the intermediary or wishes the intermediary to be responsible for broadly marketing the manufacturer’s medical devices.

2. Identification of the Territory and Customer Groups

The agreement should specifically identify the geographic territory in which the intermediary will market the medical devices. The manufacturer should beware ambiguous definitions of the territory. Some agreements describe a territory as “America” or “North America” or “Europe.” While such descriptions may be perfectly clear to the negotiating parties at the time they enter into the agreement, the ambiguity can

47 Assuming that “Territory” is a defined term. See infra Parts II.A.2, II.B.4.a.
Distribution Contracts

create subsequent interpretative difficulties. For example, it is unclear whether “America” means only the United States or also Canada and Latin and South American countries. Likewise, “North America” is commonly understood to refer to the United States and Canada, but arguments could possibly be made that parts of Mexico were intended to be included. Europe is not a country and can be interpreted to mean the European continent (including parts of Russia and Turkey), the twenty-five member countries of the European Union (EU), or the member countries of the European Free Trade Association. Thus, it is almost always preferable to define the territory by specific national boundaries, or subdivisions thereof, such as states, provinces, counties, or cities.48

When defining a territory by national boundaries, the manufacturer should consider whether any outlying territories or political enclaves or areas of the countries should be included in or excluded from the territory. For example, if the territory is the United States, the manufacturer should determine whether it wishes to include all states and the District of Columbia as well as the territories, such as the U.S. Virgin Islands, Guam, and Puerto Rico. In some cases, the manufacturer may envision outlying territories to be within the territory of another intermediary. For example, the manufacturer may intend to give another intermediary responsibility for the Caribbean, including the U.S. Virgin Islands. If so, the U.S. Virgin Islands should be carved out from the U.S. intermediary’s territory. Based on the potential for overlapping descriptions of territories, it is generally desirable to define the territory of the United States as “all fifty states and the District of Columbia of the United States,” and if the inclusion of all or some of the territories is desired, they should be listed in the definition.

Clear definition of the territory is also important for international marketing agreements because many countries have outlying areas. For example, defining the territory as the United Kingdom can be interpreted to include all overseas

48 For more protection, the appointments clause can include an express prohibition of the intermediary to market any products outside the territory or inside the territory for shipment or distribution outside the territory. As such, the agreement does not permit the intermediary to establish an indirect line of marketing into any areas outside the territory. Nonetheless, to prevent the loss of sales from opportunities from outside the territory, the intermediary should be required to notify the manufacturer promptly of such opportunities and provide the manufacturer with the relevant information necessary to pursue such opportunities.
Distribution Contracts territories and crown possessions, such as Bermuda or the British possessions in the West Indies. Thus, if the manufacturer only wishes to grant rights with regard to the areas of England, Wales, Scotland, and Northern Ireland, and possibly the Channel Islands and Isle of Man, the territory should be defined accordingly. Political enclaves include embassies, consulates, military installations, and vessels. In most cases, the nature of the intermediary’s marketing will not necessitate a determination whether such enclaves should be included or excluded. In some cases, however, it may be relevant and the manufacturer should be mindful of this issue.

In some instances, the manufacturer may wish the intermediary to focus on particular customer groups, such as hospitals or private physicians. The agreement should then specifically delineate the customer group for which the intermediary is appointed. This may be particularly relevant with regard to medical devices that can be used for human as well as veterinary purposes. If the manufacturer wants the intermediary to market only in the human-medical market, the agreement should define the customer group to exclude veterinarians. Likewise, in some cases, the manufacturer may wish to exclude certain customer groups. For example, government health plans or programs should be carved out from the intermediary’s customer group if the manufacturer wishes to use another specialized intermediary to sell to government health plans or programs.

3. Exclusive vs. Non-Exclusive Appointment

The appointment of an intermediary may be exclusive or non-exclusive. Without any designation, the appointment will generally be interpreted to be non-exclusive. A non-exclusive appointment gives the manufacturer the right to appoint any other party to market the products in the appointed territory, or to directly market or sell the medical devices in the territory. An exclusive appointment generally does not permit the manufacturer to appoint other intermediaries in the same territory. A non-exclusive appointment provides the manufacturer with more flexibility. For example, if the manufacturer decides that the intermediary’s performance is substandard,

49 The UCC recognizes exclusive agreements to the extent they are lawful. U.C.C. § 2-306(2) (2002). The lawfulness of an exclusive agreement is often a question of antitrust law. Section 3 of the Clayton Act prohibits contracts that may substantially lessen competition or tend to create a monopoly in a line of commerce. Clayton Act, ch. 323, §3, 38 Stat. 730, 731 (1914) (current version at 15 U.S.C. § 14 (2005)). Nevertheless, exclusive dealing arrangements are
the manufacturer is free to appoint any other intermediary. Many, if not most, intermediaries, however, will argue for an exclusive appointment.

Many of the most important considerations for manufacturers are in the area of exclusivity. This aspect of the intermediary agreement must be carefully considered because it affects the manufacturer’s entire distribution structure. Exclusivity is very important to the intermediary. Many, if not most, intermediary agreements, particularly with experienced intermediaries, will be exclusive, at least in the United States. Nevertheless, whenever possible, the manufacturer should reserve the right to market and sell its medical devices directly in the territory through its own employees. This right will allow the manufacturer to continue serving specific customers directly, as may be necessary or desirable for business reasons. Such a reservation may be useful even if the manufacturer does not currently intend to conduct any direct marketing and sales. For example, the manufacturer may not wish to disclose specific customers, such as large direct accounts. In addition, the intermediary will be aware that a decrease in the intermediary’s performance might cause the manufacturer to increase marketing through its employees in the territory, which can serve as an added incentive for the intermediary to succeed.

One technique to mitigate the constraints of an exclusive appointment is the negotiation of exceptions to exclusivity. A primary example is the right of the manufacturer to convert an exclusive appointment to a non-exclusive one in the event of underperformance of the intermediary. In the event of the intermediary’s underperformance, the manufacturer may have numerous contractual remedies, including termination of the intermediary agreement either immediately or after notice and an opportunity to cure.

The ability to convert an exclusive arrangement to a non-exclusive one allows the manufacturer to use other distributors or

generally upheld under this provision “unless the court believes it probable that performance of the contract will foreclose competition in a substantial share of the line of commerce affected.” Tampa Electric Co. v. Nashville Coal Co., 365 U.S. 320, 327 (1961).

If such right is not reserved, it may not be clear whether the exclusive appointment prevents the manufacturer from conducting any direct marketing and sales in the territory, which is a question that will depend on the interpretation of the intermediary agreement. Thus, it is preferable to expressly reserve the manufacturer’s right of direct marketing in the territory.
sales representatives without completely eliminating its relationship with the intermediary. Again, since the intermediary is aware of that right, it will serve as an incentive to continued performance. The exercise of this right should be reserved to be used in the manufacturer's discretion based on failure to meet agreed performance standards. Underperformance can be defined broadly as the intermediary's failure to make the required efforts for marketing the medical devices as well as the failure to meet specific quantitative performance goals. It is desirable that the determination of underperformance as well as any partial or complete termination rights be reserved in the manufacturer's sole (or alternatively, reasonable) discretion, possibly in combination with a notice and cure period.

Another exception to exclusivity should be negotiated if the manufacturer has or contemplates appointing “national” or “global” intermediaries. “National” or “global” intermediaries are intermediaries appointed for a territory encompassing one or more countries or the whole world. Such intermediaries are sometimes appointed as part of “strategic alliances” by the manufacturer to achieve effective marketing coverage of key markets through a single intermediary with broad reach. Often, these are experienced or long-standing industry “players” that are effective marketers on a national or global scale of complementary devices. Without the exception, the manufacturer's desire to enter a strategic alliance could cause a channel conflict with smaller intermediaries with more restricted territories. Based on the size of their territory, national and global intermediaries are rarely, if ever, appointed as exclusive intermediaries. Statewide or local intermediaries are more likely to be given an exclusive appointment. Therefore, the activities of any current or contemplated national or global intermediary's activities must be exempt from the exclusivity. Maintaining national or global intermediaries can also provide protection against total dependence on an exclusive local intermediary.

The manufacturer should also negotiate exceptions for current or future affiliates that the manufacturer has or may acquire in business combinations. This is obvious for any current affiliates of the manufacturer that are engaged in marketing medical devices. If exceptions to exclusivity are not carefully drafted, however, they may cover only current affiliates. As a result, any future plans to acquire other medical device entities or product lines place the manufacturer in the unenviable position of deciding whether to risk liability for breach of the intermediary agreement, forego the acquisition, terminate the
intermediary agreement, attempt to renegotiate the exclusivity provision, or limit the entity’s marketing after acquisition until the intermediary agreement is terminated or has expired. Since none of these options are desirable, the manufacturer should always negotiate an exception for current and future affiliates, even if the manufacturer has no current plans to acquire a marketing entity.

Another issue related to exclusivity is whether the intermediary may use any subrepresentatives or subdistributors to market the medical devices. Intermediaries with established marketing networks often use other intermediaries to market medical devices within subparts of their territory. In these cases, it is desirable to permit the intermediary to use subrepresentatives or subdistributors. The manufacturer should, however, negotiate an approval right with regard to these subintermediaries. The manufacturer can then ensure that the subintermediary is not a person or entity with whom the manufacturer had previously had a conflict or dispute or who the manufacturer deems to be unreliable.

B. Performance

The performance provisions are a second core component of the intermediary agreement because they establish the minimum performance obligations of the intermediary. The details of the performance provisions will vary with the specific transaction, and the following terms should not be viewed as a conclusive list of performance obligation issues.

1. Performance Standards and Goals

The most fundamental performance obligation is the intermediary’s duty to market the manufacturer’s medical devices to a standard set forth in the agreement. The performance standards in the intermediary agreement should be general (e.g., “best efforts” or “commercially reasonable efforts”) as well as specific quantitative performance goals. Typically, the manufacturer will want to impose a high standard by requiring the intermediary to make “best efforts.” “Reasonable efforts” or “commercially reasonable efforts” are lower standards and generally less desirable for the manufacturer. Specific performance requirements, also referred to as “performance metrics,” can be as extensive or narrow as desired. Typically, these take the form of minimum sales or orders, either in product units, dollar volume, or a mixture of both, that must be achieved by
the intermediary within a designated time. Specific goals can also center on the number or rate of new customer accounts developed, sales calls made, trade shows and other industry events attended, customers retained, and similar achievements.

