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Lexis Practice Advisor Mergers & Acquisitions

Mergers and Acquisitions in the U.S. Life Sciences Sector

by Reb Wheeler, Mayer Brown LLP

Reb Wheeler is a partner at Mayer Brown LLP and is global co-chair of the firm's Life Sciences industry group. His practice focuses on mergers & acquisitions, joint ventures, private equity, securities and other transactional matters. Reb has extensive experience advising participants in the pharmaceutical, biotech and medical device sectors, ranging from new ventures and investors to some of the world's largest pharmaceutical and biotech firms.

In recent years, the U.S. life sciences sector has experienced significant merger and acquisition activity. This practice note discusses recent trends in deals involving U.S. life sciences businesses and products and explores some of the key considerations legal counsel should be mindful of when representing parties to such transactions.

For present purposes, the "life sciences" sector is generally considered to include pharmaceuticals, health-oriented biotechnology products and medical devices. This practice note focuses on issues that are common in life sciences M&A transactions and issues that tend to assume more importance in life sciences deals than in deals in other industries. Industry-specific considerations affect nearly every aspect of a life sciences M&A deal, including:

- Due Diligence;
- Structuring the Deal;
- Consideration Alternatives;
- The Purchase Agreement; and
- Transition Arrangements.

Before exploring these various aspects of life sciences M&A deals, it is useful to consider the current deal landscape in the industry.

Recent Industry Trends

During the first three quarters of 2014, both the total number and aggregate value of life sciences M&A transactions has been particularly robust, outpacing activity levels in the sector in the past few years, as well as activity in most other industry sectors. According to Mergermarket, aggregate deal value for transactions involving U.S. pharmaceutical, medical and biotech companies during the first nine months of 2014 totaled $175.7 billion, an increase of more than 77% over all of 2013. There are a number of factors influencing this trend, including:

- The need for mid-size and larger pharma and biotech companies to shore up their revenue and growth prospects in the face of increased generic competition for conventional pharmaceuticals and

the prospect of more prevalent competition for biologic products as a result of biosimilar products gaining a clearer path to regulatory approval;
- Large companies continuing focus on their core business, leading to divestitures of non-core assets or lines of business;
- The evolving regulatory landscape in the U.S. and abroad;
- A more positive outlook in the "C" suite as U.S. and global economic conditions continue to emerge from the dark days of the financial crisis;
- Strong U.S. debt and equity capital markets, which have recently favored life sciences companies in particular, leading to easier acquisition financing; and
- Companies looking for ways to diversify and focusing attention on issues and opportunities in areas such as patient compliance programs, personalized medicine, telemedicine, use of biometric data from wearable devices, and the like.

Recent life sciences M&A activity has taken many forms, ranging from discrete acquisitions of products or product candidates, either outright or through licensing or other structures, to enterprise level acquisitions and combinations. The frothy life sciences M&A market has given rise to a number of exotic transactions and unorthodox tactics. For example, until recently, tax inversions undertaken by U.S. life sciences companies were arguably the most significant driver of M&A activity in the life science sector. An inversion involves a U.S. company combining with a foreign target using one of several different deal structures that result in the foreign target or a newly-formed foreign holding company surviving the combination as a tax resident of the foreign target's home country or, in some cases, a third country. The resulting parent company is or becomes a tax resident of a country with more favorable corporate tax rates than the U.S. Ireland, in particular, has been a favored destination for U.S. companies pursuing such transactions. The first three quarters of 2014 alone saw the announcement of at least seven inversion transactions involving public U.S. life sciences companies, several of which have involved valuations in the tens of billions of dollars. That figure does not include Pfizer's highly publicized overtures for Astra-Zeneca which did not ultimately lead to a transaction, or other inversion deals that the parties have acknowledged were discussed, or that were rumored to be under discussion, but that have not yet resulted in a transaction. The inversion trend seems to have lost some steam, however, in the wake of new rules meant to curb the practice announced by the U.S. Department of the Treasury in September. At least two pending inversion transactions have been called off since the new rules were announced.

Participants in the life sciences M&A market have also begun employing more aggressive tactics. For example, Valeant's increasingly hostile overtures for Allergan are noteworthy not only because of the relative rarity of hostile transactions in recent years, but also for the involvement of Pershing Square, a hedge fund with whom Valeant has joined forces. More generally, there is intense competition for life sciences targets, with auction processes yielding more bids, higher multiples and more favorable terms for sellers, including, in some cases, buyers foregoing post-closing indemnification.

Executing Life Sciences M&A Deals

The remainder of this practice note discusses considerations that legal counsel should be mindful of when representing parties to M&A transactions in the life sciences industry. It should be noted that the following is generally focused on U.S.-specific issues in transactions involving U.S. targets and following a U.S.-style approach to M&A terms and documentation. Many U.S. life sciences companies, of course, conduct business and have personnel and assets in multiple countries. Thus, international and cross-border issues will often be an important focus of participants in life sciences M&A deals. It should also be noted that not all of the considerations discussed in this practice note will be relevant, or relevant in the same way, to different participants in the pharmaceutical, biotech and medical device industries. Finally, this practice note is not intended as a guide to every issue that should be considered in a life sciences M&A transaction. It instead focuses on issues that are of particular relevance to life sciences deals.

Due Diligence

As with any M&A transaction, a careful due diligence exercise is a crucial element of a successful life sciences acquisition. Some aspects of legal due diligence in the context of life sciences M&A will be more or less the same as in M&A transactions involving businesses in any other industry. Buyers should assess the target's pending litigation and other contingent liabilities, labor agreements, employee benefits arrangements, commercial contracts, owned and leased real property, taxes, environmental issues and other matters. There are, however, certain areas of due diligence that tend to assume particular significance in life science M&A. These include product-specific issues, such as intellectual property, marketing approvals and post-marketing obligations, and licensing and collaboration relationships, as well as enterprise-level issues, such as compliance and supply chain issues. Evaluating and understanding a life sciences target and its products on these levels is critical to assisting clients in effectively assessing value, risk and appropriate deal structures and terms.

Product-Focused Due Diligence. Because life sciences companies are often dependent on a handful of products (or even one product) for a substantial portion of their revenue, a useful way to approach due diligence is to focus on each of the target's products, or each of the products involved in the transaction, separately. If many products are involved, time and resources may necessitate prioritizing these efforts, based on the products' relative contributions to revenue, future market potential, or perceived risk. In any case, a product-focused diligence exercise will require as assessment and understanding of a number of different complex legal, regulatory, technical and other issues that bear on the assessment of a life sciences product's value and risk profile.

Product Life Cycle. Pharmaceutical companies and biotech firms often think about their products in terms of their life cycle. In the most common case, in the U.S., a novel pharmaceutical or biotech product's life cycle begins during its development - well before its approval by the FDA - and proceeds through a period during which the product enjoys an exclusive position in the marketplace and into a phase in which market share is ceded to competing generic or "biosimilar" products that can be substituted for the innovator product. A discussion of generics and biosimilars is included below. The goal of innovator or "brand" companies, of course, is to maximize the period during which the product enjoys market exclusivity and to delay entry of generic or biosimilar competition for as long as possible. These considerations inform many aspects of a pharmaceutical or biotech company's business and products, as the discussion below illustrates. It is often helpful, therefore to bear these life cycle considerations in mind when undertaking product-focused due diligence on a life sciences target.

A number of factors can affect the timing and extent of market competition for a particular product, including practical considerations such as the difficulty of manufacturing the product and the existence and success of arrangements such as patient assistance programs and other outreach efforts and special arrangements with payers and providers. By far the most significant factors bearing on market exclusivity, however, are intellectual property rights and regulatory exclusivity periods. M&A practitioners advising participants in life sciences M&A deals need to understand these different sources of rights in order to help their clients properly assess products' potential and assist them in negotiating and documenting transaction structures, different approaches to consideration and other terms that appropriately take into account these key factors that bear on a product's life cycle.

Life cycle management is less of a consideration for medical device companies, as medical devices do not benefit from the kinds of regulation-based market exclusivity that is available to drugs and biologic products and thus do not face generic competition in the same way that drugs and biologics do. Patent and trade secret protection can, however, have significant bearing on a medical device's market posture.

Intellectual Property

The intellectual property ("IP") underlying a drug, biologic or medical device, and the legal rights associated with that IP, are a key determinant of whether and how long a product is likely to enjoy an exclusive market position. Relevant intellectual property rights include:

- *Patents*. Patents, of course, are particularly important to life sciences companies given that they allow the holder to preclude others from making, using, selling, offering for sale or importing the claimed invention during the patent term. Life sciences companies' products are often covered by a number of different patents covering various aspects of the product or its manufacturing or use. In addition to composition of matter patents claiming the actual formulation of a drug or the technical specifications of a device, patents covering manufacturing processes, methods of use and even distribution systems may also be obtained.
- *Trade Secrets*. Trade secrets can also be important, particularly where patent protection may not be possible or where the innovator seeks to protect an invention beyond the term of a patent.
- *Trademarks.* Finally, though not typically as determinative a factor of market share as patent rights or trade secret protection, branding is also an important part of marketing innovative life sciences products. As such, trademarks should also be evaluated as part of due diligence.

