



MORGAN LEWIS - ON LIFE SCIENCES

A NEWSLETTER FROM THE LIFE SCIENCES PRACTICE ■ www.morganlewis.com

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LIFE SCIENCES MERGERS AND ACQUISITIONS: POTENTIAL INTELLECTUAL PROPERTY PITFALLS

When negotiating a life sciences merger or acquisition agreement, the merged or acquired entity must fully understand the chain of title and scope of the intellectual property to be merged or acquired, and the degree of freedom it will have to use products and services of the merged or acquired entity. How thoroughly intellectual property due diligence is conducted can mean the difference between landing in or safely negotiating around possible pitfalls when entering into such transactions. This is particularly important in the life sciences context.

Identified and discussed below are common pitfalls associated with certain provisions of merger and acquisition agreements. In particular, we focus on certain definitions and on representations and warranties. These

provisions are typically highly negotiated, and in some instances cause the parties to terminate negotiations prior to signing, or form the basis of disputes after closing. This analysis is not intended to be exhaustive; rather, it is meant to identify and facilitate discussion of certain pitfalls.

Definitions

The definitions sections of merger and acquisition agreements are critical to the remainder of the provisions of such agreements, and set the scope of the assets of the merged or acquired entity. Among the terms whose definitions usually require the most thought and negotiation are “products” and “intellectual property.”

From the acquirer’s perspective, the definition of products should include all those products it believes are owned by the entity to be merged or acquired. The more thorough the due diligence efforts have been, the more detailed this list will be. From the seller’s perspective, the definition should be restricted to only those products it does not wish to retain. The degree of specificity in the definition is especially important where the entity to be merged or acquired is a subsidiary of a corporation that will carry on similar lines of business as the merged or acquired entity post-sale, and when the next best product may not fall within the definition.

The definition of intellectual property should include a list of specific patents, patent

continued on page 5

IN THIS ISSUE

- 1 LIFE SCIENCES MERGERS AND ACQUISITIONS: POTENTIAL INTELLECTUAL PROPERTY PITFALLS
- 2 REALIZING VALUE FROM BIG PHARMA NEW VENTURE SPIN-OUTS
- 3 SUPPLY ISSUES IN ACQUIRING A PHARMACEUTICAL PRODUCT
- 5 EVENTS, SPEECHES & ARTICLES

BIO 2005

ANNUAL CONFERENCE • JUNE 19–22, 2005 • PHILADELPHIA

MORGAN LEWIS LIFE SCIENCES PARTNERS LEAD SPEAKING PANELS

JUNE 21 • 4:00–5:30 PM
EMERGING COMPANY ISSUES TRACK

Fundamental Business and Legal Strategies for Life Science Ventures

Manya S. Deehr

JUNE 22 • 9:30–10:45 AM
TECHNOLOGY TRANSFER / LICENSING TRACK

Realizing Verifiable Economic Value from New Venture Spin-Outs

Steven M. Cohen

Join us for the discussions or stop by exhibit booth #1708.

Morgan Lewis will sponsor a cocktail reception in conjunction with BIO 2005 at the Pennsylvania Academy of Fine Arts in the Samuel M.V. Hamilton Building’s Second Floor Main Gallery (118 North Broad Street) on June 20, 2005, at 6:00 pm.

Morgan Lewis
C O U N S E L O R S A T L A W

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REALIZING VALUE FROM BIG PHARMA NEW VENTURE SPIN-OUTS

Increasingly, Big Pharma is seeking to realize the latent value of its intellectual property (IP). Major pharmaceutical companies develop dozens of drug candidates for each product that they can fully fund through the clinical trial process. Thus, many potentially viable products have been — or are in jeopardy of being — “put on the shelf.” These potential products often do not promise a sufficient upside to garner high priority in the Big Pharma research and development (R&D) pipeline, or they may simply lie outside a company’s core competency or strategic focus. One way to realize value for such a product is simply to sell it to another pharmaceutical or biotechnology company that focuses on that therapeutic area. However, any obvious candidate to acquire the patented product may be willing to pay only for a product farther down the FDA investigational pipeline, or it may be working on a competing methodology and favor its “in-house” approach without objectively analyzing which approach is better. One alternative way to realize value from these assets is through a new venture spin-out.