Specific performance goals may differ between sales representatives and distributors. For example, for sales representatives, a performance metric may be a minimum number or monetary value of orders from customers. For distributors, the performance metrics usually represents a minimum unit number or monetary value of purchases from the manufacturer. The negotiation of specific performance metrics will likely be more intricate with regard to sales representatives. Since sales representatives do not purchase from the manufacturer, their success is directly dependent on the number of sales to or orders from customers arranged by the sales representative. Practically, the manufacturer will sell to almost all of the customers introduced by the sales representative. Nonetheless, the manufacturer should reserve the right to accept or reject any customer orders. This allows the manufacturer at least theoretically to affect the amount of successful customer orders procured by the intermediary, and as such, the sales representative’s ability to meet performance metrics. Therefore, sales representatives may negotiate for performance metrics consisting of introductions made or orders submitted in good faith to the manufacturer, rather than orders accepted or sales made by the manufacturer.

Performance metrics vary with commercial reality. As such, the manufacturer must decide whether to establish performance goals for the intermediary’s territory as a whole, for specific areas or regions of the territory, or both. Regional or local performance goals are preferable in large territories with regional or local market differences and where the manufacturer intends to monitor the intermediary’s performance in each of the regional or local areas. Regional or local performance goals may also be necessary when an intermediary appoints subintermediaries. Control over the intermediary’s performance can be useful when the manufacturer has little experience with the intermediary and desires a more detailed track record. A distributor or sales representative seeking a large territory may not

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51 Specific performance goals are particularly valuable in exclusive appointments. Establishing a failure to meet specific performance goals is generally easily substantiated. Thus, by reserving the right to terminate the exclusivity if the intermediary fails to meet the agreed-upon performance goals, the manufacturer can quickly convert the exclusive appointment into a non-exclusive appointment.
adequately consider its ability to produce results throughout the entire territory. This should be discussed during negotiations and appropriate metrics identified for any geographical subdivision.

The time period designated to achieve the performance goals is the second important factor in establishing performance goals. There are arguments for and against selecting shorter time periods (e.g., a calendar quarter rather than a year) at the outset of a relationship with an intermediary. Shorter time periods permit the manufacturer to determine the intermediary’s effectiveness more quickly and to terminate the relationship, or exclusivity within a geographical subdivision of the territory if such termination right has been negotiated, at the end of the initial term if necessary. On the other hand, the intermediary will argue that a longer start-up period is required. This argument is more persuasive if made by intermediaries with little experience in marketing the manufacturer’s medical devices or medical devices of the same type. If an intermediary claims to have extensive experience, a short start-up period should not be a problem. Thus, the duration of the time period for the performance goals can be a way to test the experience touted by the intermediary.

In addition, the manufacturer should anticipate the need to change the performance metrics. Typically, the manufacturer will want a unilateral right to increase the performance metrics, which the intermediary will resist. Manufacturers and intermediaries often compromise on this point by agreeing to revisit and adjust the performance goals at certain intervals or to set a specific rate of increase in advance.

2. Marketing Obligations—Efforts and Materials

The basic obligation of the intermediary will be to market, offer for sale, and sell the manufacturer’s medical devices. It is often useful to state the specific types of marketing expected from the intermediary, such as active representation at trade shows and physician visits. The manufacturer may also require that the intermediary make a minimum number of such visits and attend specific trade shows along with the requirement to maintain a booth and prominently display and advertise the manufacturer’s devices. In addition, the manufacturer should consider requiring the intermediary to submit marketing plans at regular intervals, at least annually, and have responsible executives meet with the manufacturer to discuss the plan. A
marketing plan is useful because it identifies the intermediary’s anticipated efforts and provides a standard against which the intermediary’s performance can be measured. However, establishing standards in a marketing plan means that the manufacturer has to monitor compliance with the plan, or potentially lose the right to enforce whatever standards have been agreed under principles of laches or waivers. Under certain circumstances, the lack of enforcement of a right can result in its waiver or give rise to a course of performance implicitly changing the intermediary’s contractual obligations.\footnote{See WILLISTON & LORD, supra note 17, § 39:30.} Thus, if the manufacturer is not able to monitor the marketing plan in practice, requiring it may not be desirable.

The intermediary agreement should also address the marketing materials that will be used by the intermediary for marketing and selling. Marketing materials are important because they impact the effective marketing of the products, reflect on the manufacturer, and shape its reputation. They can also give rise to liability, for example, on the basis of representations or warranties contained therein. Furthermore, when the products are marketed and sold in another country, the manufacturer should ensure that the marketing materials meet that country’s legal requirements, such as consumer or fair marketing laws.

Accordingly, the manufacturer should reserve the right to approve all marketing materials prior to use. Otherwise, a careless statement in marketing material could give rise to the manufacturer’s liability for misrepresentation, deceptive trade practices, or even product liability. In some cases, the manufacturer may have already produced marketing materials that it wishes to sell or provide without charge to the intermediary. In other cases, the manufacturer will wish to impose the obligation of creating and producing the marketing materials on the intermediary at the intermediary’s cost and subject to the manufacturer’s approval. Either situation would provide the manufacturer with control over the content and substance of the marketing materials.

It is worth mentioning that control over the marketing materials is particularly important when the medical devices are marketed and sold in a language other than English. The manufacturer should ensure that the materials are accurate, complete, and legally sound. Therefore, the intermediary agreement should designate the party responsible for preparing translations. If
the intermediary is that party, the manufacturer should reserve the right to review and approve the translations.

3. Legal Compliance

The intermediary should be subject to a general obligation to comply with all applicable laws. Typically, the intermediary is also required to give a warranty of legal compliance. A standard legal compliance provision reads as follows:

Intermediary shall perform all of its obligations and carry out any activities under or in connection with this Agreement at its own cost and expense in accordance with all applicable Laws, including, but not limited to, any Laws regarding unfair competition, data privacy, consumer protection, and requirements to obtain approvals, consents, licenses, registrations, payment of taxes, customs fees or duties, or other fees or charges.

The manufacturer should be aware that two areas of legal compliance have particular relevance in the context of marketing medical devices: healthcare regulatory law and privacy law. Numerous articles and publications have been devoted to these topics. Thus, a discussion of these matters is not only beyond the scope of this Article, but risks being duplicative. Nevertheless, the particular relevance of these areas in the manufacturer’s relationship with the intermediary must be noted.

Healthcare regulatory law spans many diverse areas that are relevant in the distribution or sales representative relationship, but a specific concern is compliance with regulations controlling the sale and marketing of medical devices paid for under government health plans, such as Medicare or Medicaid. Depending on the type of health plan, the regulations may be federal law, such as the federal Anti-Kickback Statute, the False Claims Act and other federal regulations, state law, or local law. The general purpose of these regulations is to prevent overcharging or overbilling of these health plans. Violations of

53 The term “Laws” is typically defined to include federal, state, and local laws, statutes, regulations, rules, ordinances, and orders. It should be adapted as needed for international intermediary agreements.
56 See Robert N. Rabecs, Kickbacks As False Claims: The Use of the Civil False Claims Act to Prosecute Violations of the Federal Health Care Program’s Anti-Kickback Statute, 2001 LAW REV. MICH. ST. U. DETROIT C.L. 1, 38 ("[T]he False Claims Act has
these regulations are generally diligently investigated, and violators can face significant liability. Moreover, the manufacturer can be liable even if the intermediary violated the regulations. Since compliance with healthcare regulations constitutes a specific risk area for the manufacturer, the intermediary agreement should explicitly require the intermediary to comply with healthcare law in general and the Anti-Kickback Statute and similar laws and regulations in particular.

Similarly, compliance with privacy laws has become an increasing concern, in particular because of the growing management of information through Internet-accessible databases. In the United States, the most important privacy law in the healthcare area is the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the regulations issued thereunder by the U.S. Department of Health and Human Services (DHS). The manufacturer must also be aware of state privacy laws or regulations not preempted by federal law. Contractors of the manufacturer that have access to protected health information must agree to maintain the confidentiality of such information by signing a business associate agreement.

been increasingly used to combat fraud in the health care industry, including the submission of allegedly false or fraudulent claims for Medicare and Medicaid reimbursement.


59 For example, California law requires

[a]ny person or business that conducts business in California, and that owns or licenses computerized data that includes personal information, shall disclose any breach of the security of the system . . . to any resident of California whose unencrypted personal information was, or is reasonably believed to have been, acquired by an unauthorized person.

CAL. CIV. CODE § 1798.82(a) (2005). Personal information is defined as an individual’s first and last name together with at least one of certain identifying items of information, such as an account, credit or debit card number. Id. § 1798.82(e). In 2003, Sen. Dianne Feinstein of California introduced a bill for the Notification of Risk to Personal Data Act, S. 1350, 108th Cong. (2003) (pending in the Senate Judiciary Committee).

60 Protected health information is defined as “individually identifiable health information . . . that is: (i) Transmitted by electronic media; (ii) Maintained in electronic media; or (iii) Transmitted or maintained in any other form or
with the manufacturer.\textsuperscript{61} Since the intermediary may have access to protected health information through its marketing and sales activities, intermediary agreements typically require the execution of a business associate agreement. Most manufacturers already have a standard business associate agreement, which can be attached as an exhibit to the intermediary agreement and executed separately by the parties. DHS has published a sample business associate agreement that serves as a guide to the relevant provisions.\textsuperscript{62}

The following is an example of a legal compliance provision focused specifically on healthcare and privacy laws:

The parties mutually agree that it is their understanding and intent that this Agreement complies with applicable federal and state laws and regulations, including, without limitation, the federal anti-kickback statute (42 U.S.C. § 1320a-7b) and to the extent possible, the Office of Inspector General’s Safe Harbor regulation for personal services and management contracts (42 C.F.R. § 1001.952) and any Safe Harbors available under state Law. Nothing contained in this Agreement shall be construed in any manner as requiring Intermediary to cause a Customer [as defined] to purchase any product from, or otherwise refer any business to, the Manufacturer. The parties further agree that this Agreement does not involve, or cause the provision of, counseling or promotion of a business arrangement that violates federal or state Law. The parties acknowledge that Intermediary is a “business associate,” as that term is

\textsuperscript{61} 45 C.F.R. § 164.502(e)(2), 504(e) (2005). Business associates are defined to include “with respect to a covered entity, a person who ... [p]rovides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation ... , management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.” \textit{Id.} § 160.103.

Distribution Contracts

defined in the Standards for Privacy of Individually Identifiable Information and the Security Standards, which were promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (“HIPAA”). Intermediary shall maintain the confidentiality, privacy and security of all protected health information and shall otherwise comply with HIPAA and all of the provisions set forth in Attachment ___ to this Agreement hereto, which is expressly incorporated herein and made a part of this Agreement.

Outside the United States, privacy laws vary widely among countries. For example, as a result of the implementation of various EU privacy directives,63 EU member countries have strict privacy laws, even though the particular requirements differ among the member countries. In most countries, protection of data privacy is a serious matter. Noncompliance can result in criminal and civil liability as well as a prohibition to transfer protected data by or to the manufacturer. Therefore, prior to entering a foreign country, the manufacturer should verify the requirements under the country’s privacy laws. In addition, the intermediary should explicitly agree to comply with the privacy laws, in particular prior to storing or transmitting any data to or for the manufacturer. The manufacturer may also consider an indemnity requiring the intermediary to defend and indemnify the manufacturer with regard to any privacy law violations.