Patent Term Extension. It should be noted that novel pharmaceutical and biologic products, and medical devices that must undergo clinical trials by virtue of a premarket application process, may be entitled to an extension of their patent terms pursuant to the Drug Price Competition and Patent Term Restoration Act of 1981 (98 Stat. 1585,98 P.L. 417,98 Stat. 1585) (the "Hatch-Waxman Act"). The extension, designed to make up for the portion of the patent term lost during the clinical trial and approval process, can be for up to five years; provided, however, that the extension cannot result in an overall remaining patent term in excess of fourteen years. Several requirements must be met in order to qualify for patent term extension.

Specific IP Due Diligence Considerations. Diligencing intellectual property issues associated with a drug, biologic or medical device can become very technical and complicated. Any such effort should focus on a number of factors, including the following:

- *The nature and validity of the intellectual property and the target company's rights in the IP*. Among other things, consideration should be given to the following:
    - Subsisting Patents: What, if any, subsisting patents claim the product or its manufacture or use and what are their remaining terms?
    - Pending Patent Applications: The likelihood that any pending patent applications claiming the product or its manufacture or use will be granted and whether and how the claims asserted in those applications might be narrowed.
    - Strength of Claims: The strength of the claims included in patents and patent applications and the likelihood that they might be challenged by a generic or biosimilar entrant or that a competitor might be able to engineer around them.
    - Patent Term Extension: For products that have not yet been approved, the prospects for patent term extension pursuant to the Hatch-Waxman Act, as described above.
    - Supplemental Claims/Additional Patents: Whether there are opportunities to supplement the claims of existing patents or seek additional patents in respect of other aspects of the product.
    - Trade Secret Protection: To the extent that the target relies on trade secret protection, the validity of its security and confidentiality procedures for safeguarding the secrecy of those trade secrets.
    - Trademarks and Trade Dress: For marketed products, whether applications to the U.S. Patent and Trademark Office for the registration of trademarks or trade dress marks in respect of important branding elements of the product have been filed and

allowed and, if so, the classes of use for which registration has been sought, as well as the target's practices relating to marking, quality control and enforcement.
    - Third-Party Infringement: Any allegations by the target that third parties have infringed or otherwise violated its intellectual property rights, including the status of any pending litigation involving such allegations.
- *Freedom to operate*. Particularly for product candidates that have not yet reached the market, it is important to assess the risk that the product's manufacture and/or commercialization might infringe a third party's intellectual property rights. Although it may not be practical to conduct fulsome freedom to operate analyses for each of a target company's products and product candidates, such analyses may be warranted for the most important products or candidates. Due diligence should also focus on any past or pending claims or allegations that the target is infringing a third party's intellectual property and the terms of any settlement or other resolution relating thereto.
- *Third party rights*. An important part of conducting due diligence on a target company's IP is tracing the heritage of that IP and confirming that the target possesses all the rights it purports to possess in that IP. Practitioners should be on the lookout for the following situations:
    - Incomplete Assignment of IP Rights: Individuals involved in the conception of an invention were not party to invention assignment agreements or such invention assignment agreements did not effectively assign all rights to the purported IP owner, which could mean that the target is not the sole owner (or even an owner) of the relevant IP.
    - Acquired IP: IP was acquired by the target company or its predecessor from a third party, in which case counsel should review all relevant transfer documentation and confirm that the transfers have been properly recorded with the U.S. Patent and Trademark Office and applicable foreign equivalents.
    - Collaboration IP: IP was the product of a collaborative development effort by the target company and a third party, in which case it is important to carefully review the terms of the collaboration agreement and other related agreements in order to assess ownership of the intellectual property, any limitations that may apply to the target company's use of, or ability to transfer the IP, and the rights that the third party may have in the IP, as further discussed below.

Marketing Approvals and Marketing Exclusivity

In the United States, pharmaceuticals and biologics must, in most cases, be approved by the FDA before they can be marketed to the public. Novel pharmaceutical products are typically approved pursuant to a new drug application, or "NDA". Generic pharmaceuticals are typically approved through a more streamlined process pursuant to an abbreviated new drug application or "ANDA". Similarly, biologics are approved pursuant to a biologic license application or "BLA" and biosimilar products are approved pursuant to an abbreviated BLA process. Each of these different approval pathways for drugs and biologics imposes different requirements and raises different issues and considerations that are important to understand when evaluating the legal and commercial positioning, or potential positioning, of a drug or biologic. A particularly relevant consideration, the degree to which an NDA or BLA product will enjoy market exclusivity, is discussed below.

Except in the case of Class I devices, such as simple bandages and tongue depressors, medical device manufacturers are required to submit either a premarket notification under Section 510(k) of the Federal Food Drug and Cosmetics Act or a premarket application ("PMA") to the FDA. A 510(k) submission is a relatively limited filing that includes information showing that the product is substantially equivalent to a predicate device already lawfully on the market. A PMA may be required in the case of a truly new device that presents novel questions as to safety or efficacy. A PMA is a much more substantial filing that involves extensive documentation of safety and effectiveness, generally demonstrated through clinical trials.

Market Exclusivity. In the case of drugs and biologics, the other key determinant of a new product's prospects for market exclusivity in the U.S., in addition to its patent coverage, is the regulatory exclusivity afforded to it

in relation to its FDA approval. Developing new drugs and biologics commonly takes many years and involves enormous investments of money and resources. At the same time, innovators often apply for patents early in the development process. As a result, it is not uncommon for a number of years of the term of the patents covering a novel product or related process to have elapsed by the time the product is approved for sale. Congress has passed legislation to address this issue and ensure that innovators will have some period of exclusivity during which they will be able to market novel products free of generic competition in order to recoup their investment in a product's development. One such legislative fix is the patent term extension program provided for under the Hatch-Waxman Act, as described above. Other legislation has provided for additional periods of statutory exclusivity during which the FDA may not approve (and in some cases, may not accept) applications for competing generic or biosimilar products. It is important for counsel to understand these different possibilities for market exclusivity in order to assess: (1) what forms of market exclusivity attach to a given product, (2) how much time remains on such exclusivity terms and (3) whether there are possibilities for obtaining additional forms of exclusivity.

Pharmaceuticals. In the case of conventional drugs, several types of statutory exclusivity are available, as follows:

- *New Chemical Entity (NCE)*. NCE exclusivity is available for new drug products. NCE exclusivity means that the FDA cannot approve or even accept an ANDA or a NDA relying on §505(b)(2) for a generic product relying on the same active moiety during a period of five years after approval of the innovator drug's NDA.
- *Clinical Investigation (CI) Exclusivity*. CI exclusivity is available in some circumstances in which a product has an existing approved NDA and the sponsor conducts certain qualifying new clinical trials that support a change in the product's dosage form, a new indication, or a change from prescription status to over-the-counter. If CI exclusivity attaches, the FDA is precluded from approving an application for a competing generic for a period of three years following approval of the supplemental NDA relating to such change or new indication, but not from accepting such an application.
- *Orphan Drug Exclusivity*. Products that target treatment of an indication that affects fewer than 20,000 patients in the U.S. and products for which the development costs are likely to exceed product sales may be designated orphan drugs. In that case, the product will enjoy seven years of market exclusivity following approval, during which the FDA will be precluded from approving an application for a competing generic product (but may accept such an application for filing). Companies pursing orphan drugs are also eligible for certain research grants and tax credits, which make orphan drug designations even more sought after.
- *Pediatric Exclusivity*. To encourage testing of drugs and biologics on children, the FDA sometimes requests that manufacturers undertake certain clinical studies in pediatric populations. Manufacturers who undertake pediatric trials in response to the FDA's request benefit from an additional six months of exclusivity beyond whatever other exclusivity (including by virtue of patent terms) covers the product. Such additional exclusivity period covers all formulations, dosage strengths and indications of the same drug.

Existing exclusivity and patent terms applying to marketed conventional drugs can be assessed relatively easily by referring to the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), which is accessible online through the FDA's website (see http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm). The Orange Book is searchable in a variety of ways and identifies the types of exclusivity attaching to listed drugs and when that exclusivity, as well as patent coverage, expires.

In the case of products in development for which an NDA has not yet been approved, a buyer will need to assess the current state of development efforts, when the NDA is likely to be filed (if it has not yet been filed) or where it stands in the approval process (if it has been filed), and whether an orphan drug designation or pediatric exclusivity may be available.