While Big Pharma will likely not spin out its blockbuster drug candidates, profitable businesses can be built with smaller- or niche-market biotechnology, pharmaceutical, diagnostic or device products. Generally, a spin-out involves

the transfer of IP by the Big Pharma “parent” company to a newly created company (Newco) in exchange for equity in Newco. While it is hoped that the parent will receive a return on Newco equity, often the measure of success for Big Pharma in a new venture spin-out is simply to have the product development work completed and the product turned into a revenue generator for its sales force.

Experienced venture capitalists do not view a new venture spin-out as a cast-off, but rather as a tremendous opportunity to take advantage of the Big Pharma R&D system. Newco can be capitalized with private equity and other venture financing and continue the development of a technology, free of the resource allocation, planning decisions and other constraints of the parent. Newco can focus on and nurture its product and often license in or otherwise acquire synergistic IP from other Big Pharma companies or other sources. Newco can also use stock options, higher-level titles and greater entrepreneurial spirit to lure new talent to the enterprise.

Some of the key issues in structuring a new venture spin-out are:

Structuring IP Transfer

In order for Newco to be fundable, it must have the complete right to use the transferred IP for its intended field of use, subject to termination only under very

limited conditions. Whether the IP transfer is structured as an assignment or a license, defining the terms of the technology transfer from the parent to Newco involves a delicate process in which the parent company often negotiates with itself. An internal executive or one recruited from outside the company must be designated to represent the interests of Newco. At this stage, experienced venture capital counsel should be engaged on behalf of Newco to provide a “reality check” on the one-party spin-out negotiation process. Issues to focus on include:

- IP to be transferred,
- Scope of Newco’s exclusive field of use,
- Rights to the technology outside the exclusive field of use,
- Rights to improvements made by each of Newco and the parent, and
- “Strings attached,” such as any right of the parent to market or co-market products developed from the transferred IP.

Often, it is the “strings attached” that make or break Newco’s ability to be funded by a venture capitalist.

Valuation

Newco’s pre-investment valuation is a key component in the venture capital investment decision-making process. Factors in this valuation include:

- Market value of companies at a similar stage of development,
- R&D expense attributable to the technology,
- Value of the technology if sold to a third party,
- Negotiations with potential investors, and

continued on page 4

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Morgan Lewis’ Life Sciences Practice is one of the largest in the nation, with approximately 200 lawyers whose practice and experience are significantly devoted to the life sciences industry. Additionally, we have more than 200 professionals with life sciences scientific degrees, nearly a third of whom have advanced degrees. For more than two decades, we have developed our practice to “protect the complete life sciences product life cycle,” with depth and quality in all important areas: regulatory, transactional and litigation. For more information regarding Morgan Lewis’ Life Sciences Practice, please contact the group’s Chair, Stephen Paul Mahinka, at 202.739.5205 or smahinka@morganlewis.com.

SUPPLY ISSUES IN ACQUIRING A PHARMACEUTICAL PRODUCT

When a buyer acquires a marketed pharmaceutical product from a seller, most transactions require that the parties enter into both a product acquisition agreement and a long-term supply agreement. The need for a supply agreement is common since most buyers are not in a position to manufacture, or have a third party manufacture, the purchased product following the acquisition, particularly when the product is a prescription drug or a biological product.

While a significant amount of time and energy is devoted to negotiating the acquisition agreement, and rightfully so, less time often is devoted to negotiating the supply agreement and conducting adequate due diligence on the supply chain. This is true even though, assuming that no misrepresentations have been made in the acquisition agreement, most of the operative provisions in the acquisition agreement have no bearing after closing, and there are few provisions that govern the ongoing activities between the buyer and seller.

A supply agreement, on the other hand, continues to govern the ongoing relationship between the buyer and seller for the term of the supply agreement (which may last more than five years) and addresses many operational issues that are likely to have a significant economic impact on the buyer. The supply chain is critical to the buyer's profitability (e.g., the supply price will govern the buyer's margins in connection with the product acquisition), and from a diligence standpoint (e.g., if there are supply disruptions, there is no product and no revenue).