In summary, the importance of ensuring compliance with healthcare and privacy law should not be underestimated. Apart from the legal compliance provisions in the intermediary agreement, the manufacturer should be alert to any suspected violations in these areas. Experienced manufacturers already have in-house or outside counsel with expertise in these areas and will likely have implemented a compliance regime. A start-

up manufacturer should become familiar with the legal rules in this area and develop a compliance program in conjunction with experienced legal counsel.

4. Restrictions

Intermediary agreements typically contain a number of restrictions that limit the authority or rights of the intermediary. The following are the most relevant in the context of intermediary agreements.

a. Territorial or Customer Restrictions

From the manufacturer’s point of view, the corollary to appointing the intermediary to a specific territory is a prohibition to market and sell outside that territory. This ensures that the intermediary agreement is not implicitly extended to cover other territories. Generally, limiting the intermediary to a specific territory is permissible in the United States.64 Territorial restrictions to a state or set of countries or, indeed, particular cities are common when dealing with independent distributors or sales representatives. These restrictions avoid destructive channel conflict, preventing commercial antagonism between intermediaries or between an intermediary and marketing employees of the manufacturer.

Problems, however, may arise under foreign law. A notable example is EU competition law. Under Article 81 of the EC Treaty,65 “agreements . . . which may affect trade between [EU member countries] and which have as their object or effect the prevention, restriction or distortion of competition within the common market” are prohibited.66 Such agreements are automatically invalid.67 The prohibition includes agreements that “limit or control production, markets, technical development, or investment”68 (i.e., vertical agreements, which

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66 EC Treaty art. 81(1).
67 Id. art. 81(2).
68 Id. art. 81(1)(b).
include intermediary agreements that restrict the territory or customer groups of the intermediary). Article 81, however, applies only if there is an appreciable impact on competition or trade between EU member countries, thus excluding *de minimis* agreements. Consequently, many intermediary agreements, at least by smaller manufacturers, may not be covered by Article 81. Agreements may be exempted from the prohibition if they receive an individual exemption granted by the Commission or fall under the scope of a block exemption.

The most important block exemption in this area is the regulation dealing with the application of Article 81(3) of the EC Treaty to vertical agreements relating to the purchase, sale, or resale of goods or services between two or more undertakings that operate at different levels of the production or distribution chain. The block exemption has no application if the market share by the supplier exceeds thirty percent of the relevant market in which it sells the goods or services. The market share

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69 The EU Commission’s Notice on Agreements of Minor Importance of December 22, 2001 established a guideline for determining an appreciable restraint on competition. *Commission Notice on Agreements of Minor Importance Which Do Not Appreciably Restrict Competition Under Article 81(1) of the Treaty Establishing the European Community (de minimis)*, 2001 O.J. (C 368) 7, 13, available at [http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/c_368/c_36820011222en00130015.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/c_368/c_36820011222en00130015.pdf) (last visited Sept. 22, 2005). Under § 7, agreements do not appreciably restrict competition under article 81 of the EC Treaty (a) if the aggregate market share held by the parties to the agreement does not exceed 10% on any of the relevant markets affected by the agreement, where the agreement is made between undertakings which are actual or potential competitors on any of these markets (agreements between competitors); or (b) if the market share held by each of the parties to the agreement does not exceed 15% on any of the relevant markets affected by the agreement, where the agreement is made between undertakings which are not actual or potential competitors on any of these markets (agreements between non-competitors).


71 EC Treaty art. 81(3). However, the exemption does not protect against violations for abuse of a dominant market position under article 82.


73 *Id.* at 23 art. 2(1).

74 *Id.* at 23 art. 3(1).
is determined on the basis of the sales during the preceding year.\textsuperscript{75} The relevant market is determined by the market of the products as well as the geographic market covered by the supply agreement. While the geographic market will often be clearly identifiable, it can be difficult to determine the product market, specifically, how broadly or narrowly the relevant product market should be defined.\textsuperscript{76} Under the block exemption, restrictions on the territory or customer groups to which the goods or services may be marketed, as well as active or passive sales to end users by retailers are among the impermissible hardcore restrictions.\textsuperscript{77} The block exemption, however, excepts territorial and customer group restrictions if they apply to “active sales into the exclusive territory or to an exclusive customer group reserved to the supplier or allocated by the supplier to another buyer,” as long as the sales by the buyer’s customers are not limited.\textsuperscript{78} Passive sales, i.e., sales in response to unsolicited orders (including general advertising and sales over the Internet) may not be barred.\textsuperscript{79} It is permissible, however, to bar “sales to end users by a buyer operating at the wholesale level.”\textsuperscript{80} In light of these strict and detailed competition regulations, the manufacturer should ensure that intermediary agreements containing any territorial or customer group restrictions are reviewed for compliance with EU competition law.

\begin{itemize}
\item \textsuperscript{75} Id. at 24 art. 9(2)(a).
\item \textsuperscript{76} For example, depending on the type of medical devices, the relevant market can consist of the market for identical medical devices or the market for medical devices having the same purpose or function. The Commission’s interpretative Guidelines on Vertical Restraints describe the determination of the relevant market as follows:

In order to calculate the market share, it is necessary to determine the relevant market. For this, the relevant product market and the relevant geographic market must be defined. The relevant product market comprises any goods or services which are regarded by the buyer as interchangeable, by reason of their . . . use. The relevant geographic market comprises the area in which the undertakings concerned are involved in the supply and demand of relevant goods or services, in which the conditions of competition are sufficiently homogeneous, and which can be distinguished from neighbouring geographic areas because, in particular, conditions of competition are appreciably different in those areas.

\item \textsuperscript{77} Commission Regulation 2790/1999, supra note 72, at 23 art. 4(b)–(c).
\item \textsuperscript{78} Id. at 23 art. 4(b).
\item \textsuperscript{79} See id. at 23 art. 4(c).
\item \textsuperscript{80} Id. at 23 art. 4(b).
\end{itemize}
b. Covenants not to Compete

The medical device market is highly competitive, continuously invigorated by new products and technologies. Therefore, it is not only important for the manufacturer to stay technologically competitive, but also to market competitively. Covenants not to compete are useful because they prohibit the intermediary from marketing and selling competing devices or DME articles manufactured by others. Covenants not to compete are governed by state law in the United States. Thus, depending on the scope of the intermediary’s territory, the manufacturer must ensure that a covenant not to compete meets the requirements of the state where the medical devices will be marketed. While most states recognize and enforce covenants, they are generally disfavored and interpreted restrictively. Generally, covenants not to compete must be reasonable. In addition, the covenant must be ancillary to a valid contract. In a growing number of jurisdictions, covenants not to compete are regulated by statute. These statutes generally enacted the reasonableness and ancillary requirements. Reasonableness is measured by the scope of the restriction that the covenant not to compete places on geography, time, and subject matter. There is no bright-line rule as to when a covenant not to compete is reasonable. Instead, it is a matter of the specific circumstances.

81 An exception is California. California’s Business and Professional Code provides that “every contract by which anyone is restrained from engaging in a lawful profession, trade, or business of any kind is to that extent void.” CAL. BUS. & PROF. CODE § 16600 (2005). The statute recognizes exceptions in the event of a sale of a business or following dissolution of a partnership or disassociation of a partner from a partnership. Id. §§ 16601–16602.
82 See, e.g., Reed, Roberts Assoc., Inc. v. Strauman, 353 N.E.2d 590, 592 (N.Y. 1976) (holding that “negative covenants restricting competition are enforceable only to the extent that they satisfy the overriding requirement of reasonableness.”); RESTATEMENT (SECOND) OF CONTRACTS § 186 cmt. a (1979).
84 See, e.g., id. § 15.50(a).
85 A covenant not to compete is enforceable if it is ancillary to or part of an otherwise enforceable agreement at the time the agreement is made to the extent that it contains limitations as to time, geographical area, and scope of activity to be restrained that are reasonable and do not impose a greater restraint than is necessary to protect the goodwill or other business interest of the promisee.

Id.
86 Id.
87 Reed, 353 N.E.2d at 593 (“[T]he formulation of reasonableness may vary with the context and type of restriction imposed.”). Unreasonable covenants not
In intermediary agreements, it is not uncommon to agree on a covenant not to compete covering the appointed territory and products that are identical or substantially similar to those marketed by the intermediary for the manufacturer and lasting for the duration of the intermediary agreement and a period of up to two years thereafter.

Outside the United States, the law on post-termination covenants not to compete varies. In the EU member countries, covenants not to compete are generally restraints of trade under Article 81 of the EC Treaty. Specifically, the block exemption of the 1999 European Communities’ Commission Regulation Number 2790 provides that noncompete obligations in vertical agreements are not permissible if their term is indefinite or exceeds five years. The Commission Regulation defines noncompete obligations as:

any direct or indirect obligation causing the buyer not to manufacture, purchase, sell or resell goods or services which compete with the contract goods or services, or any direct or indirect obligation on the buyer to purchase from the supplier or from another undertaking designated by the supplier more than 80% of the buyer’s total purchases of the contract goods or services and their substitutes on the relevant market, calculated on the basis of the value of its purchases in the preceding calendar year.

Non-compete obligations are obligations that require the buyer to purchase from the supplier or from another undertaking designated by the supplier more than 80% of the buyer’s total purchases during the previous year of the contract goods and services and their substitutes (see the definition in Article 1(b) of the Block Exemption Regulation), thereby preventing the buyer from purchasing competing goods or services or limiting such purchases to less than 20% of total purchases. Where for the year preceding the conclusion of the contract no relevant purchasing data for the buyer are available, the buyer’s best estimate of
Specifically, post-termination covenants not to compete by sales representatives are governed by the provision of the Agency Directive.\textsuperscript{92} Under the Agency Directive, a post-termination covenant not to compete is valid only if it is in writing and “relates to the geographical area or the group of customers and the geographical area entrusted to the commercial agent and to the kind of goods covered by his agency under the contract”\textsuperscript{93} and is not longer than for two years.\textsuperscript{94} Individual member countries can impose additional restrictions and some have done so. For example, German law obligates the manufacturer to pay a reasonable compensation for the duration of the post-termination non-compete covenant.\textsuperscript{95} To the extent courts have applied the Agency Directive by analogy to distributors,\textsuperscript{96} its restrictions on post-termination covenants not to compete also apply to distribution agreements.\textsuperscript{97}

c. Product Restrictions

Product restrictions are limitations on the marketing of another manufacturer’s products in combination or jointly with the manufacturer’s medical devices. Intermediaries may represent a large array of manufacturers or products, some of which can

his annual total requirements may be used. Such non-compete obligations are not covered by the Block Exemption Regulation when their duration is indefinite or exceeds five years.

Commission Notice on Vertical Restraints, supra note 76, at 13 para. 58.