Biologics. The Patient Protection and Affordable Care Act of 2010 (124 Stat. 119,111 P.L. 148,124 Stat. 119) (the "Affordable Care Act") established a separate regulatory exclusivity regime for biologicals. Under that regime, a biologic using a novel biological structure is entitled to data exclusivity for twelve years, meaning that the FDA will not accept an application for a biosimilar product claiming comparability to the applicable innovator biologic for a period of twelve years from approval of a BLA in respect of the innovator biologic. As with "small molecule" drugs, biologics can be eligible for a six-month extension with qualifying pediatric studies and can receive orphan designations.

The FDA has recently released the "Purple Book" (the formal name is *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*), which, in some respects, is to biologics what the Orange Book is to traditional drugs. See www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm. The Purple Book is significantly more limited in its scope, however. Accordingly, for now, practitioners will need to evaluate the BLA and patents covering biological products in order to assess exclusivity.

Medical Devices. Unlike pharmaceuticals and biologics, medical devices do not benefit from any regulatory market exclusivity provisions. Accordingly, market exclusivity for medical devices will typically be determined by intellectual property and other barriers to entry, as discussed above.

Generic and Biosimilar Competition

As a public policy counterweight to market exclusivity for pharmaceutical and biologic products and the benefits exclusivity affords innovator companies, U.S. law has established pathways for generic and biosimilar products to reach the market once patent protection and regulatory exclusivity of the innovator, or "reference," product has expired and sometimes earlier. As noted above, the timing of generic or biosimilar competition will almost always be a key consideration for buyers when assessing the value and prospects of a pharmaceutical or biologic product. It is therefore important for counsel to understand and be able to evaluate the prospects for and timing of generic competition for products involved in an acquisition.

Generics. In the case of pharmaceuticals, the Hatch-Waxman Act permits manufacturers of generic versions of approved drugs to utilize more streamlined applications for marketing approval. Most generic drugs are marketed under an abbreviated new drug application, or "ANDA". An ANDA filer is not required to carry out either animal or human trials to demonstrate safety or efficacy, rather it must demonstrate that the generic product is "bioequivalent" to the reference product in that it performs the same way as the reference drug. This is typically established through far more limited clinical trials than are required for new chemical entities.

As noted above, there are two key barriers to generic competition for pharmaceuticals: regulatory exclusivity and patents protecting the innovator drug. As discussed above, the type of regulatory exclusivity attaching to a particular innovator drug will dictate whether and when the FDA can accept or approve an ANDA in respect of a generic version of that drug. Applicants must address the issue of patent coverage by certifying in the ANDA one of the following with respect to the patents protecting the reference drug: (1) that no patent covering the reference drug was submitted to the FDA; (2) that all patents covering the reference drug that were submitted to the FDA have expired; (3) that the applicant seeks approval only once the applicable patents covering the reference drug expire; or (4) that the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the abbreviated application is submitted (a "Paragraph IV certification").

The Hatch-Waxman Act requires that an ANDA filer must notify the holder of the NDA for the reference drug of its filing and further provides that the act of filing an ANDA with a Paragraph IV certification is an act of patent infringement such that the NDA holder has standing to initiate a patent infringement suit against the ANDA filer. If the NDA holder does so within 45 days after notice of the ANDA filing, the Hatch-Waxman Act establishes a 30-month stay during which the FDA cannot approve the ANDA unless the patent at issue

expires or a court rules that there is no infringement or that the patent is invalid. If none of these occurs prior to the expiration of the 30-month stay and the regulatory exclusivity period covering the reference drug has lapsed, the FDA will be permitted to approve the ANDA for the generic product. If patent infringement litigation is still pending at the time of approval, however, any commercial launch of the generic product would be deemed "at risk" in that the generic company would face a substantial damages award in the event that it ultimately loses.

The Hatch-Waxman Act provides an important incentive for generic manufacturers to find their way through these regulatory and patent hurdles. The first manufacturer to file an ANDA for a generic version of a particular reference drug is generally awarded a 180-day marketing exclusivity period during which no other generic version of the same reference drug can be sold in the U.S. This gives the "first-to-file" generic company a distinct advantage in terms of both pricing and market share over future generic entrants.

Given the high stakes involved in the timing of generic competition for a given drug, it is important that M&A practitioners understand the various dimensions of the generic approval process so that they are able to assist buyers in determining how to appropriately factor the specter of generic competitors to a target's key products into their assessment of those products' value and future prospects. The existence or prospect of generic competition is also taken into account in various deal terms, as discussed below.

Biosimilars. Biosimilar products are to biologics what generics are to traditional "small molecule" drugs. As the name implies, however, biosimilars, by their nature, are not exact replicas of the innovator biologic products. This creates a complicated situation for regulators endeavoring to develop streamlined approval pathways for biosimilar products while still ensuring their safety and efficacy are equivalent to that of the innovator biologics. This is a relatively new and still evolving area of law and policy in the United States and other countries. The legislative basis for an approval pathway for biosimilars in the U.S. was established as part of the Affordable Care Act in 2010 and the FDA has published guidance relating to the approval of biosimilars in 2012 and 2014. Under this guidance, manufacturers are permitted to rely to some extent on safety and efficacy data filed in respect of the reference biologic, but the biosimilar still must be shown to have no significant clinical differences from the reference biologic. Because a biosimilar will never be exactly the same as an innovator product, demonstrating the requisite level of similarity will typically require a combination of structural analyses, functional assays, and data from animal and human studies. The FDA has significant discretion over what it will require for a particular biosimilar. In any event, obtaining FDA approval of a biosimilar is a significantly more time consuming, costly and uncertain undertaking than obtaining approval of a generic drug.

There are other differences between the approval process for a traditional generic product and a biosimilar. For example, biosimilar applicants are not required to make patent certifications and are not subject to an automatic 30-month stay if infringement litigation is initiated. They are, however, required to provide certain notices to the holder of the BLA for the reference product. As with generic products, the first applicant for a biosimilar version of a particular reference biologic is, however, entitled to a period of marketing exclusivity during which no other biosimilar based on the same reference product may be sold in the U.S.

Because of the evolving nature of the approval process for biosimilars and the challenges associated with obtaining FDA approval for a biosimilar, competition from biosimilars is not yet the threat to biologic products as competition from generics is to traditional drugs. It seems inevitable that will change, though, as regulators catch up with the science of biotechnology and manufacturers become more adept at replicating and manufacturing biosimilars. It therefore also seems inevitable that M&A practitioners will need to understand and keep up with this important and developing dimension of the life sciences industry in order to assist clients pursuing acquisitions of biotech targets in properly evaluating and planning for the likelihood and potential timing of biosimilar competition.

Licensing and Collaboration Agreements

In-licensing of intellectual property and product development collaborations in various forms are very common in the life sciences industry. Such arrangements can give rise to a range of considerations and traps for the unwary acquirer. Among other things, buyers should assess the following in the context of in-licensing and collaborative development transactions:

- *Allocation of Rights*. Licensing and collaboration agreements often have elaborate provisions that allocate rights to develop and commercialize products using licensed or developed intellectual property and other resources between the parties. These provisions typically allocate rights based on both geographical territories and field of use (e.g., for particular therapeutic areas (like immunology) or particular diseases (like Hepatitis C)). Terms such as rights of first refusal and similar concepts that create the potential for an expansion or shifting of one party's rights may also be included. These provisions should be carefully reviewed to ensure that the buyer has a fulsome understanding of where and how a target's product or technology that is the subject of a licensing or collaboration arrangement may be exploited. An additional consideration is whether the counterparty could gain access to the buyer's preexisting IP after an acquisition; through a license grant that extends to the target's affiliates, for example.
- *Diligence Obligations Imposed on the Target*. Licensing and collaboration transactions commonly involve a requirement that the licensee or collaborator commit to exercise a certain level of diligence in carrying out its responsibilities under the collaboration, in respect of development activities, pursuing marketing approvals or commercializing the product(s). Often these obligations are based on detailed definitions of "Commercially Reasonable Efforts" or "Reasonable Best Efforts" which may be either inwardly focused (e.g., a commitment to use a level of effort comparable to that which the party would use in relation to its other products) or outwardly focused (e.g., a commitment to use a comparable level of effort that participants in the industry would generally use in relation to a comparable product). Buyers and their counsel should consider how these obligations will be construed post-closing. For example, would an inwardly-focused diligence obligation pick up the efforts of buyer and its affiliates after an acquisition of the target? Is the diligence obligation consistent with buyer's intentions relating to the product or collaboration at issue? Perhaps buyer views a particular indication for which one of target's products is being developed as not commercially viable. The diligence obligations in the contract pursuant to which target has in-licensed that product may limit buyer's ability to abandon development of that indication. More generally, the status of target's relationship with its licensing and collaboration partners should be assessed. Such relationships are fertile ground for differing expectations and potential disputes, particularly when the stakes are higher for one party than the other or when one party is ceding significant control over an asset to the other party.
- *Non-compete and Similar Limitations*. Non-competition, exclusive dealing and similar covenants in licensing and collaboration agreements should be carefully assessed. Such covenants frequently either expressly bind affiliates (such that they could bind a buyer and its pre-closing affiliates) or establish protocols for dealing with competing products in which an acquirer may have an interest (such as mandating a divestiture of the competing product within some period after closing, or providing for a shifting of rights under the agreement if the product is not divested within the specified time period). Such terms warrant careful attention to ensure that buyer is not signing up to commitments that will have undesirable consequences for its existing products or business or result in loss or diminution of rights to a product that it is counting on retaining after the acquisition.
- *Change of Control and Assignment Provisions*. Licensing and collaboration agreements often include change of control clauses. Frequently, such clauses are highly negotiated and permit a counterparty to terminate the agreement or trigger a change in the contract terms if the buyer meets, or fails to meet certain criteria. For example, such provisions may be applicable in the context of an acquisition of the target company by a competitor of the collaboration partner or licensor; or they might come into play if the acquirer does not meet specified minimum financial criteria. Assignment clauses should also be carefully reviewed. Generally, an acquisition of a target company through a purchase of its equity or a merger or other statutory combination will not trigger a contractual prohibition on assignment unless the provision is crafted so as to deem such a transaction to be an assignment.