Some of the key diligence and legal issues that need to be addressed in connection with the negotiation of a supply agreement are:

Supply Chain; Remedy for Supply Failures

It is crucial to review the entire supply chain (e.g., the active pharmaceutical ingredient, the formulation work, and the suppliers of excipients and components) to ensure that there are no material threats to the continuous supply of the finished pharmaceutical or biologic. The situation is simplified if the seller controls the entire

manufacturing process since there are fewer parties involved.

Even in a situation where the seller controls the entire manufacturing process, the buyer should confirm that the seller has a written contract with each vendor that is part of the supply chain and that the term of each agreement is similar in duration to the term of the buyer's supply agreement with the seller. If not, the buyer needs to assess the likelihood that the seller can extend the term of such agreement or find alternate suppliers for any affected components.

To the extent alternate suppliers must be used, the buyer needs to determine what, if any, regulatory clearances or approvals are required to permit such alternate suppliers to become part of the supply chain, including whether any clinical or other types of studies are required. If regulatory clearances or additional clinical studies are required, the buyer must assess the likelihood of obtaining such clearances and/or the delays associated with them. Obviously, any disruption in the supply of finished products can have a catastrophic effect on relationships with wholesalers, clinicians and patient groups, as well as on the future sales of the product.

The importance of performing diligence on the supply chain cannot be overemphasized since the available remedies for a prolonged supply failure will be limited. Except under certain circumstances (e.g., when a buyer uncovers certain supply chain risks during due diligence), a seller will not be willing to accept unlimited damages (which could potentially exceed the purchase price paid for the pharmaceutical product) in the event of a prolonged or permanent supply failure.

As an alternative to a seller's accepting unlimited responsibility for supply failures, the parties may negotiate to qualify secondary or tertiary suppliers in order to minimize the risk of a supply failure. The costs associated with qualifying alternate

suppliers could be substantial (because of higher up-front costs as well as higher supply costs resulting from minimum purchasing requirements for such secondary and tertiary suppliers), and significant discussions usually ensue as to who will bear such costs. Another way to minimize supply interruptions is to maintain minimum stocks of finished products or stockpile components of the supply chain that carry the greatest risk of supply failure, recognizing the limitations imposed on such a strategy by expiration dates.

Product Liability; Recalls

The manufacturer will generally bear responsibility for the risks and assume the liabilities associated with product liability or product recalls if they result from the product's failure to meet applicable specifications. Conversely, the buyer will generally bear responsibility for the risks and assume the liabilities resulting from commercialization activities (such as off-label or other marketing claims). Less time, however, is spent considering and allocating risk between buyer and seller resulting from "no fault" claims. These issues have become more prominent since the Vioxx® and Bextra® product market withdrawals.

Licensing and Technology Transfer Issues

When a product acquisition involves the seller's continuing to manufacture the product, the seller will generally license to the buyer the know-how, patent rights and other intellectual property necessary to manufacture the product. The buyer should consider whether the license to manufacture should be exclusive, with respect to both the product and the active pharmaceutical ingredient (other than the seller's retaining certain rights to manufacture solely for the buyer), if the active pharmaceutical ingredient also is manufactured by the seller, or whether the license rights should be nonexclusive so that the seller may manufacture the active pharmaceutical

Less time is often devoted to negotiating the supply agreement and conducting adequate due diligence on the supply chain.

continued on page 4

SUPPLY ISSUES IN ACQUIRING A PHARMACEUTICAL PRODUCT

continued from page 3

ingredient for itself or other third parties for potential use in other products.

The buyer should also consider whether the license rights are broad enough to cover not only the marketed product, but also any improvements or modifications to the product. If the manufacturing license rights are merely tied to the marketed product under its NDA, then, to the extent there are any subsequent improvements or modifications to the product, the buyer may not have the right to manufacture the product with such improvements, which may require filing of a supplemental NDA. The buyer should also ensure that, to the extent the seller makes any changes to the product's specifications or manufacturing processes during the period that the seller is manufacturing the product, the manufacturing licenses include the intellectual property resulting from such changes. The buyer should ensure that when it is ready or otherwise required to take back the manufacturing responsibilities from the seller, it has all the necessary intellectual property rights required to manufacture the product as most recently manufactured by the seller.