A non-compete arrangement is based on an obligation or incentive scheme which makes the buyer purchase practically all his requirements on a particular market from only one supplier. It does not mean that the buyer can only buy directly from the supplier, but that the buyer will not buy and resell or incorporate competing goods or services. The possible competition risks are foreclosure of the market to competing suppliers and potential suppliers, facilitation of collusion between suppliers in case of cumulative use and, where the buyer is a retailer selling to final consumers, a loss of in-store inter-brand competition. All three restrictive effects have a direct impact on inter-brand competition.

\textit{Id.} at 28 para. 138.


\textsuperscript{93} \textit{Id.} at art. 20(2).

\textsuperscript{94} \textit{Id.} at art. 20(3).

\textsuperscript{95} Handelsgesetzbuch [HGB][Commercial Code] May 10, 1897, RGBl. 1897, 219, as amended, § 90a(1).

\textsuperscript{96} \textit{See infra} note 139 and accompanying text.

\textsuperscript{97} Otherwise, post-termination covenants not to compete in distribution agreements are subject to the country’s treatment of contractual restriction of competition, which may vary from country to country.
be used or marketed in connection with the manufacturer’s products. Joint marketing or sales of such products raises a number of issues. Since the intermediary interacts with the end user on behalf of the manufacturer, the intermediary’s actions may be binding on the manufacturer under the principle of apparent authority. Thus, if another manufacturer’s product is combined or jointly packaged or sold with the manufacturer’s medical device, an end user may view them both as jointly sourced from or endorsed by the manufacturer, and the manufacturer may be exposed to liability for defects in such other product or any harm caused by the combination of the medical device with the product.

Issues may also arise under trademark law exposing the manufacturer to claims of “reverse passing off” by the manufacturer of the other product. Reverse passing off occurs when a producer “misrepresents someone else’s goods or services as [one’s] own.” If the marks of the other product’s manufacturer are removed or obscured by the intermediary as a result of the combined marketing, the manufacturer may be found to have permitted the intermediary to market and sell the other product under the manufacturer’s mark, and thus be liable for reverse passing off. Therefore, the intermediary agreement should state that the intermediary may not market any of the manufacturer’s medical devices jointly with other products without the manufacturer’s express prior written approval.

The manufacturer must be careful to avoid the appearance of a tying arrangement, which typically constitutes a violation of U.S. antitrust law. Tying arrangements are “agreement[s] by a party to sell one product but only on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that product from any other supplier.” To be illegal, a tying arrangement requires the manufacturer’s use of its dominant position to require the distributor to purchase a separate product. Thus, the

98 See Restatement (Second) of Agency § 8 (1958).
100 “[B]ecause tying arrangements generally served no legitimate business purpose that cannot be achieved in some less restrictive way, the presence of any appreciable restraint on competition provides a sufficient reason for invalidating the tie.” Fortner Enter. v. U.S. Steel Corp., 394 U.S. 495, 503 (1969).
102 “[T]he essential characteristic of an invalid tying arrangement lies in the seller’s exploitation of its control over the tying product to force the buyer into the purchase of a tied product that the buyer either did not want at all, or might
restriction on joint marketing of nonmanufacturer products should be drafted to avoid the appearance that its purpose is requiring the distributor to purchase a separate product from the manufacturer or not purchase such product from another manufacturer.

d. Scope of Authority

From the customer’s viewpoint, the intermediary may appear to be a representative or agent of the manufacturer rather than only a reseller or independent sales representative. Therefore, the intermediary’s authority should be narrowly defined in the intermediary agreement. In distribution agreements, the manufacturer may wish to state explicitly that the intermediary has no power or authority to represent the manufacturer or make any representations, warranties, or covenants in the name or on behalf of the manufacturer. In sales representative agreements, the manufacturer may wish to provide that the sales representative may only receive purchase orders from customers for transmission to the manufacturer, but not enter into any sales contract with customers on behalf of the manufacturer. In each case, the intermediary should be required to disclose its limited authority at all times and avoid the appearance of any agency or authority to bind the manufacturer.

Limiting the intermediary’s authority in this way, however, does not eliminate the risk of being bound by the intermediary’s conduct. Under the principle of apparent authority or authority by estoppel, the manufacturer can be bound by the intermediary’s actions, if the intermediary’s actions gave the appearance of authority to act for the manufacturer and the manufacturer is found to have permitted such actions.\textsuperscript{103} Thus, the risks for the manufacturer can be significant if the intermediary is viewed to have apparent authority. For example, the intermediary might make an unauthorized statement about the capability of a medical device in addition to, or in conflict with, the manufacturer’s product warranties, thus potentially exposing the manufacturer to liability for breach of warranty or misrepresentation if the statement is incorrect or inaccurate. The manufacturer can take steps, however, to counteract unauthorized statements or actions by the intermediary.

\begin{footnotesize}
\begin{itemize}
\item \textsc{Restatement (Second) of Agency} § 8 (1958) (“Apparent authority is the power to affect the legal relations of another person by transactions with third persons, professedly as agent for the other, arising from and in accordance with the other’s manifestations to such third persons.”).
\end{itemize}
\end{footnotesize}
If the intermediary is a sales representative, the manufacturer can insert an integration clause into its standard terms of sale with the customer, which expressly negates any prior agreements, statements, or representations by the sales representative. In addition, the manufacturer can explicitly state in its terms of sale and product warranties that any warranties and representations made by the intermediary are invalid or ineffective. These steps, however, cannot completely eliminate the risk of liability under the principle of apparent authority.

Accordingly, two additional steps should become important aspects of any distribution arrangement, if feasible. First, the intermediary’s sales personnel should be required to attend the manufacturer’s product training at their expense. Second, the manufacturer should reserve a termination right in the event that the intermediary, or any of its sales personnel, makes unauthorized statements, promises, or warranties regarding a medical device.

6. Manufacturer’s Intellectual Property

As detailed above, the manufacturer should engage in thorough due diligence to protect its IP before deciding to expand its operations into a foreign country. Of equal importance are the terms in the intermediary agreement, whether for a domestic or international intermediary, dealing with the manufacturer’s IP.


To protect the manufacturer’s trade secrets and confidential information, the intermediary agreement should include a confidentiality and nondisclosure provision. Under this provision, the intermediary agrees to: (i) not use or disclose any confidential information other than to the extent such use is necessary to perform the intermediary’s obligations under the intermediary agreement; (ii) disclose any confidential information only to such employees that have a need to know during the performance of the intermediary’s obligations; and (iii) take at least the same, but not less than reasonable, precautions to secure and maintain the confidentiality of the manufacturer's confidential information as the intermediary takes for its own confidential information. In some circumstances, the inter-

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104 Confidential information is typically defined to include trade secrets and any information, materials, documents, and items of or relating to the manufacturer that are either marked as confidential or secret or are or should reasonably be deemed to be confidential based on their content or other circumstances.
b. Protection of Marks and Names

The most important IP consideration in an intermediary relationship is typically the protection of the manufacturer’s marks and name. Both the manufacturer and the intermediary are typically interested in the intermediary’s use of the manufacturer’s marks and name. The benefit to the manufacturer is the increased brand awareness among the customers of its medical devices. The benefit to the intermediary is the advantage of marketing products with a well-known brand. Thus, intermediary agreements typically contain a license to the intermediary to use the manufacturer’s marks and name. However, to avoid any loss of rights in, or dilution of, the marks and name, the intermediary’s use thereof should be tightly controlled by limiting the license’s grant.

The license should permit the use of the marks and name solely in marketing the manufacturer’s products. Whenever possible, the license should clearly identify the marks and name that the intermediary may use. Often, licenses are granted to “all marks and names of the manufacturer.” Such a grant is too broad. The manufacturer should only grant use rights to the extent that the intermediary needs them to market the specific medical devices. The license should be limited to marks and names that are explicitly listed in the intermediary agreement. Since the manufacturer may wish to add new, or retire old, marks or brands, or make changes to a mark, the manufacturer can ex-
pressly reserve the right to add to, delete from, or change the marks and names that are expressly listed in the license. The intermediary will likely require notice sufficiently in advance of any change. This request is not unreasonable, especially if the intermediary produced the marketing materials bearing the changed marks and name at its cost and thus would want to deplete its inventory of marketing materials before the change. The manufacturer should, however, always reserve the right to make any change immediately effective, if this is necessary for important business reasons, e.g., if the mark or name is reasonably believed to infringe a third party’s trademark or, for logos, copyright. A convenient way to identify the specific marks and names that are covered by the license is to set them forth on a schedule or exhibit to the intermediary agreement, to be changed or amended at the manufacturer’s sole discretion.

The manufacturer should also identify the specific use rights granted to the intermediary. Again, a broad license, such as “any use of the marks and names of the manufacturer in connection with the marketing of the products sold under this agreement,” would potentially give the intermediary more rights than necessary, increasing the risk of abuse by the intermediary or loss of the manufacturer’s rights through uncontrolled use. The manufacturer should limit the license by permitting the intermediary only to display and use the marks on authorized marketing material for the sole purpose of performing the intermediary’s marketing obligations. To prevent any later implicit extension of the licensed rights, it is useful to state that no rights other than those expressly granted are conferred on the intermediary. In many cases, the intermediary agreement lists specific types of conduct that are particularly unacceptable to the manufacturer and thus prohibited. These types of conduct include the use of the manufacturer’s marks and names for the intermediary’s own goods or services or those of any other person or entity, the intermediary’s application for or the registration of any of the manufacturer’s marks or names, or the intermediary’s changing or modifying any of the marks or names.

The scope of the license should be expressly stated. Typically, the license granted is non-exclusive, nontransferable, limited to the geographic territory of the intermediary’s appointment, and limited in time to the duration of the intermediary agreement. The intermediary agreement should also state whether the intermediary may grant sublicenses. The right to grant sublicenses should be given sparingly because it creates indirect control problems. If the intermediary uses subintermediaries
for marketing medical devices, the manufacturer may expressly extend the scope of the license to all authorized subintermediaries rather than permitting the granting of sublicenses by the intermediary. While the subintermediaries would then be third-party beneficiaries under the license with an enforceable right, all quality and other control mechanisms in the license would directly apply to the subintermediaries (as a condition for the license). The manufacturer would not have to rely on the intermediary separately imposing them completely and fully on to the subintermediary. The manufacturer should reserve the right to terminate the license immediately with regard to a particular subintermediary if the subintermediary violates any term of the license. If the license is terminated, the use right of all subintermediaries would terminate automatically (without need of any action by the intermediary). As a result, the manufacturer is able to more directly police the subintermediary’s use of the marks and name and the termination of the license.