Assignment clauses are much more important in the context of an asset purchase transaction. In the context of a patent license agreement or a collaboration agreement involving a license to a third party collaborator's patents, it is important to remember that common law principles relating to assignment of contracts may be trumped by federal common law principles relating to transferability of patents. In many states, most contractual rights are assignable without consent absent an express contractual limitation to the contrary. In contrast, patent rights are generally not transferrable without the patentee's consent, such that if a contract does not expressly permit assignment of the contract, the license rights under the contract will likely not be assignable without consent.

Product Development Considerations

Bringing a new drug or biologic and certain types of medical devices to market is typically a very lengthy process fraught with legal and regulatory pitfalls. In addition to assessing the prospective market exclusivity the product is likely to enjoy once it is approved, there are a number of elements of the development process that acquirers and their advisors should be mindful of during the due diligence process, including the following:

- *Requisite Approvals*. Before a developer can begin clinical trials for a drug or biologic product involving human subjects, an investigational new drug application ("IND") must be submitted to the FDA. Clinical studies of medical devices require a comparable filing called an investigational device exemption ("IDE"). Due diligence should include a review of target's open IND/IDE applications to ensure that ongoing clinical trials are being conducted in accordance with valid INDs/IDEs and that the terms of such INDs and IDEs are being adhered to.
- *Contract Research Organizations*. Many companies engage third party contract research organizations ("CROs") to carry out clinical trials for their products. It is advisable to review the target's agreements with CROs to understand risk allocation provisions, insurance requirements, publication rights for investigators and confidentiality obligations, among other things.
- *Confidentiality and Intellectual Property*. To the extent that third parties are involved in product development efforts, it is important to review agreements with those parties to ensure that they include appropriate confidentiality obligations and to assess the parties' respective rights to intellectual property arising from those efforts. It is also important to ensure that employees involved in the development of owned IP are subject to valid invention assignment agreements effectively assigning their rights in the underlying inventions to the target or have otherwise made such assignments.
- *Other Third Party Rights and Obligations*. Many drug development processes do not begin and end exclusively within the control of the same party. Situations where development work has been transitioned to the target from another party or has been undertaken in collaboration with another party will require careful consideration. See the further discussion of this topic above.

Regulatory Obligations Relating to Marketed Products

Completing development and achieving FDA approval or clearance is in many ways just the beginning of a product's regulatory life. Life sciences companies are subject to a wide range of regulatory requirements specific to their products. It is important to involve regulatory specialists in any due diligence investigation of a life sciences target. A discussion of all the various possible regulatory issues that can bear on a transaction is beyond the scope this practice note; however, the following are among the more significant considerations:

- *Post-marketing Commitments*. As part of its approval of a new drug or biologic product, the FDA will sometimes require an applicant to undertake additional "Phase IV" clinical trials or other studies to further assess the product's safety and efficacy, in specific populations or otherwise. It is important for buyers and their advisors to review such obligations and any reports to the FDA of their progress or outcome to understand what efforts and costs are involved and what implications their outcome may have for the product.

- *Labeling Requirements*. As part of a product's approval, the FDA will approve its label, which includes detailed prescribing information, warnings about side effects, contraindications and other information. Once the product is on the market, additional requirements can sometimes be imposed. For example, if there is a pattern of a particular serious adverse event occurring, the FDA may require that the manufacturer include a "boxed" warning highlighting that risk on the label. It is important to understand any such evolution in product labeling after its launch. The addition of a boxed warning after a product has been on the market suggests that there could be a basis for product liability claims associated with the side effect that had not previously been described or highlighted.
- *Risk Evaluation and Mitigation Strategies ("REMS")*. In situations where the FDA identifies a particular risk associated with a product that it determines cannot be sufficiently addressed with product labeling, it may direct the manufacturer to undertake a risk evaluation and mitigation strategy, or "REMS" to mitigate such risk. REMS can take many different forms, and may involve medication guides or packaging inserts, a communications plan, elements to assure safe use ("ETASU"), an implementation system or some combination of these elements. REMS can become significant and costly commitments. In some cases, they can also pose an impediment to a product's commercial success. For example, ETASU elements can involve putting on physician training programs and certification programs for pharmacies, which can have the effect of limiting the community of those capable of prescribing the product and filling prescriptions. As part of due diligence, any REMS or potential REMS should also be carefully assessed.
- *Recalls, Market Withdrawals, Safety Alerts*. In circumstances where it is determined that specific quantities of products that have entered the market have been compromised or "adulterated" by virtue of a problem with the manufacturing process or otherwise, a manufacturer will typically undertake a recall or market withdrawal to remove the product from the marketplace. Usually the company takes such steps of its own volition, but in extreme cases, the FDA may direct that a recall or other corrective action be initiated. In circumstances where the FDA perceives a serious risk associated with a product, it will issue a safety alert that is posted to its web-based MedWatch adverse event reporting system and disseminated through other relevant channels.

Product Liability

One does not need to be particularly involved in the pharmaceutical, biotech or medical device business to know that product liability claims are a big concern for companies in this industry. Evaluating existing product liability claims and potential sources for future claims should be an important part of any due diligence effort for a life sciences transaction. Where there is a history of claims or significant concerns over future claims, it may be worthwhile to get the perspective of a product liability litigator as part of the diligence process. Things to consider include the following:

- *Nature of Past Claims.* To the extent the target has experienced product liability claims, do they relate to unrelated episodic issues or are they indicative of a more fundamental problem with the product involved, such as a design flaw or systemic quality problem?
- *Class Actions.* Are any claims arising from similar circumstances likely to be aggregated into one or more class action suits?
- *Adverse Event Reporting.* Adverse event reporting should be reviewed with an eye toward identifying serious problems with the target's products, or patterns of problems, that could lead to claims. Particular attention should be paid to any serious or recurring adverse events that are not within the scope of the side effects or warnings contemplated on the relevant product's labeling.
- *Changes to Labeling.* Similarly, as noted above, a change or pending change to a product's label include additional cautionary guidance could signal the possibility of claims associated with harm suffered by consumers of the nature addressed by the label change.
- *Misleading Statements.* Is there any indication that the target may have made misleading statements to the FDA in its application for approval of any of its products or otherwise in connection with the approval process? If so, such statements could support not only civil liability to injured consumers, but also potentially civil or criminal liability under the False Claims Act (31 USCS § 3729).

- *Insurance.* Consideration should be given to the target's insurance coverage for product liability claims, including its claims history.

Compliance

In addition to the regulatory hurdles that life sciences companies face in shepherding their products through the regulatory approval process and complying with product-focused regulations after approval, industry participants are also subject to extensive regulation of their operations. Various compliance regimes address a range of issues likely to be relevant to a target company, including how its sales force markets its products, its manufacturing operations, its pricing and price reporting in relation to different health care payers, and how it handles patient information. Non-compliance can be costly in terms of not only fines, but also restrictions on a target company's activities and increased regulatory oversight. Among the regulatory compliance matters a buyer should assess during due diligence are:

- *Sales Force Considerations*. One of the biggest sources of potential liability for a life sciences company is compliance missteps by its sales force. Among other potential problems, issues can arise in the form of:
    - submitting inaccurate government reimbursement forms, or causing or enabling healthcare providers to do so, which can lead to civil or criminal fraud claims and enforcement actions by federal and state regulators, including under the False Claims Act;
    - improper payments, benefits or incentives to healthcare providers, which can lead to civil or criminal liability under the federal Anti-Kickback Statute (42 USCS § 1320a-7b);
    - violations of the U.S. Foreign Corrupt Practices Act (15 USCS § 78dd-2) resulting from payments or gifts to foreign officials in order to obtain business or accommodations; and
    - promotion of products for "off-label" uses – uses for indications other than those for which the product has been approved – and use of unapproved promotional materials, all of which can lead to civil or criminal enforcement actions by regulators and civil lawsuits by consumers.