For more information, please contact Denis Segota, a partner in the firm's Business and Finance Practice, at 609.919.6622 or dsegota@morganlewis.com.

REALIZING VALUE FROM BIG PHARMA NEW VENTURE SPIN-OUTS

continued from page 2

- Analysis of the expected level of government reimbursements for the proposed product's intended use.

Before the venture capital investment, this value will be represented by the Newco stock issued to the parent company plus a pool of Newco equity (usually 15%-20% post-financing) reserved for Newco's initial management and future employees. The parent should be flexible with valuation and seek the best venture capital partner (rather than the cheapest) for Newco in

order to increase the likelihood of achieving its long-term goals (e.g., realizing value from underutilized IP, bringing new products to market and achieving a return on its equity).

Continuing Relationship

Newco and the parent company are likely to have a continuing relationship. Typically, the parent will have a representative on Newco's board and Newco will draw initial members of its management and scientific teams from the parent. In addition to IP, the parent may contribute hard assets (such as equipment), third-party contracts, infrastruc-

ture services for a transition period (e.g., HR, accounting, regulatory) and even temporary facility sharing. It may be desirable to conduct limited joint R&D if both the parent and Newco are interested in the same improvements for different fields of use. In order to promote a healthy and functional future relationship, care should be taken up front to focus on the respective rights of the parties when it comes time for Newco to seek Big Pharma strategic alliances.

For more information about new venture spin-outs, please join us at BIO 2005 or contact Steven M. Cohen, a partner in the Business and Finance Practice, at 609.919.6604 or scohen@morganlewis.com.

PLEASE JOIN US

BIO 2005 Annual Conference

Wednesday,
June 22, 2005

9:30 AM –
10:45 AM

Panelists on new
venture spin-outs
include:

Ting Pau Oei, who was the point person for Johnson & Johnson's new venture spin-out program, will discuss J&J's approach to alternative means of maximizing value from its R&D efforts. Ting Pau, who is now a partner at L Capital, a life sciences venture capital firm, will also describe why L Capital considers new venture spin-outs from Big Pharma to be an attractive investment opportunity.

Geert Cauwenbergh, CEO of Barrier Therapeutics, one of the most successful recent new venture spin-outs. Prior to the founding of Barrier, Dr. Cauwenbergh was Vice President for Technology Transfer, J&J Consumer and Personal Care Products, and was previously Vice President for Research and Development, J&J Skin Care Center. Barrier began by licensing a group of dermatology products in various phases of clinical development from J&J in May 2002 with funding from blue-chip venture capital firms led by JPMorgan Private Equity and TL Ventures. Barrier successfully completed an IPO in May 2004 and a secondary offering in February 2005, in which J&J was able to begin to realize cash proceeds from its Barrier equity.

Howard Weisman, a founder and President of ESP Pharma. ESP Pharma began operations in May 2002 with the acquisition from Wyeth of four late-stage or marketed cardiovascular drugs, including its flagship product, Cardene I.V., and was funded by blue-chip venture capital firms Domain, Apax and NEA. By the end of 2004, the company had grown revenues to \$90 million, which was helped by the purchase in 2003 of I.V. Busulfex, a specialty oncology drug. In January 2005, Protein Design Labs of Fremont, California announced it had agreed to purchase ESP Pharma. The total purchase price was \$325 million in cash and \$175 million in stock.

applications, registered and unregistered trademarks, trade secrets, confidential information and copyrights owned by the merged or acquired entity, and relevant regulatory clearances or approvals. The definition at a minimum should include all intellectual property necessary to operate the merged or acquired entity's business. From the acquirer's perspective the definition should also include all intellectual property that may be useful to operate the merged or acquired entity's business, while from the seller's perspective, it should include the smallest set of intellectual property necessary to operate the business. Again, the due diligence process is essential to

ensuring that the definition is both accurate and complete.