An important part of any trademark license is the quality control provisions. The manufacturer risks loss of its rights in the marks and name if it grants the license without any quality control provisions, i.e., a so-called “naked license.”¹⁰⁶ Granting use of a mark without control, such as by permitting the marketing of low quality products, is deemed to be an abandonment of the mark causing the owner to lose its rights in the mark.¹⁰⁷ Therefore, under the law in the United States and many other countries, the intermediary must have the express obligation to maintain at all times the quality of the products and the reputation of the marks. A quality requirement is not sufficient, however, if the manufacturer does not exercise quality control. Therefore, the manufacturer must have the right under the intermediary agreement to control the maintenance of quality and reputation, and must exercise that right. The manufacturer should also reserve the right to terminate the trademark license (not necessarily by terminating the intermediary agreement as a whole), in the event of violations of the quality control provisions.

7. Sales Terms

In a sales representative relationship, the sale of the products occurs directly between the manufacturer and the customer. Typically, terms of sales that accompany devices shipped to

¹⁰⁶ Barcamerica Int’l USA Trust v. Tyfield Imp., Inc., 289 F.3d 589, 596 (9th Cir. 2002).
¹⁰⁷ Id.
the customer or delivered to a hospital (often by the sales representative for a surgical case) are standard terms that include a limited warranty, warranty disclaimers, and limitations of liability.

In a distributorship, however, the intermediary purchases and resells the medical devices. Thus, as stated above, each order by the distributor constitutes a separate sales contract. To provide for consistency and ensure that each of these individual sales contracts is subject to the same terms, the distribution agreement should set forth the terms under which the manufacturer sells its medical devices to the distributor. Depending on the negotiations with the distributor, these terms may often not be much different from the general sales terms used by the manufacturer for sales generated by the sales representative.

In the United States, all states (except Louisiana) have adopted, with some variations, Article 2 of the UCC, which governs the sale of goods, including medical devices, and provides the default terms for a sale of goods transaction. With some exceptions, such as in the area of limitation of damages for personal injury, the UCC permits the parties to vary their agreement from the Code’s provisions. Thus, the manufacturer has relative freedom in preparing its sales terms. When selling to a distributor outside the United States, however, the manufacturer should be mindful that other countries, especially civil law jurisdictions, such as those in Latin America and continental Europe, have different legal regimes. While almost all jurisdictions permit the parties to negotiate the terms of an agreement, they may impose limits on specific terms, such as disclaimers of warranty, limitation of liability, or remedies for defects. Therefore, the manufacturer must ensure that its terms, and also its product warranties, are valid and enforceable under the law of the country in which products are sold.

The terms of sale should at least specify the process for ordering the medical devices, the manufacturer’s right to accept or confirm any order, the shipping of the products and risk of loss, the transfer of title (which typically follows the risk of loss), and inspection of the medical devices upon receipt. In the inspection provision, the manufacturer typically seeks a waiver of the distributor’s rights with regard to any defect, damage, loss, or discrepancy in quantity that the distributor has, or should have, noticed as a result of the inspection, but regarding which the distributor failed to provide notice to the manufacturer. The manufacturer may also wish to provide for a security to
Distribution Contracts

ensure payment of the purchase price. In the United States, this will typically be a purchase money security interest.\textsuperscript{108} The manufacturer should be mindful, however, that civil law jurisdictions, such as the legal systems of continental-European countries, do not recognize purchase money security interests. Such jurisdictions recognize different types of securities, such as retention of title.\textsuperscript{109} Since the distributor immediately resells the medical devices purchased from the manufacturer, retention of title is not an effective form of security in the distribution context. Thus, the manufacturer should consider other forms of security permitted in such jurisdictions, such as a personal or bank guarantee or bond.

In international transactions, a letter of credit (“LOC”) is often used to secure payment. An LOC is issued by a bank for payment to a named person against presentation of specified documents, typically bills of lading, which must comply strictly with the terms of the LOC.\textsuperscript{110} The LOC minimizes the credit risk for the manufacturer and provides some protection to the distributor: the manufacturer is ensured payment upon receipt of the goods by the distributor; the distributor will not have to make advance payments and is ensured that payment is made only upon proof of its receipt of the goods. The most desirable is an irrevocable confirmed LOC because the advising bank (i.e., the manufacturer’s bank), confirms payment by the issuing bank (i.e., the distributor’s bank), thus removing any risk associated with the issuing bank. An irrevocable LOC cannot be amended or cancelled without the agreement of all parties. Use of an LOC is associated with fees. If a manufacturer is dealing with an intermediary of dubious credit standing, an LOC may be warranted as a condition of entering into the intermediary agreement. The manufacturer should then negotiate for allocation of the costs to maintain the LOC to the intermediary, but may have to be prepared to bear the costs.

Shipping and passage of risk of loss are important considerations. In United States transactions, the parties can use shipping terms, such as “FOB” (place of shipment or destination) or “CIF,” but the Uniform Commercial Code (UCC) cautions that parties should expressly agree to the meaning of those terms.\textsuperscript{111}

\textsuperscript{108} U.C.C. § 9-103(b)–(c) (2002).
\textsuperscript{109} Id. § 2-401(1) (provides reservation of title is ineffective and will be deemed to be a security interest).
\textsuperscript{110} Id. § 5-102(10).
\textsuperscript{111} Id. § 2-319 cmt. (Recognizing the shipping term “FOB,” but stating that it has been repealed as inconsistent with modern commercial practices. The effect
Distribution Contracts

Since the UCC for the most part defers to the specific agreement between the parties,\textsuperscript{112} it is preferable to specify shipping terms, any insurance requirements during shipment, and the moment when risk of loss passes to the distributor.

In the international context, it is typical to refer to the commercial terms established by the International Chamber of Commerce (INCOTERMS).\textsuperscript{113} There are thirteen different INCOTERMS with a spectrum of rules for different methods of shipping and allocation of shipping and insurance costs, risk of loss, and export and import clearance. On one end of the spectrum, the INCOTERM “EX WORKS” would require the distributor to receive the purchased goods at the manufacturer’s place of business, be responsible for shipping and import clearance, and bear the risk of loss after the goods have been placed at the distributor’s disposal.\textsuperscript{114} The other extreme is “DDP” (Delivered Duty Paid), which obligates the manufacturer to ship, export, and import the goods and place them at the distributor’s disposal at the designated location at the manufacturer’s cost and risk of loss.\textsuperscript{115} The other INCOTERMS allocate the shipping obligations, cost, and passing of risk of loss between the two extremes of “EX WORKS” and “DDP.” The rights and obligations under the respective INCOTERMS can be included in the agreement simply by referring to the INCOTERM selected by the parties. Since there are different editions of INCOTERMS, the selected edition should be identified. For example, the latest current edition is the 2000 edition; thus, the sales terms should refer to, for example, “EX WORKS (INCOTERMS 2000).” To avoid ambiguity under the respective INCOTERM as to the location at which the risk and shipping obligations shift from seller to buyer, the location should be clearly and specifically identified.

\textsuperscript{112} Id. § 2-303.
\textsuperscript{113} See Incoterms 2000 Rules at the Core of World Trade, at www.iccwbo.org/index_incoterms.asp (last visited Sep. 20, 2005), for more information.
The distributorship is an ongoing relationship, and any substandard performance or defect in the products will reflect negatively on the manufacturer. Thus, the intermediary agreement should ensure that the distributor serve its customers (the manufacturer’s end users) appropriately. Specifically, the distributor should be obligated to promptly deliver medical devices to its customers, in certain circumstances to keep an inventory of these devices, and not open or tamper with any product (especially any sealed packaging). Medical devices, in particular, may be extremely susceptible to incorrect handling or storage (such as in temperatures that are too high or low). It is particularly important that the intermediary agreement provide for medical products to be stored and handled consistent with all regulatory labeling. Thus, the intermediary must be obligated to ensure proper storage and shipment, and any assembly, in accordance with the manufacturer’s specifications and instructions. In some cases, the distributor may be required to assemble or assist the customer with the assembly and use of the medical devices. To ensure that the customer or end user receives all manuals and limited warranties intended for a specific product, the distributor should be obligated to ship all medical devices with the complete set of documentation provided by the manufacturer. Again, training of sales representative or distributor employees is critical to achieving some control over these customer-related functions.

C. Pricing and Payment

The intermediary agreement should include clear provisions regarding pricing and payments, including definite terms when payments are payable and due. While pricing under an intermediary agreement is a pure business matter, the pricing structure in the intermediary agreement differs fundamentally for distributors and sales representatives.

1. Distributors

Since a distributor purchases and acquires title to medical devices, pricing in a distribution agreement is generally the price agreed between the manufacturer and distributor. Establishing prices can be difficult, however, because of the conflicting interests. While both the manufacturer and the distributor are interested in offering products to customers at a lower price than the manufacturer’s competitors, antitrust law prohibits the manufacturer from setting the resell prices for the distribu-
Thus, the manufacturer can only indirectly affect the market price for a medical device by negotiating the price at which the distributor purchases from the manufacturer. Here, the manufacturer’s and distributor’s interests naturally diverge because each wants to secure as large a profit margin as reasonably possible. The manufacturer’s interest is in a higher price charged to the distributor (and thus a greater profit margin for the manufacturer), while the distributor’s interest is in keeping this price low (and thus increasing its profit margin). In the end, this is a matter of negotiation between the manufacturer and the distributor.

2. Sales Representatives

Sales representatives do not purchase the medical devices from the manufacturer, but are paid for their marketing efforts. Typically, the compensation is in the form of a commission (i.e., a percentage of the price at which the manufacturer sells the medical device to a customer that was introduced by the sales representative). The intermediary agreement should clearly define the basis on which the commission is calculated, and include the following:

a. any deductions, such as shipping costs, refunds, returns, discounts, duties, and taxes, that will be permissible before determining the base price for the commission;
b. the time when the commission will accrue;
c. the circumstances under which the sales representative should be obligated to refund the commission, such as in the event of a return of the medical device, a recall or a defect.

Each of these issues will have to be carefully negotiated. For example, it is in the manufacturer’s interest to permit greater deductions and broader refund obligations. Determining the time at which the commission becomes payable and due is a matter of risk allocation. If the commission is payable and due upon the manufacturer’s acceptance of the customer order or


\[117\] These factors are generally not relevant in a distribution agreement because the distribution agreement is a buy-sell relationship, under which payment typically occurs within a certain time of delivery of products or receipt of the manufacturer’s invoice. The distributor is often required to bear the cost of any shipping costs, duties, and taxes, although this may be negotiated.
the shipment of the medical device to the customer, the risk of nonpayment is borne by the manufacturer because the manufacturer would be obligated to pay the commission even if the customer does not pay the purchase price. On the other hand, if the commission is payable and due upon the customer’s payment of the purchase price, the sales representative shares the risk of nonpayment because no commission will be due without payment by the customer. From the manufacturer’s perspective, this is optimal because it will keep the sales representative focused on customer service if commissions are dependent on closed sales. In any event, all issues relating to commission payment should be considered and clearly addressed in the intermediary agreement.