Due diligence of these kinds of compliance issues should include, among other things:

    - an assessment of whether the target's sales force compensation structures give undue incentives for unlawful activities;
    - a review of any completed or pending regulatory investigations, enforcement actions and lawsuits involving conduct of the target's employees;
    - a review the policies and procedures and training programs the target company has in place for its sales force and other personnel;
    - an assessment of how the target has handled prior compliance problems;
    - an assessment of the target's compliance functions and their role and authority within the organization;
    - if the target uses a contract sales force, a review of the terms of its agreement with the provider; and
    - consideration of whether any identified deficiencies are "one-off" problems or indicative of a more widespread problem.

- *Requirements of Physician Payments Sunshine Act.* The Physician Payments Sunshine Act (42 USCS § 18001) imposes public reporting obligations on many life sciences companies in relation to any transfer of anything of value to physicians or teaching hospitals. Disclosure must include the nature of the transferred items, the reason for the transfer, the identity of the recipient and the reporting entity's product associated with the transfer. Non-compliance with these reporting obligations can result in the imposition of significant fines. Moreover, such required disclosure may reveal instances of violations or potential violations of the federal Anti-Kickback Statute or the False Claims Act, paving a smoother path for investigations and enforcement actions. Acquirers should carefully assess a target's policies and procedures for complying with these requirements, any instances of

non-compliance, and the results of any compliance audit by the Department of Health and Human Services (the agency charged with enforcing these rules).

- *HIPAA Considerations*. The Health Insurance Portability and Accounting Act (45 CFR 164.502) ("HIPAA") imposes stringent requirements for the handling of Protected Health Information or "PHI", as well as civil and criminal penalties for non-compliance. HIPAA and related privacy regulations are a significant area of concern for life sciences companies that are privy to health information of individuals, particularly as their requirements converge with the issues associated with data security in the era of "big data". Due diligence should include an assessment of:
    - the nature of PHI that has or may come into the target's possession, for example, in connection with clinical trials or by virtue of patient assistance programs;
    - the target's technological systems, policies and procedures for handling and maintaining the security of PHI;
    - the findings of any internal or external audits that have been undertaken in respect of target's technological systems that process PHI and follow-up reports of steps taken to address any shortcomings identified; and
    - whether target has experienced any data breaches involving PHI and, if so, how they were handled.
- *Inspections*. The FDA carries out various types of inspections of facilities engaged in the manufacture of drugs, biologics or medical devices. They can be routine or "for cause" and they can be narrowly focused or fulsome. An important part of due diligence is reviewing the reports of these inspections and particularly any notices of identified non-compliance with FDA requirements, which are reported on Form 483. To the extent that a manufacturer has received Form 483's, it is important to review subsequent communications between the company and the FDA to confirm that the identified problems were adequately resolved or are on a path to resolution. Form 483's are publicly available on the FDA's website. More serious issues or continued deficiencies can lead the FDA to issue a warning letter, which can be the predicate to more serious enforcement action, including mandating the shut-down of a facility. Warning letters are also publicly available on the FDA's website.
- *Adverse Event Reporting*. Drug and biotech companies are obligated to implement systems to monitor adverse events involving their products that are reported to them and others with whom they do business. Once identified, the company must report the adverse event to the FDA Adverse Event Reporting System ("FAERS"). Medical device manufacturers are subject to a similar regime - medical device reporting ("MDR") – in respect of malfunctions, deaths and serious injuries involving their devices. The FAERS system is accessible to the public. Similarly, MDR reports are accessible through the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database. Due diligence should include a review of the nature and extent of adverse events reported in respect of the target's products on the FAERS system or MAUDE, as applicable. Extensive and/or a series of adverse events could signal a risk of product liability claims or regulatory action, such as a required labeling change. It is also important to evaluate a target's compliance with its adverse event reporting obligations as part of an overall assessment of the effectiveness of its compliance functions.
- *Settlements with Regulators*. In the highly regulated life sciences industry, it is not uncommon for participants to enter into settlement arrangements with regulators as part of the resolution of investigations or enforcement actions. Such settlements, which often take the form of Corporate Integrity Agreements ("CIAs"), can impose a range of different limitations or specific requirements on the company's operations, as well as increased regulatory oversight through audits and reporting obligations. Acquirers should carefully review the requirements imposed under settlements of regulatory investigations or claims, as well as the target's experience and performance under any CIA to which it may be subject. What policies and procedures have been implemented to comply with the requirements of the CIA? Has the target's compliance been audited? If so, what was the outcome? Counsel should also evaluate any implications the CIA or any other settlement may have on the target's ability to consummate the contemplated transaction.
- *New Frontiers.* In the current environment, as pharmaceutical and other life sciences companies search for new ways to expand their offerings and justify the cost of their products to payers, many are finding themselves enmeshed in new areas of regulation and, in some cases, finding that the

regulatory landscape for some new products and services is undefined at best. For example, many companies are becoming involved in patient assistance and monitoring programs for patients using their products. Such programs often give rise to questions of whether the company is practicing medicine or nursing within the meaning of state laws and whether additional licensing may be required. Many medical device companies are faced with a host of new issues associated with the wealth of data generated by biometric devices that access the Internet. Data privacy issues become particularly salient in that context. There are many other examples of changes like this that are resulting in a blurring of the boundaries between life sciences and healthcare and giving rise to new regulatory questions and challenges that counsel should be mindful of.

Supply Chain

A functioning supply chain is part of the lifeblood of most life sciences companies. Manufacturers of not just finished products, but also active ingredients, excipients and packaging components are subject to extensive FDA regulation. As a result, switching from one supplier to another is often not as simple as it would be in other industries. Switching suppliers, or even to a new facility of the same supplier, will often necessitate establishing the new site with the FDA as an approved supplier for the product or component involved, which can be a complicated and time consuming process. There can also be practical difficulties associated with transferring the technical process for producing a product or a component. Manufacturing antibodies for a complex biologic is often not something that is easily replicated by a new manufacturer in a new facility, for example. For these and other reasons, it is very important that due diligence in a life sciences M&A transaction include a careful review of the third party relationships and agreements involved in the target's supply chain. Particular attention should be paid to the following:

- *Manufacturing and Supply Agreements*. Ideally, a target will have long-term supply agreements for any products that it does not manufacture itself and for key active ingredients and other components. The absence of agreements with any key suppliers should be flagged as a potential concern. For those manufacturing agreements that are in place, consideration should be given to terms dealing with, among other things:
    - exclusive purchase obligations, including the circumstances in which the target can obtain its requirements from another supplier and the supplier's obligations to assist in establishing an alternate supplier in that circumstance (or in anticipation of the possibility);
    - limitations on the supplier's ability to supply competitors with the same or comparable products;
    - the parties' respective obligations for assessing conformity of the supplied product or material with specifications and the target's recourse in the event supplier supplies non-conforming product;
    - obligations to maintain safety stock to mitigate the effect of any supply disruption;
    - term and renewal provisions; and
    - termination rights, particularly in the context of a change of control.
- *Quality Agreements.* Although not strictly required by law, the FDA has made clear that it expects drug and biologic companies to have in place quality assurance agreements with their suppliers setting out the parties' respective obligations for ensuring compliance with good manufacturing practices. Due diligence should include a determination of whether the target has entered into suitable quality agreements which each of its suppliers and, if it hasn't, why not.
- *Audits of Suppliers.* Life sciences companies often have the right to audit their suppliers and to receive copies of reports of audits by the FDA and other regulators. Reports of internal or governmental audits can reveal concerns with suppliers and are therefore another useful item to include in a due diligence review.

Structuring the Deal

Traditional M&A Structures. It will usually be possible to structure an acquisition of a life sciences business in a number of different ways, including asset acquisitions, acquisitions of stock, various types of mergers and

recapitalizations. Determining which of these approaches is appropriate for an acquisition of a particular life sciences business will typically involve the same set of considerations that influence such determinations in any M&A transaction, including matters such as the parties' respective tax objectives, the buyer's willingness to take on the target company's historical liabilities, and how employees will be handled in the transaction. Among the factors that warrant particular consideration in the context of a life sciences M&A deal are the following:

- *Where the Value Lies.* Particularly in acquisitions of smaller drug development companies, a buyer may have little need for more than the target's intellectual property and other assets specific to the target's products or product candidates and possibly a few knowledgeable employees. In that scenario, buyer may push for a limited asset purchase that allows it to leave behind what it views as extraneous personnel, assets and liabilities.
- *Key Third-Party Agreements*. Life sciences targets are often party to particularly important third party agreements, such as license agreements in respect of intellectual property underlying key products. Such agreements are apt to include prohibitions on assignment or provisions that allow the other party to terminate upon the occurrence of certain types of transactions. In such cases, parties may gravitate towards a particular deal structure that circumvents such provisions, particularly in cases where the parties are reluctant to discuss the transaction with the counterparty prior to signing a purchase agreement.
- *Tax Planning*. Creative and sometimes elaborate tax planning is common among life sciences companies. Particular transaction structures may be necessary in order to avoid disrupting arrangements relating to transfer pricing, intercompany licensing and supply agreements and other arrangements that involve tax sensitivities.