Representations and Warranties

The representations and warranties should be informed by and reflect all that was learned from intellectual property due diligence. Of the time involved in merger and acquisition transactions, intellectual property attorneys typically devote the most to drafting and negotiating the representations and warranties. The most important representations and warranties related to intellectual property typically include:

- Identification of intellectual property,
- Ownership of intellectual property,

- All patents are valid and enforceable to the merged or acquired entity's knowledge,
- Reasonable measures have been taken by the merged or acquired entity to protect and document trade secrets and confidential information,
- No infringement or misappropriation of third party intellectual property, and
- No infringement or misappropriation by a third-party of the merged or acquired entity's intellectual property.

Common pitfalls related to representations and warranties include:

continued on page 6

EVENTS, SPEECHES & ARTICLES

Morgan Lewis–Sponsored Life Sciences Events

6th Annual Philadelphia-Japan Health Sciences Dialogue

International Expansion Across the Ocean: The Business Case for Doing It Alone Versus Partnering
June 18, 2005, Philadelphia

Biotechnology Industry Organization Annual Conference

June 19–22, 2005, Philadelphia

MedTech Investing Europe

September 15–16, 2005, London

Life Sciences Speeches & Articles

Business and Finance/Securities

New Jersey Technology Council Bootcamp: A Conference for Entrepreneurs

Panel Discussion: Must Haves of Funding
Steven M. Cohen
May 25, 2005, Princeton

New Jersey Technology Council Panel

Partnering with Large Pharma
Randall B. Sunberg
June 8, 2005, Princeton

Biotechnology Industry Organization Annual Conference

Fundamental Business and Legal Strategies for Life Science Ventures
Manya S. Deehr
June 21, 2005, Philadelphia

Realizing Verifiable Economic Value from New Venture Spin-Outs

Steven M. Cohen
June 22, 2005, Philadelphia

FDA/Healthcare Regulation

Obesity and the Bottom Line: Strategies for the Food Industry and Its Advisors

Panel Discussion: The Global Marketplace
Mark Mansour
June 30, 2005, Arlington

Pharmaceuticals/Biotechnology/Medical Devices

The In-House Counsel Forum on Pharmaceutical Antitrust

Defining the "Market" and Its Effect on Antitrust Analysis of Pharmaceutical Company Conduct and Transactions
Scott A. Stempel
May 24, 2005, Washington, D.C.

Pharmaceutical Industry Mergers: Anticipating Antitrust Issues and Surviving the Investigation
Stephen Paul Mahinka*
May 24, 2005, Washington, D.C.

6th Annual Philadelphia-Japan Health Sciences Dialogue

Panel Discussion: Getting Started by Yourself: What Are the Realities?
Stephen Paul Mahinka
June 18, 2005, Philadelphia

*Note: Speaker Change

POTENTIAL INTELLECTUAL PROPERTY PITFALLS *continued from page 5*

- The merged or acquired entity's insistence on including a "materiality" qualifier without defining "materiality."
- The merged or acquired entity's refusal or inability to represent and warrant that it owns the merged or acquired intellectual property without a knowledge qualifier.
- The merged or acquired entity's refusal or inability to represent and warrant that the patents are valid and enforceable.
- The merged or acquired entity's refusal or inability to represent and warrant that it has taken reasonable steps to protect and document trade secrets and confidential information.
- The merged or acquired entity's limiting a knowledge qualifier to the knowledge of a handful of individuals

who may not have any knowledge of ownership, validity, enforceability or infringement of intellectual property rights or products.

Conclusion

Mergers and acquisitions offer many potential rewards for the parties involved. However, if the parties fall into any of the many traps that await the unwary, the value of such transactions can be significantly diminished. In many instances, intellectual property due diligence is the key to safely negotiating around possible pitfalls in life sciences merger and acquisition agreements.

For more information, please contact Louis W. Beardell, a partner in the firm's Patent Practice, at 215.963.5067 or lbeardell@morganlewis.com.

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