D. Protective Clauses

While the foregoing sections of this Article dealt with the main performance obligations of the parties (e.g., the intermediary’s marketing and payment obligations), the following discusses provisions that are primarily intended to protect or shield the manufacturer from liability.

1. Warranties

Warranties have an important role because they establish minimum standards. They may relate to future performance obligations, such as performance warranties, or to current or future factual circumstances. Examples of the former category are warranties by the intermediary to perform the marketing obligation in a professional and workmanlike manner and in accordance with applicable law and warranties by the manufacturer regarding the products. Examples of the latter category are warranties regarding a party’s ability to enter into and perform the intermediary agreement and the lack of any conflicting obligations.

Generally, the manufacturer will want to negotiate at least the following warranties by the intermediary:

a. it has the full right and authority to enter into the intermediary agreement;

b. it will perform all of its obligations without being in conflict with any other contract and without disclosing another’s confidential information;

c. it will perform its marketing obligations in a professional and workmanlike manner and in compliance with any applicable law and good business ethics; and
d. it will specifically comply with any healthcare regulatory law as well as medical privacy law.

The manufacturer will generally not wish to make any performance warranties. The intermediary may demand that the manufacturer warrant that its medical devices are free from any defects in design or manufacture. Product warranties, however, are generally directed to the end user or consumer. If product warranties are included in the intermediary agreement in favor of the intermediary, the intermediary could use the occurrence of a defect to argue that the manufacturer has breached the warranty and the intermediary agreement, entitling the intermediary to immediate termination or other remedies, even though the defect never directly affected the intermediary. Therefore, the manufacturer should generally provide that its product warranties are directed and made only to the end user.

In addition, the manufacturer will include an express warranty disclaimer, in which the manufacturer disclaims all express and implied warranties. The UCC establishes certain implied warranties, such as implied warranties of merchantability, fitness for particular purpose, title, and non-infringement, and provides specific rules for effectively disclaiming such warranties in sales of good cases. Since the distributorship involves the sale of goods in addition to the marketing obligation, the warranty disclaimer in the distribution agreement should be drafted to meet the requirements of the UCC. The obligations of the sales representative are primarily service obligations; thus, the UCC does not have any direct application. Instead, the rules for effectively disclaiming service warranties are a matter of state law, mostly state common law. Nevertheless, because the UCC’s standards for disclaimers are strict, use of the UCC’s standards will likely improve the enforceability of the disclaimer. Thus, it is optimal to prepare the disclaimer in the sales representative agreement in accordance with the UCC’s standards.

119 Id. § 2-316(2).
120 Article 2 of the UCC applies to the sale of goods. U.C.C. § 2-102 (2002). While distribution agreements involve both the sale of goods and the provision of services (i.e., marketing services), it has been held that distribution agreements come within the scope of the UCC. See, e.g., Sally Beauty Co. v. Nexxus Products Co., 801 F.2d 1001, 1006 (7th Cir. 1986); Ralph’s Distributing Co. v. AMF, Inc., 667 F.2d 670, 673 n.6 (8th Cir. 1981).
121 See U.C.C. § 2-102 (2002).
2. Indemnity

Indemnities obligate the indemnitor to indemnify the indemnitee against certain risks, damages, or liabilities, often coupled with an obligation to defend the indemnitee against claims by third parties. As such, indemnities are affirmative performance obligations, rather than a form of legal remedy. This distinction is important, as illustrated in the following example. The manufacturer sells a device to a distributor who, in breach of the distribution agreement, modifies the device. The modification causes injury to an end user, who sues the manufacturer for product liability. Rather than defending the lawsuit and seeking reimbursement of the costs for defense or payment under a settlement or judgment from the distributor in a subsequent breach of contract claim, an indemnity would require the distributor to step in and defend the manufacturer at its cost and pay any resulting damages. Thus, assuming the financial viability of the distributor, the risk of the manufacturer for liability from claims covered by the indemnity has been significantly lowered. Consequently, the manufacturer should negotiate an indemnity by the distributor against any claims resulting from the distributor’s marketing activities, or any claims resulting from the distributor’s breach of the intermediary agreement, violation of law, negligence, or willful misconduct.

An indemnity provision is only as useful as the intermediary’s ability to pay for the defense and indemnification. In the case of smaller intermediaries, in particular, the manufacturer should consider requiring an obligation to obtain and maintain insurance with a reputable insurance provider. The insurance requirement should set forth the specific types of insurance (e.g., general commercial liability insurance) and the minimum coverage limits for each. In addition, the intermediary should be required to have the manufacturer named as a beneficiary on the insurance policies and notified in the event of termination of or material change to the insurance coverage. The intermediary should also be obligated to provide the manufacturer with copies of the insurance policies at the outset of the parties’ relationship.

123 Indemnification coverage against fines or penalties imposed on the manufacturer based on the manufacturer’s own violation of law is generally not enforceable. See Kansas City Operating Corp. v. Durwood, 278 F.2d 354, 358 (8th Cir. 1960) (“[W]here an indemnitee has participated in and brought about the loss he has suffered by his own wrongful or fraudulent conduct, or is found to be in pari delicto with the indemnitor, he cannot recover the loss through an action for contribution or indemnity.”).
In typical contract negotiations, however, if the manufacturer insists on indemnification by the intermediary, the intermediary will require an indemnification from the manufacturer. Depending on the relative bargaining power of the parties, the manufacturer may have to agree to give some form of indemnification. Thus, if a broad indemnification obligation by the intermediary would engender a demand for a broad indemnification obligation by the manufacturer, the manufacturer should determine whether it has the bargaining power to negotiate a unilateral indemnity by the intermediary or should agree to a limited mutual indemnity.

Two particular indemnities often requested by intermediaries can result in significant liability for the manufacturer: indemnity against claims for products liability, and indemnity against claims of patent or other IP infringement. The products liability indemnity may be acceptable because, in the event of a products liability case, the manufacturer would be the primary defendant in any event. Furthermore, the risk associated with product defects is controllable to a large extent through the development and manufacturing process. The manufacturer, however, should exclude from its indemnity obligation any claims or liabilities arising from the intermediary’s negligence, willful misconduct, bad faith, breach of the intermediary agreement, or violation of law.

In contrast, due to the large number and myriad types of patents for devices and technologies, patent infringement claims in particular can be difficult to predict, and the resulting liability can be extensive. Therefore, the manufacturer may be agreeable to a products liability indemnity, but not an infringement indemnity. If an infringement indemnity is unavoidable, the manufacturer can limit it to any infringement that the manufacturer has known or should reasonably have known. This limitation would restrict the exposure somewhat. Naturally, the manufacturer should exclude any indemnity obligation for infringement claims resulting from any modification or unauthorized use of the medical device.

3. Limitation of Liability

Limitations of liability either exclude or limit the liability of the parties. Unless the manufacturer has far superior bargaining power, they are typically mutual (i.e., protect both the manufacturer and the intermediary). Limitations of liability are
generally enforceable in the United States, subject to some limitations.\textsuperscript{124} Other countries, however, have more stringent rules against the exclusion or limitation of liability for damages.\textsuperscript{125} Therefore, it is normally advisable to structure a limitation of liability clause in three layers: the full exclusion of damages, a ceiling or cap of damages in the event of any liability despite the exclusion, and a savings clause, which provides for the reformation of the limitation of liability provision to the extent it violates any applicable law.\textsuperscript{126}

4. Recall

Particularly with regard to medical devices, the manufacturer should be prepared for a recall, either a voluntary recall upon discovery of a material defect or a recall required under applicable law. In either case, the manufacturer should retain control over the recall and any statements and releases made in connection with it. Except to the extent that applicable law requires otherwise, the intermediary should not be permitted to initiate or implement the recall without the manufacturer’s prior consent. Handling the recall from a crisis management perspective is an important issue because it can affect not only the public’s confidence in the specific medical device, but in the manufacturer and its products in general. The intermediary is in direct contact with the customers and end users of the medical devices, and thus may be the first to learn of product issues that may warrant a recall. Therefore, the manufacturer should obligate the intermediary to provide the manufacturer written notice immediately upon knowledge or suspicion of any defects or malfunction. The parties should also address who bears the costs of the recall. Typically, this will be the manufacturer, unless the recall is based on some action of the intermediary (such as an unauthorized modification).

E. Term and Termination

The term and termination provisions are among the most important provisions in an intermediary agreement because

\textsuperscript{124} Exclusions or limitations are generally enforceable unless they are unconscionable. For example, an exclusion of damages is \textit{prima facie} unconscionable if it limits damages for personal injury in the case of consumer goods. U.C.C. § 2-719(3) (2002).

\textsuperscript{125} See supra note 22 and accompanying text.

\textsuperscript{126} Such a savings clause should also be inserted to apply to the intermediary agreement in general to prevent a partial invalidity from affecting the whole agreement.
they determine how quickly and at what cost the manufacturer may exit the intermediary relationship. In the experience of the authors, the manufacturer negotiates the intermediary agreement with the understandable expectation that it will be a lasting and beneficial relationship. The reality, however, is often different. Examples that may require a relatively quick exit may be unsatisfactory performance by the intermediary, better business opportunities with different intermediaries or direct marketing, change of business focus away from the types of medical devices marketed by the intermediary, acquisition or potential acquisition of the manufacturer’s business, or simply a feeling of discomfort with regard to the intermediary. The manufacturer may have an early termination right in some cases, such as if the unsatisfactory performance amounts to a breach of the intermediary agreement. Unless the substandard performance amounts to a clear case of a breach, however, it may not be advisable for the manufacturer to give notice of termination, which, in any event, may be subject to an opportunity to cure. For example, if the manufacturer cannot prove the grounds for termination, it may be liable for breach of the intermediary agreement. In addition, suing or risking a suit by the intermediary is often costly and undesirable. In such situations, the manufacturer may be able to end the relationship by mutual agreement, but likely at a hefty price. For this reason, the manufacturer should build an exit strategy into the intermediary agreement when it is being negotiated.

One partial exit strategy has already been introduced: termination of the exclusivity upon substandard performance. Causing the intermediary to be non-exclusive may often be a tolerable solution until the final termination of the intermediary agreement is possible. The other planned exit strategy revolves around the term and termination provisions.

1. Term

The manufacturer has essentially two basic options for the term of the intermediary agreement: a definite (limited) term and an indefinite (unlimited) term. The definite term provides for a specific end date, such as a specific calendar date or the end of a certain time period. The indefinite term provides for the continuation of the intermediary agreement until it is termi-
ated by either party, usually by written notice to the other party with a minimum notice period.\textsuperscript{127}

In the intermediary relationship, the parties typically do not opt for an indefinite term because each party expects to make substantial financial and other investments in the relationship and wants to prevent the other party from leaving before the “break-even” point or the achievement of at least a modest return. On the other hand, for the reasons discussed above, the manufacturer should be careful about long-term commitments. As a result, the parties to an intermediary agreement usually agree on a definite term with an extension clause, which is essentially a hybrid between the definite and indefinite term. Under such a clause, the intermediary agreement’s term would end on a specified date or after a specified term, but continue thereafter for additional terms unless terminated by either party with minimum notice before such specified date or the end of such term. In some cases, the parties agree on extending the term of the intermediary agreement only upon mutual agreement. From a business perspective, this is often not preferred in that it essentially amounts to a definite term because it would take both parties’ agreement to continue the relationship. From a legal perspective, it is typically also less preferable than an automatic extension because the parties may in practice forget to formally extend the term, which leads to ambiguity whether and under what terms the intermediary agreement has continued.