Exclusive License. Often deals that transfer rights to life sciences assets and businesses are not purely acquisitions or not acquisitions at all. For example, exclusive licenses can be structured so as to have many of the practical effects of an acquisition while permitting the parties to accomplish other goals, such as allowing the seller/licensor to treat the proceeds of the transaction as ongoing royalty income rather than income on the sale of assets and allow the buyer/licensee to defer some portion of the "purchase price." Such an arrangement will often include an option that permits the buyer to acquire outright ownership of the licensed assets within some time parameters and for consideration based on a predetermined formula. Such arrangements may work well for mature products that have a reasonably predictable commercial trajectory.

Options. Another alternative sometimes seen in the life sciences industry is the pure option transaction whereby a would-be acquirer pays a would-be seller an upfront amount, or commits to certain funding obligations in return for an exclusive option to purchase rights to an asset (usually a product in development) in the future upon pre-agreed terms. Such arrangements can be useful in situations where a buyer is not confident enough to commit to an outright acquisition of an asset, but is willing to make a smaller commitment to preserve its ability to acquire the asset in the future if its viability becomes clearer.

Consideration Alternatives

Deferred Consideration, Generally

While plenty of M&A deals in the life sciences sector are consummated for a sum certain or a specific number of shares of the buyer's stock at closing, many involve structures whereby a portion of the consideration is paid at some future time, generally subject to certain contingencies. Deferred consideration arrangements are perhaps more prevalent in M&A deals in the life sciences industry than in any other sector. One study has suggested that as many as 80% of deals for life sciences companies involve some deferred consideration. The primary reason for this is the high stakes associated with a number of unpredictable events involving life sciences companies' products and product candidates, such as FDA approval and generic competition.

The role of deferred consideration in life sciences M&A may be best illustrated with an example. Consider a hypothetical company, Brandco, that markets Superdrug, the leading branded pharmaceutical product for a

particular indication in the U.S. U.S. sales of Superdrug generate half of Brandco's revenue. A generic company, Generico, has developed a generic version of Superdrug, Supergeneric, and filed an ANDA with the FDA, which includes a paragraph IV certification that Supergeneric does not infringe any of Brandco's patents protecting Superdrug. Based upon the paragraph IV certification, Brandco has sued Generico for patent infringement, thereby triggering a 30-month stay precluding the FDA from approving Generico's ANDA while such infringement suit is ongoing. Although Brandco is confident in its position, the outcome of Brandco's patent infringement suit against Supergeneric will not be known for some time.

While Brandco's infringement suit against Generico is pending, Brandco is approached by a larger pharma company, Acquisico, which has proposed an acquisition of Brandco. Brandco and Acquisico commence negotiations regarding a possible transaction. It quickly becomes clear, however, that Acquisico is less confident that Brandco will prevail in its efforts to keep Generico's Supergeneric off the market and thereby preserve Superdrug's exclusive market position and premium pricing. Brandco's and Acquisico's divergent views of the Generico litigation have resulted in equally divergent views of Brandco's present value.

It is at this point that negotiations often veer into the realm of deferred consideration. Staying with our hypothetical, given the apparent impasse over Brandco's present valuation, Acquisico, still keen to acquire Brandco, proposes that a portion of the deal consideration be paid only if and when the trial court rules that Supergeneric does in fact infringe the patents covering Superdrug. Brandco agrees to this approach and negotiates for a bit more deferred consideration to compensate it for the time value of money and the parties proceed to complete their deal and await the outcome of the Supergeneric infringement litigation. Brandco has gotten its deal done and Acquisico has protected itself from the possibility of overpaying for Brandco in the event that the worst comes to pass and Supergeneric gets to market and erodes Superbrand's market share.

This hypothetical is a simplified illustration of one possible scenario in the life sciences context that could give rise to a deferred consideration structure. Many other circumstances can lead parties to pursue such an approach, including uncertain outcomes of clinical trials, uncertainties associated with FDA approvals, such as whether a drug will be approved for a particular indication or will receive a particular exclusivity status, the possibility of one or more competing products for a particular indication beating a target's drug to market and divergent views of a product's commercial prospects. Any of these uncertainties can bedevil buyers and their financial advisors when trying to develop financial models to determine an appropriate price for a target company or asset.

Alternatives for Structuring Deferred Consideration

There is a range of different ways that deferred consideration can be structured. The most straightforward arrangements involve clear, binary triggers that lead to payment of a specified amount. For example, a payment is made if a new drug application for a product candidate is approved by a date certain and the payment is not made if the application is not approved by that date. More complex variations might call for tiered milestones linked to differing outcomes, such as the elements of a product's label on approval or what claims in a patent application are allowed.

Differing views of a product's commercial viability may lead parties to agree to a structure involving payments at intervals based on sales of the product. These may be in the form of milestones that are paid once certain targets are reached or a more traditional "earnout" arrangement involving periodic payments based on a percentage of net sales or net profit or some other metric during the preceding period. In these structures, a lot of attention is typically paid to how net sales or whatever other metric supporting the earnout payments will be defined and calculated.

Covenants Supporting Deferred Consideration

To complicate matters further, sellers who are amenable to a deferred consideration structure will typically insist that the buyer commit to adhere to contractual covenants designed to support the deferred

consideration. In the most seller-favorable form, these covenants may involve a broad commitment that buyer will use its reasonable best or commercially reasonable efforts to ensure the satisfaction of the criteria for payment of the deferred consideration or maximize product sales or whatever other performance criteria supports the deferred consideration payments. Buyers should approach such broad, non-specific commitments with caution. A better approach, from buyer's perspective, is to include clearly defined obligations that can be readily evaluated. Earnouts and other deferred consideration payments very often give rise to disputes when sellers, having given up control of their asset, end up receiving less than they had anticipated. In that situation, sellers are likely to second guess the buyer's actions and commitment to the business or the product that is the subject of the deferred consideration arrangement. Sellers will often be inclined to scrutinize the contractual commitments the buyer made in connection with the acquisition, searching for a basis to assert a claim for breach. In that situation, buyers will generally be well served by having spent the time during negotiations to craft covenants that are as specific and objectively verifiable as possible.

It should also be noted that even a buyer that is able to successfully avoid committing to covenants to support a deferred consideration arrangement may not be able to simply do as they wish with an acquired business or asset without regard to the implications for the deferred consideration. Courts in some states have relied on concepts of good faith and fair dealing to imply some level of commitment to an acquired business that is the subject of a deferred consideration obligation, even in the absence of express contractual provisions. This is a particular concern in the scenario where a buyer is inclined to discontinue some aspect of an acquired business or plans to take some other action that eliminates or substantially undermines a deferred consideration obligation. Accordingly, if possible, buyers who wish to be free of any obligation whatsoever with respect to a business or an asset that is the subject of a deferred consideration arrangement will be best served by including in the purchase agreement an express statement to that effect, disclaiming any such obligations based on theories of good faith and fair dealing or otherwise.

Contingent Value Rights

Notwithstanding the complexities described above, once terms are negotiated, deferred consideration arrangements are relatively easy to implement in the context of an asset purchase or an acquisition of a private company with a limited number of selling shareholders. The terms are generally memorialized in the purchase agreement. Things get more complicated in the context of an acquisition of a public company. It is typically not possible to fashion a commitment in the merger agreement to make future payments to what could be thousands of public shareholders in a way that is acceptable to the seller. Instead, deferred consideration obligations in the context of public deals are typically memorialized in an instrument called a contingent value right or "CVR" which is delivered to the selling shareholders upon closing together with whatever cash or share consideration they are to receive.

A fundamental question associated with CVRs is whether or not they will be viewed as securities for purposes of U.S. securities laws. If they are, the implication of issuing them to a broad group of public shareholders of a target company is that the CVRs will need to be registered under the Securities Act of 1933 and the buyer will have reporting obligations in respect of the CVRs under the Securities Exchange Act of 1934 for as long as the instruments remain outstanding. That can pose a significant burden, particularly for a private equity purchaser or other non-public buyer that lacks public reporting infrastructure.

There is no precise definition of what constitutes a security for purposes of the U.S. securities laws. Rather, the determination of whether or not a CVR is a security hinges on an assessment of a number of factors that the SEC has articulated in various no-action letters. See *Minnesota Mining and Manufacturing Co. SEC No-Action Letter (available October 13, 1988)* and *Genentech Clinic Partners III SEC No-Action Letter (available April 28, 1989) and Northwestern Mutual Life Insurance Co. SEC No-Action Letter (available March 3, 1983)*. In many cases, however, practitioners need not consider more than one key factor: whether or not the instrument is to be transferrable by recipients. If it is, the CVR will almost certainly be a security and buyer will need to be prepared for everything that goes along with that. It is, of course, possible to make a CVR non-transferrable by its terms and thereby possibly avoid it being classified as a security. Doing so, however,

would likely significantly diminish the value that the target company and its shareholders place on the instrument, as an element of the deal consideration.

Thus, parties considering including a deferred consideration component in a public M&A deal, in the form of a contingent value right, typically face a difficult choice. They must either make the instrument non-transferrable, which is objectionable to sellers, or they must register the instrument under the U.S. securities laws and complying with ongoing SEC reporting obligations, which is undesirable from buyer's perspective. For this reason, CVRs are discussed far more often than they are ultimately used. That being said, because of the factors inherent in the life sciences industry that lead parties to gravitate to deferred considerations arrangements in M&A deals, as described above, the life sciences industry has seen more prevalent use of CVRs in public deals than other sectors.

The Purchase Agreement

As in any other M&A transaction, how parties approach the terms of a definitive agreement for the acquisition of a life sciences business or life sciences assets will be informed by industry-specific sensitivities, buyer's findings in its due diligence process, and the structure of the transaction and consideration. Industry-specific considerations flow through several aspects of the acquisition agreement for a life sciences deal, as discussed below.

Purchase Price Provisions

As in any transaction, the provisions of the acquisition agreement dictating how the purchase price will be calculated and paid should be crafted carefully and in a manner that minimizes the risk of differing interpretations of elements such as post-closing adjustments or earnout calculations. Among other things, parties to life sciences deals should pay particular attention to the following:

- *Working Capital Adjustments*. Purchase price adjustments based on the variance in a target company's working capital from a target working capital are among the most common sources of disputes in M&A deals. Parties will be well served by thinking carefully about how the target company has historically calculated working capital and the different components of current assets and current liabilities. Where possible, specific guidelines and examples should be included in an attachment to the acquisition agreement. For life sciences companies, parties should pay particular attention to how inventory is to be treated and how things such as discounts, allowances, rebates, refunds, and chargebacks are to be factored into the calculation, as such items often play a significant role in life sciences companies' promotion and sale of their products and they can be subject to differing accounting treatment.
- *Deferred Consideration*. To the extent that a transaction involves an earnout or other deferred consideration, the parties will typically spend a lot of time negotiating and refining provisions relating to the triggers for deferred consideration payments (to the extent they are tied to specific events or milestones) or how they are calculated (to the extent they are tied to ongoing net sales or other ongoing performance). As noted above, deferred consideration provisions are another common source of disputes. The more potential variables and contingencies are considered and addressed at the time the acquisition agreement is negotiated, the greater the parties' chances will be for avoiding disputes after closing.

  As noted above, covenants and other provisions relating to deferred consideration are also an important aspect of acquisition agreements for deals that include such a feature. These related or supporting provisions are likely to include:
  - covenants meant to ensure that the buyer maximizes the potential of the business or product(s) involved in the deferred consideration calculus;
  - covenants precluding buyer from selling or otherwise deriving benefit from products that compete with acquired product(s);

- provisions addressing what happens if the buyer experiences a change in control or sells some or all of the relevant assets; and
- provisions addressing the seller's ability to transfer its rights to deferred consideration payments to third parties.

Representations and Warranties

A number of seller's representations and warranties in a life sciences acquisition agreement tend to assume greater importance and become the subject of more extensive negotiation than in other industries. These tend to track the areas discussed above that buyers commonly focus on in their due diligence process. Representations and warranties that tend to fall into this category include the following, all of which are commonly subject to typical negotiations over such limitations as knowledge and materiality qualifiers and the length of look back periods:

- *Intellectual Property*. IP representations and warranties in life sciences acquisition agreements often span numerous subsections and can go on for a few pages. In addition to calling for disclosure of all significant registered and sometimes unregistered IP, they address numerous considerations that affect, among other things, the validity of the IP, the target company's rights in its IP, any third party rights in respect of the target company's IP, and the absence of infringement, misappropriation or other violation of the target's IP by third parties and of any infringement, misappropriation or other violation of third parties' IP by the target company's activities.
- *Product Approvals*. Buyers will typically seek representations confirming the disclosure of all of the regulatory approvals underlying the target company's products and product candidates (INDs, NDAs, BLAs, premarketing notices, etc.) and representations as to the status of such approvals and matters such as the absence of misstatements in the application or approval process, among other things.
- *Compliance*. Compliance-related representations and warranties in life sciences acquisition agreements are often second only to the IP reps in their breadth and detail. It's common practice to include a laundry list of the important industry-specific laws and regulations the target is subject to (many of which are discussed above) and have the seller warrant compliance with those various laws and regulations, often over a period looking back several years. It is also common for sellers to be asked to represent and warrant as to specific conduct prohibited or required under key compliance regimes, particularly in cases where instances of prior non-compliance have been identified. Compliance representations and warranties will also commonly focus on matters such as recalls, withdrawals and similar actions. In some cases, buyers will also seek disclosure on a schedule of all interactions (or all material interactions) with the FDA and other regulators over some period of time, which can be burdensome for the seller.
- *Third Party Contracts*. In instances where key elements of a life sciences target's business are dependent upon rights arising under a third party contract, buyers will sometimes seek representations and warranties specific to that contract beyond the customary representations to matters such as the contract's validity and enforceability. For example, if the buyer derives its rights to some critical IP pursuant to a license agreement with a third party which imposes certain development or commercialization obligations in respect of such IP on target, buyer may seek representations as to the satisfaction of such obligations.
- *Inventory*. Buyers will commonly ask for representations and warranties relating to the target's inventories of products and sometimes active ingredients and other product components. These generally will cover the quality of the inventory – that it meets specifications and has been manufactured and handled in accordance with current good manufacturing practices and other regulatory requirements – and its age (in the case of products that have a specified shelf life). Buyers may also seek representations that the quantities of inventory on hand at signing and/or closing are neither excessive nor insufficient based on the target's historical commercial experience.
- *Product Liability.* Life sciences acquisition agreements also often include seller representations and warranties addressing product liability exposure. These will typically include representations as to any known claims or bases for claims and can also include representations relating to the

completeness of the target's adverse event reporting under applicable reporting regimes and its product liability insurance coverage.

Interim Covenants

Most M&A transactions involve a delay between the signing of a binding acquisition agreement and closing. There are several reasons for this. As with acquisitions in any other industry, if a life sciences deal and the parties meet specified "size of transaction" and "size of person" thresholds, a pre-merger notification is required under the Hart-Scott-Rodino Act (Hart-Scott-Rodino Antitrust Improvements Act of 1976., 90 Stat. 1383,94 P.L. 435,90 Stat. 1383), which the parties typically wait to file until the definitive agreement is signed (although notifications can be filed on the basis of a letter of intent). Acquisitions of public companies will involve a period after signing during which either a tender offer is conducted or proxies for a shareholder vote are solicited. Finally there are a range of practical issues that can lead the parties to bifurcate signing and closing, such as the need to solicit consents from third parties whom the parties are reluctant to approach prior to having a binding agreement.

After a buyer has committed to an acquisition, it will be particularly focused during the interim period between signing and closing on ensuring that the seller continues to appropriately operate the business or maintain the assets. The buyer will therefore seek to bind the seller to a number of covenants relating to what the seller must and may not do between signing and closing. In addition to the typical laundry list of interim covenants that are common to acquisitions in any industry, life sciences M&A agreements often include covenants dealing with the following:

- *Channel Stuffing.* Life sciences companies often have some ability to manipulate their distribution channels through actions such as special promotions, offering special discounts and rebates and modifying shipping, billing or collections practices. When done for the purpose of boosting short term sales, this practice is sometimes referred to as "channel stuffing." Particularly in deals that involve an adjustment to the purchase price based on the target's working capital at closing, such actions that have the effect of increasing sales and accruals before closing could artificially inflate buyer's purchase price. Accordingly, buyers will often seek to include specific prohibitions on actions that could result in channel stuffing and artificial inflation of the purchase price.
- *Third Party Consents*. In most cases, subject to the expiration or termination of the waiting period associated with pre-merger notifications under the HSR Act, discussed above, the acquisition of a U.S. life sciences company will not involve any significant U.S. governmental approvals. Consents required under third party contracts are sometimes required, however. This is commonly the case in a deal structured as an asset purchase as a result of anti-assignment provisions in agreements that must be assigned. As a general matter, such contractual consents are somewhat less common in transactions structured as stock purchases or in merger transactions, as they typically only arise where a third party agreement contains a clause giving one party the right to terminate or modify the terms of the relationship in the event of a change of control of the other party. Some types of contracts prevalent in the life sciences industry, such as those involving significant licensing arrangements, contracts relating to joint ventures and other collaborative arrangements and sometimes even significant supply agreements often include such change of control clauses. Thus, it is arguably more common that parties find themselves navigating third party contractual consents even in the context of an equity transaction in the life sciences sector than is the case in other industries. How and when the parties go about soliciting such a consent or the waiver of a termination or other right triggered by a change of control can be a very delicate topic. Often parties will want to specify how the process will go, or at least establish certain ground rules, in the pre-closing covenants. Among other things, parties should consider whether the buyer will play a role in the solicitation and what obligations the seller will have if the consent or waiver is not forthcoming (e.g., Will seller be obligated to agree to concessions requested by the counterparty? Within what limits?).
- *Product-Specific Items.* Depending on the status of the target company's products, a buyer may wish to impose specific covenants relating to conduct bearing on matters such as product approvals, post-approval commitments, initiation or settlement of IP infringement lawsuits and

other activities that could have significant implications for the product or product candidate. Such covenants can take the form either of notice and consultation requirements or consent requirements. It should be noted, though, that these kinds of covenants and other covenants that permit buyer to exert control over the target business prior to closing can give rise to antitrust concerns if they allow buyer to unduly influence seller's ability to conduct its business.

Closing Conditions

Acquisition agreements for life sciences M&A transactions tend to include the same kinds of closing conditions common to transactions in other industries, including in relation to the accuracy of representations and warranties, compliance with covenants, competition clearance, absence of legal impediments, no material adverse effect, etc. Life sciences-specific considerations may lead buyers to also seek additional conditions, such as the following:

- *Third-Party Consents/Waivers.* As noted above, life sciences companies are apt to be party to third party contracts that are critical to the viability of certain aspects of their business. It is common to condition a buyer's obligation to close on receipt of any consents or waivers that may be required in connection with mission critical contracts by virtue of the transaction.
- *No Competitor Filing or Launch*. For pharmaceutical or biotech companies, if there is concern that a competitor may seek approval for or launch a generic version of one of the target's key products, buyer may seek a closing condition that no such filing or launch has occurred.
- *Favorable Ruling in Patent Infringement Suit.* Similarly, if a pharmaceutical or biotech target is awaiting a critical ruling in a patent infringement lawsuit against a would-be generic competitor that could come prior to the anticipated closing date, a favorable ruling (or the absence of an unfavorable ruling) could be a closing condition.

Post-Closing Recourse

Generally, post-closing recourse provisions in life sciences M&A transactions involving private targets are comparable to those commonly seen in deals in other industries. A few things are worth noting, however. Specifically:

- *Survival*. It is not uncommon for buyers of life sciences companies or assets to seek longer survival periods for representations and warranties covering matters of particular importance in the life sciences industry, such as intellectual property and compliance-related representations.
- *Specific Indemnities*. Some transactions (most transactions structured as asset purchases and some stock purchase and merger transactions) will include indemnification rights for specific liabilities or problems. In the context of a life sciences M&A deal, buyers will often focus on matters such as product liability claims stemming from products manufactured or sold prior to closing, IP or other litigation against target and liabilities flowing from pre-closing compliance deficiencies.
- *Set-Off*. An issue that is likely to arise in transactions involving an earnout or other deferred consideration, which is common in life sciences deals, is whether the buyer will be entitled to offset indemnification claims against such future payment obligations. Whereas buyers would prefer to withhold from deferred consideration payments the full amount of any indemnification claim pending its resolution, sellers will argue that indemnification claims should be handled separately from consideration payment obligations and that set-off, if permitted at all, should only be possible once a claim is fully resolved and a sum certain is owing.

Transition Arrangements

As is the case in other industries, transactions that involve an acquisition of less than the entirety of a life sciences enterprise will often require the seller to provide certain services or accommodations to the buyer for some period of time after closing. Such arrangements in the context of a life sciences transaction tend to involve many of the same considerations that commonly arise in transition arrangements in other industries,

such as the scope and duration of the services to be provided, how the seller will be compensated, risk allocation considerations, and so on. The services to be provided will also often include many that are common to M&A transactions generally, relating to matters such as transitioning human resources functions and information technology systems, for example. Other transition issues are especially relevant to life sciences companies, however, and navigating them can sometimes be tricky. Among other things, parties to transactions where a transition period will be involved should be mindful of the following:

- *Supply Chain Considerations*. If the seller will continue to manufacture or perform some aspect of the manufacturing of the product or products to be acquired by buyer, it will typically be necessary for the parties to enter into a manufacturing or supply agreement covering that link of the supply chain for some period of time. These arrangements can sometimes be for longer periods than are commonly seen for other transition arrangements. Also, the terms of such supply agreements are often different from those commonly seen in supply relationships outside the M&A context. Sellers often take the position that they are supplying as an accommodation to the buyer and should therefore not be subject to terms relating to things like price controls and liability that a more traditional supplier might expect to be bound by. In such arrangements, the parties should also consider how third parties involved in the supply chain will fit in. For example, should a contract with an active ingredient supplier be assigned at closing, such that the buyer would then be responsible for procuring that active ingredient is supplied to the seller for purposes of the post-closing supply agreement, or should assignment not occur until the supply agreement ends? Other issues arise in the situation where a seller is dependent on one or more suppliers for materials used for divested products as well as retained products.
- *NDC Numbers.* If pharmaceutical products are acquired through an asset purchase, it will typically be necessary to transition the products' National Drug Code or "NDC" numbers, which are unique identifiers assigned by the FDA to all drugs in the United States. A portion of a drug's NDC code identifies its manufacturer, such that a new code must be obtained when a drug is acquired by another manufacturer. Obtaining new NDC numbers can take time. Accordingly, it is often necessary for the seller to permit the buyer to use seller's NDC numbers for a period of time. At a minimum, such an arrangement will be necessary to permit buyer to sell acquired inventory bearing seller's NDC numbers.
- *Price Reporting.* Life sciences companies are subject to extensive price reporting obligations to the Centers for Medicare and Medicaid Services ("CMS") and other governmental agencies as a condition to having their products covered under Medicare, Medicaid and other federal and state programs. A buyer will need to ensure that pricing information for periods prior to closing are reported accurately and in a manner consistent with seller's reporting and may need seller's assistance or at least access to seller's records for some period of time after closing to facilitate buyer's price reporting.
- *Federal Contracts and Supply Schedules.* Federal agencies play an important role in the commercial success of most life sciences products. Aside from the government's regulatory function, governmental entities are major consumers of life sciences products and government-sponsored programs pay for vast quantities of products consumed by patients covered by Medicare and Medicaid. Accordingly, in an asset acquisition transaction, transitioning products from seller's relationships with relevant governmental agencies to buyer's relationships is critical. This will typically involve at least notice to relevant agencies, including CMS, the Department of Defense, the Department of Veterans Affairs and the Office of Pharmacy Affairs, and transitioning the acquired products from seller's Federal Supply Schedule to buyer's.
- *Chargebacks, Rebates, Credits and Returns.* Asset transactions involving marketed life sciences products often include detailed provisions addressing which party will bear economic responsibility for matters such as chargebacks, rebates, credits and returns, which are common in the industry. Transition provisions will also typically address which party is responsible for processing such items. Although parties will often seek to allocate responsibility based on whether or not a product was sold on "our watch" versus "your watch," implementing such an approach can sometimes be difficult, especially in cases where products from a particular lot are sold both before and after closing. Sometimes parties find it simpler to establish a set period after closing during which seller will remain responsible based on perceived market pull-through.

- *Notice to FDA of Transfer of Approvals.* Although FDA approval is not required to transfer marketing approvals associated with life sciences products, it is necessary to notify the FDA that an NDA or other approval has been transferred in the case of an asset purchase transaction.
- *Trademarks and Trade Dress.* As with NDC numbers, buyer may need a license to any trademarks or trade dress of seller that is not acquired in order to permit buyer to sell off acquired inventory. A buyer may also seek such a license for a longer period if it needs to produce additional quantities packaged with seller's trademarks or trade dress before labeling changes can be implemented.
- *Reporting of Adverse Events, Complaints and Inquiries.* Seller is likely to receive reports of adverse events, complaints and inquiries from medical professionals or others relating to products it has divested for some period after closing. It will be important for buyer to ensure that such matters are promptly communicated to buyer, particularly given that such matters will commonly give rise to regulatory reporting obligations for buyer and could be the basis for liability.

Conclusion

Doing deals in the life sciences industry involves a wide range of challenges and opportunities. Although it is always important to include appropriate specialists on the deal team, M&A practitioners should have an understanding of the various legal, regulatory and practical issues that are particularly relevant to life sciences companies. Grasping these concepts is key to being able to structure, negotiate and document a successful life sciences deal.