2. Termination

In the event of an indefinite agreement or a definite agreement with automatic extension, the parties generally have a right of termination by giving notice with a minimum notice period, which typically ranges from thirty to a hundred twenty days or, in some cases as long as six months or one year.\textsuperscript{128} As in most of the other terms discussed above, there is no single best notice

\textsuperscript{127} If the intermediary agreement is silent on term and termination, U.S. courts would typically interpret the agreement to be for an indefinite duration and either last for a reasonable term or be terminable at will. \textit{Compare} First Commodity Traders, Inc. v. Heinold Commodities, Inc., 766 F.2d 1007, 1012 (7th Cir. 1985) (terminable at will under Illinois law), \textit{and} Roberts v. S. Wood Piedmont Co., 571 F.2d 276, 278 (5th Cir. 1978) (terminable at will with reasonable notice under Mississippi law), \textit{with, e.g.,} Haines v. City of N. Y., 364 N.E.2d 820, 822 (N.Y. 1977) (reasonable term under New York law).

\textsuperscript{128} Dealer legislation may require minimum notice periods. For example, under the Agency Directive, the notice period is at least one month for the first year of the agreement, two months for the second commenced, and three months for the third and subsequent years commenced. Council Directive 86/653, \textit{supra}
period. The manufacturer should determine the duration of the notice period based on the conditions it expects to find upon termination. These include the potential need for a quick exit, the time for shifting the marketing to another intermediary or handling it in-house, and the cost of a longer notice period (specifically, any continuing payments to the intermediary). For example, a manufacturer concerned about the potential need for a quick exit would prefer a shorter notice period, such as sixty or ninety days. On the other hand, a manufacturer concerned about the loss of marketing opportunities may wish a longer transition period and would prefer a longer notice period, such as one hundred twenty days or six months.

In addition to “ordinary” termination (i.e., termination without cause), intermediary agreements typically provide for termination with cause. The most important are termination for breach of the intermediary agreement and violation of law. Breach-based termination rights typically give the breaching party a short cure period, such as thirty days, during which the breach must be cured (or alternatively substantial efforts to cure the breach must have begun). Breach-based termination is usually triggered by a material breach to prevent a party from seeking an early exit under the pretense of a minor or immaterial breach by the other party. Some breaches are so egregious, however, that the manufacturer would wish for an immediate termination without any notice or cure period. These include: serious violations of law, such as violations of U.S. export control regulations; breaches signified by disloyal conduct, such as the intermediary’s willfully exceeding the scope of authority, for example, by making unauthorized representations or warranties to the end user; breaches characterized by a depraved mind, such as fraud and misrepresentation against the manufacturer or any end user; or serious default, such as a significant failure to meet certain performance standards, such as established performance goals. Often, intermediary agreements also provide for termination upon bankruptcy or insolvency, but such termination clauses are mostly unenforceable in the U.S. because the Bankruptcy Code does not permit termination of an executory contract based on bankruptcy or insolvency.\footnote{note 40, at art. 15(2). The Agency Directive leaves it to the individual country whether to establish a minimum notice period of four months for the fourth, five months for the fifth and six months for the sixth and subsequent years. \textit{Id.} at art. 15(3).}

\footnote{129 11 U.S.C. § 365(e)(1) (2005). This rule is subject to narrowly drawn exceptions that typically do not apply to intermediary agreements. \textit{Id.}}
3. Rights and Obligations Upon Termination or Expiration

The termination or expiration of the intermediary agreement is rarely the end of the relationship. A distributor, for example, will often have a stock of unsold devices. A sales representative may still be contacted by potential customers even after the end of the relationship with requests to purchase medical devices from the manufacturer. A distributor that is permitted to retain its stock of medical devices would be in a position to directly affect the manufacturer. For example, a distributor with a significant stock of medical devices could directly compete with the post-termination marketing efforts of the manufacturer or the distributor’s successor. Or the distributor could harm the manufacturer by, deliberately or negligently, shipping out medical devices that have become defective, such as medical devices that are past their expiration date or were improperly stored, without fearing any repercussions from the manufacturer. Likewise, it is not in the manufacturer’s interest if a sales representative receiving orders from its customers after termination channels the orders to a competitor for the manufacturer. Therefore, the manufacturer has an interest in the orderly winding-up of the relationship.

With regard to distributors, the termination clause may provide for a short post-termination right to sell the existing stock of medical devices and subsequently return any remaining medical devices. In such case, the manufacturer is typically required to make some payment for the returned medical devices, which reflects the opportunity to sell such medical devices in the market. If the medical devices have an expiration date or are about to become outdated technology, the manufacturer will wish to consider a cut-off date. For example, the intermediary agreement can provide that medical devices ordered from the manufacturer prior to a certain date are not eligible for any refund and have to be properly disposed off by the distributor. If the medical devices are highly valuable on the market, the intermediary agreement can provide that the manufacturer has an immediate buy-back right upon termination or expiration of the intermediary agreement. The decision as to which of these options is the most appropriate will depend on the surrounding circumstances, especially the medical device, its useful life, and its market value. The same concepts apply for sales representatives that are required to retain a stock of products.

Apart from the disposition of any medical devices, the intermediary should be obligated to immediately return any confidential information, cease using the manufacturer’s name or
marks, and return or destroy any marketing materials that were provided by the manufacturer or contain any information regarding the medical devices or display any of the manufacturer’s marks, names, or other IP. Similarly, the intermediary should immediately deactivate or modify any Internet websites that relate to the medical devices or display the manufacturer’s marks, names, or other IP. The intermediary should also be required to delete immediately and irrevocably any electronically stored copies of any confidential information or materials relating to the medical devices. For better protection, the manufacturer can require the intermediary to certify in writing compliance with all of the foregoing obligations.

4. Termination Considerations Outside the United States

Dealer legislation typically requires the payment of a severance or termination indemnity to the dealer if the dealer agreement is terminated without cause by the principal. The EU’s Agency Directive requires an indemnification of a sales representative if and to the extent that the sales representative brought new customers or has significantly increased business with existing customers of the manufacturer, and the manufacturer continues to derive substantive benefits from business with such customers. The amount of the indemnity must be equitable in light of all circumstances, specifically, the commission lost by the sales representative on the business transacted with such customers.

The indemnity, however, shall not exceed an amount equivalent to one year’s remuneration based on the sales representative’s average annual remunerations during the past five years or the duration of the agreement, whichever is less. In addition, the sales representative is entitled to damages as a result of the termination. The sales representative loses the

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130 For example, under Belgium’s legislation of July 27, 1961, regarding the unilateral termination of exclusive distribution agreements, the principal may terminate the distributor with immediate effect for a substantial breach of the distribution agreement, in which case the severance indemnity provisions do not apply.


132 Id. at art. 17(2)(a).

133 Id.

134 Id. at art. 17(2)(b). Remuneration consists of the sales commission, but may include other payments or benefits received by the sales representative. See id. at art. 6(1).


136 Id. at art. 17(3). Compensation for damages shall be deemed to occur particularly when the termination takes place in circumstances: - depriving the commercial agent of the commission
right to an indemnity and termination damages if the manufacturer is not notified within one year of termination that the sales representative intends to pursue these rights. 137 The sales representative is not entitled to an indemnity or termination damages if the termination is due to a default attributable to the sales representative that would justify immediate termination under the national law of the member country, or if the sales representative terminated the agreement (unless for age, infirmity, or illness of the sales representative that reasonably prevented the sales representative from continued performance), or if the sales representative assigns his rights and duties with the manufacturer’s agreement to another person. 138

While the Agency Directive applies on its face only to sales representatives, some countries have extended its severance provisions under certain circumstances by analogy to distributors. 139 For example, the German High Court held that a distributor has an analogous right to a severance indemnity if the distributor is integrated into the manufacturer’s sales organization like a sales representative (so that the manufacturer-distributor relationship is not a mere buy-sell relationship, but is economically comparable to that of a manufacturer-agent relationship) and the distributor has a contractual obligation to provide the manufacturer with the customer data, enabling the manufacturer to market to the distributor’s customer base without any further delay. 140

Thus, the risk that the manufacturer is required to pay a severance obligation increases if the distributor is required to provide the manufacturer with its customer lists or data. This puts the manufacturer in a precarious position because the manufacturer may need the customer contact information for purposes of

which proper performance of the agency contract would have procured him whilst providing the principal with substantial benefits linked to the commercial agent’s activities, - and/or which have not enabled the commercial agent to amortize the costs and expenses that he had incurred for the performance of the agency contract on the principal’s advice.

Id. 137 Id. at art. 17(5).
138 Id. at art. 18.
139 For examples, courts in Austria, Germany, and Spain have developed such analogous extension of the Agency Directive.
140 The requirements were decided by the German High Court in various cases, including Bundesgerichtshof [BGH] [Federal Court of Justice], 135 Entscheidungen des Bundesgerichtshofes in Zivilsachen [BGHZ] 14 (F.R.G.).
warranty service or product recalls. If the manufacturer has a need for the distributor’s customer lists and data, the intermediary agreement should state that customer or end user contact information is provided for the purpose of providing warranty or product recall services. In addition, the intermediary agreement should set forth other provisions indicating that the distributor is not as integrated into manufacturer’s marketing system as a sales representative. For example, the intermediary agreement should not give the manufacturer the right to control the distributor’s marketing, approve orders or customers, participate in or monitor the negotiations between distributor and customer, or otherwise make decisions that are typical of the relationship between the manufacturer and a sales representative. Moreover, it is important that the manufacturer’s course of conduct actually comply with these provisions. Otherwise, the court may likely view the contractual provisions as self-serving and be even more likely to treat the distributor as a sales representative under the Agency Directive. While taking these steps does not offer a guarantee against liability under the Agency Directive, it reduces the likelihood of such liability. If the manufacturer requires a high level of control, it may have to make the business decision of accepting potential liability under the Agency Directive. The manufacturer should realize, however, that the liability under the rules discussed above can be substantial.


The intermediary agreement should expressly state which of its provisions survive its termination or expiration. These are provisions with obligations independent from the performance of the intermediary agreement, such as provisions reserving the manufacturer’s ownership of its IP, post-expiration non-compete covenants, and confidentiality clauses. Termination of the intermediary agreement and return or destruction of all confidential material does not affect the intermediary’s knowledge of certain confidential facts related to the manufacturer or its medical devices. Therefore, confidentiality clauses should typically survive the termination or expiration of the intermediary agreement. Sometimes, the parties agree on a limited time for such survival, such as five years. This is generally not desirable if the manufacturer provides most of the confidential information under the intermediary agreement (such as marketing information, product information, strategies, customer lists, pricing formulae, or the like), unless the “life” or value of the confidential information is of limited duration. In such case, the manufacturer should ensure that the limited survival
period is at least as long as the expected life of the confidential information. Other provisions typically intended to survive the termination or expiration of the intermediary agreement are indemnity obligations and limitations of liability. Events giving rise to indemnity may occur after termination of the intermediary agreement, such as from any unauthorized activities of the intermediary, and exposure to liability continues beyond such termination, such as for the manufacturer from product defects.

F. Other Terms

Typically, intermediary agreements contain numerous miscellaneous terms and provisions. Most of such terms and provisions are standard, such as severability and integration clauses. The following are miscellaneous provisions of particular importance for the manufacturer.

1. “Independent Contractor” Clause

An “independent contractor” clause typically contains representations by both parties that they are not in an employment relationship, joint venture, partnership, or association with each other. It is an important clarifying provision, but is only as effective as the actual conduct of the parties. For example, if the manufacturer engages an individual as a sales representative and treats the individual in the same manner as its employees, such as by providing employment-based benefits and exercising or reserving substantial control over the individual’s perfor-

141 A severability clause provides that, if any provision or part of the intermediary agreement is deemed invalid or unenforceable, the remainder of the intermediary agreement shall not be affected. An integration clause states that the written terms of the agreement replace all prior oral and other agreements between the parties related to the intermediary agreement’s subject matter. Any prior agreements that shall continue in effect should be expressly excluded from the integration clause. Another aspect of integration clauses is the provision that no amendments or changes of the intermediary agreement are valid and enforceable unless they are in a written document signed by both parties. While the integration clause provides protection against a claim that a verbal understanding altered the terms of the agreement, the protection is not absolute. Courts have held that, even with an integration clause, verbal agreements or course of conduct can effectively change the terms of an agreement. See, e.g., Canada v. Allstate Ins. Co., 411 F.2d 517, 519 (5th Cir. 1969) (“Under Florida law, however, the general principle is settled that a written contract ‘may be altered or modified by an oral agreement if the latter has been accepted and acted upon by the parties in such a manner as would work a fraud on either party to refuse to enforce it.’”) (quoting Prof’l Ins. Corp. v. Cahill, 90 So. 2d 916, 918 (Fla. 1956)); see also Miller Elevator Co. v. United States, 30 Fed. Cl. 662, 701 (Fed. Cl. 1994).
mance, the individual might be deemed to be an employee of the manufacturer despite an “independent contractor” clause. This is especially true in many countries outside the United States that are more protective of employees. As a result, the manufacturer is subject to strict obligations and restrictions imposed on employers under such countries’ laws. Notably, once the individual is deemed to be an employee, many countries would restrict the manufacturer’s ability to terminate the individual or would subject the manufacturer to severance or indemnity obligations upon termination. Consequently, the manufacturer should be aware of the criteria distinguishing an employee from a true independent contractor, and both prepare and perform the agreement with the intermediary accordingly.

2. Export Control Clause

The obligation of an intermediary to perform its duties in accordance with applicable law has already been discussed. An export control clause is a specific type of legal compliance obligation that has increased in importance. Under the United States export regulations (EAR), the export to foreign countries and persons of certain items on the Commerce Control List requires a license by the Bureau of Industry and Security at the Department of Commerce, unless an exception applies. It is important to note that exports include release of technology or software to a foreign national in the United States. If the manufacturer provides technology to a foreign national even though the transfer is otherwise a purely domestic transaction, the manufacturer is subject to the EAR. Thus, the manufacturer should verify whether its medical devices fall under the EAR’s license requirements. In addition, exports are subject to the sanctions programs by the Office of Foreign Assets Control at the Department of the Treasury, which prohibit transactions with certain countries or individuals. The export control and sanction laws require the manufacturer to be vigilant. Thus, the

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142 For example, German law recognizes the concept of Scheinselbständigkeit (literally translated, it means “pretense of independence”) under which a contractor is deemed to be an employee if he is, in fact, treated like an employee.
143 The term “items” is defined as “commodities, software, and technology.” 15 C.F.R. § 772.1 (2005). Thus, intangible technologies, not just products, are covered by the United States export regulations.
145 Id. §§ 730.7, 738.1.
146 Id. § 740.1.
147 Id. § 734.2(b).
148 An overview and further information of the sanctions program can be located via the OFF. OF FOREIGN ASSETS CONTROL, U.S. DEP’T OF TREASURY, at www.treas.gov/offices/enforcement/ofac/sanctions/ (last visited Sept. 20, 2005).
manufacturer’s obligations do not end with delivering a product to an intermediary or customer, even if that intermediary or customer is neither a sanctioned individual nor located in a sanctioned country. Instead, it is clear that the manufacturer cannot ignore facts indicating that the intermediary or customer will re-export or transfer the products to an individual or country subject to sanctions. Therefore, the manufacturer should take reasonable steps to monitor the intermediary’s performance for indications of export control violations. To enforce compliance with the export control clause, the manufacturer should have the right to immediately terminate, without cure period, in the event of a violation by the intermediary.

The purpose of an export control clause is to obligate the intermediary to comply with United States export control law. The clause does not replace the manufacturer’s obligation to diligently monitor the intermediary’s activities with regard to any export control violations. If a violation occurs despite the manufacturer’s diligent monitoring of the intermediary’s compliance with export laws, however, the export control clause and immediate termination right provide important support for the manufacturer in an export control investigation.

3. Recordkeeping and Audit Clause

Recordkeeping and audit provisions are important for the manufacturer to monitor and control the intermediary’s obligations under the intermediary agreement. Without such a provision, the manufacturer would generally not have access to the intermediary’s facilities and records. Often, monitoring compliance can only be effectively accomplished through access to the facilities to determine, for example, whether the distributor properly stores all of the purchased medical devices or records and performs all marketing activities in accordance with the agreement. In a sales representative agreement, the intermediary will also likely require an audit provision to access the manufacturer’s sales records for verification of full payment of the sales commission. Such a request is reasonable, but given that financial records are generally sensitive information, the manufacturer can impose limitations on the intermediary’s audit rights, such as the following: \(^{149}\)

\(^{149}\) It is likely that the intermediary will insist on including the same limitations in the manufacturer’s audit right.
• limiting the audit to once every six months or year;
• permitting the audit only by the intermediary or an authorized representative that has been identified to the manufacturer a specific time in advance of the audit and is subject to the manufacturer’s approval not to be unreasonably withheld;
• requiring the person conducting the audit to execute or be subject to a confidentiality obligation regarding any information or materials accessed or perceived during the audit; and
• obligating the person conducting the audit to comply with all policies and directions of the manufacturer while the person is at the facility and avoid any interference with the operation and administration of the manufacturer’s business.

Typically, the cost for an audit is imposed on the party conducting the audit. It is not unusual, however, for a sales representative to require the manufacturer to bear the reasonable cost if the audit reveals an underpayment of sales commissions that exceeds a certain threshold (typically five percent of the commissions that were payable and due).

4. Governing Law and Dispute Resolution

Choice of law clauses are also standard provisions in intermediary agreements. Nevertheless, they have a particularly important function in the international context, where the legal systems can vary widely, especially between common law and civil law jurisdictions. Most countries recognize and enforce choice of law clauses, subject to exceptions for laws embodying the country’s public policy or mandatory legal principles. Without a choice of law clause, the applicable law is determined by conflict of laws or international private law rules. For intermediary agreements that provide for performance obligations in at least the manufacturer’s and the intermediary’s country, it is difficult to predict the law applicable under conflict of law rules, especially because the manufacturer’s and intermediary’s countries may have different conflict of law rules. Thus, choice of law clauses are an important means to achieve a level of certainty regarding the law that will govern the interpretation and enforcement in the event of a dispute.

150 Consumer protection and employment law are typical examples of laws rising to the level of public policy.
Dispute resolution clauses can be a simple forum selection clause or an extensive mediation-arbitration provision. Arbitration provisions are generally recognized and enforced in the United States\textsuperscript{151} and most other countries.\textsuperscript{152} From the manufacturer’s perspective, an arbitration agreement is useful because it requires the intermediary to initiate arbitration to assert a claim, typically a payment claim, against the manufacturer. Initiating and proceeding with arbitration is often more complex and burdensome for the intermediary than filing a claim in court, especially if it involves only a payment dispute and the arbitration forum designated in the arbitration clause is in the manufacturer’s home country. The manufacturer, however, needs to ensure that it will be able to protect its


A written provision in any maritime transaction or a contract evidencing a transaction involving commerce to settle by arbitration a controversy thereafter arising out of such contract or transaction, or the refusal to perform the whole or any part thereof, or an agreement in writing to submit to arbitration an existing controversy arising out of such a contract, transaction, or refusal, shall be valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for the revocation of any contract.

\textit{Id.}


\[\text{each Contracting State shall recognize an agreement in writing under which the parties undertake to submit to arbitration all or any differences which have arisen or which may arise between them in respect of a defined legal relationship, whether contractual or not, concerning a subject matter capable of settlement by arbitration.}\]

\textit{Id.} at art. II para. 1. Generally, arbitral awards shall be recognized as binding and enforced. \textit{Id.} at art. III. Recognition and enforcement may be refused under certain circumstances, however, such as invalidity of the agreement, incapacity, lack of notice of the appointment of the arbitrator or arbitration procedure leading to the award, or violation of public policy by recognition or enforcement of the award. \textit{Id.} at art. V paras. 1(a)–(b), 2(b). Agreements or awards that are entirely between U.S. citizens do not fall under the New York Convention if they do not relate either to property, performance, or enforcement abroad or have some other reasonable relation with one or more foreign countries. 9 U.S.C. § 202 (2005).
valuable rights, specifically its confidential information and IP. Therefore, an arbitration provision shall always exempt any action, in particular the right to obtain injunctions, to protect IP assets and confidential information or to enforce a covenant not to compete.

III. Conclusion

This Article provides simply an overview of the most important terms and issues that the manufacturer should consider in negotiating and preparing the intermediary agreement. In individual cases, it may be necessary to deviate from terms suggested in this Article. Likewise, the manufacturer may wish to include additional or other provisions, such as particular performance obligations. Thus, this Article is not intended to serve as a blueprint for an intermediary transaction. Instead, each transaction should be negotiated in light of its specific facts, particularly the manufacturer’s business goals and the intermediary’s reasonable demands. Nevertheless, it is important that the manufacturer be mindful of the issues discussed herein and use the assistance of a legal professional in reviewing the transactional documents before signing them.