

Divesting Biotechnology Programs from a Large Pharma Company to a Biotech Start-Up

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Introduction

For quite some time, pharmaceutical companies have recognized a strong public benefit to out-licensing certain products or programs where there is a need to address public health issues.³ Furthermore, interest in outlicensing or divestiture of research programs to small or start-up pharmaceutical companies has gained considerable momentum in the last three-to-five years. For example, in July 2008, Pfizer Inc. spun out a new venture capital-backed Japanese pharmaceutical company, RaQualia Pharma Inc., an organization which recently had a very successful initial public offering.⁴ Abbott Laboratories has announced that it is spinning off its Humira business to form a new company called AbbVie.⁵

The continuing growth of the pharmaceutical biotechnology business sector has been impressive, especially in light of the recent recession. This growth has been seen in a variety of indicators, such as employment and capital investment. Between 2001 and 2010 employment in the biosciences increased 6.4% nationwide while total employment across all sectors fell 2.9% nationwide.⁶ Particularly impressive has been the growth of the biotechnology industry in key regions of California, Massachusetts, and the Pacific Northwest, each of which has seen significant investment. The Bureau of Labor Statistics projects that between 2010 and 2020, the nation will add 7,700 biochemist and biophysicist jobs, increasing employment in the field by 31%.⁷

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³ M.A. Friedman et al., *Out-licensing: a Practical Approach for Improvement of Access to Medicines in Poor Countries*, *The Lancet*, Vol. 361 (2003) at 341.

⁴ RaQualia Pharma Inc., *RaQualia's History*, Accessible at: <http://www.raqualia.com/investorinfo/faq/history.html> (accessed September 5, 2012).

⁵ *Abbott Selects AbbVie as New Name for Future Research-Based Pharmaceutical Company*, Abbott Press Release, March 2, 2012.

⁶ BIO, *State Bioscience Industry Development (2012)* at 5. Accessible at: <http://www.bio.org/articles/battellebio-state-bioscience-industry-development> (accessed 8/18/2012).

⁷ Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook, 2012-13 Edition*, Biochemists and Biophysicists. Accessible at <http://www.bls.gov/ooh/life-physical-and-social-science/biochemists-and-biophysicists.htm> (accessed September 5, 2012).

Overall in 2011 companies in North America and Europe with revenues smaller than \$500 million received about \$16.8 billion of capital investment, a figure that has been largely constant since 2008 despite the recession.⁸

At the same time, larger pharmaceutical companies are facing increasingly tighter research budgets, forcing difficult decisions on which early drug discovery programs are to be funded and which programs are to be terminated.⁹ Many companies must determine whether to continue or terminate research programs for reasons of market size or portfolio fit, while the programs might otherwise be very viable. One solution is to try to capture value from the asset by divest it to another company within which the asset would better fit.

Frequently the divestiture is to a small biotech start-up company (a “NewCo”) which is more suitably focused for the market and patient population into which the asset would fit. Such a divestiture places with the NewCo the costs and obligations of the asset development process with a potentially risk-tolerant, high-payoff organization which can be designed specifically around the asset, and may afford the divesting company a later opportunity to re-acquire the asset after the program has met with further clinical success.

This paper examines some of the needs and issues in the process by which the larger pharmaceutical company divests a clinical drug program to a small or start-up NewCo, and how those needs and issues might be addressed.

Outlicense or Assign?

The vehicle by which the divestiture occurs should be tailored to fit the needs of both organizations. But it must be noted that the capabilities of a small NewCo are different from those of a larger entity, and the divesting company will view each of these potential partners in a very different light.

For example, when a large pharmaceutical entity is the receiving party in a transaction (in other words, they are acquiring the asset), it is expected that they will have the wherewithal to develop manufacturing and formulation technology (either internally or through a well-used contract research organization), manage a patent estate, manage clinical trials, make appropriate regulatory submissions, and market the product. But a small biotech NewCo will have few of these resources. They may seek to contract out many development and manufacturing steps and are unlikely to have the skills or organization to market the product. Indeed, a preferred end-point for a small NewCo is to be acquired after Phase 2b or Phase 3 clinical trials by a larger entity which does have such resources. Therefore the divesting company must assure that the vehicle for divestiture is appropriate for these different capabilities and goals.

⁸ Ernest and Young, *Beyond Borders: Global Biotechnology Report 2012* at 40. Accessible at: <http://www.ey.com/GL/en/Industries/Life-Sciences/Beyond-borders--global-biotechnology-report-2012> (accessed August 18, 2012).

⁹ Agres, T., *Pipelines Under Pressure Take New Paths*, *Drug Discovery & Development*, Vol. 14, No. 9, May 15, 2012. Accessible at: <http://www.dddmag.com/articles/2012/05/pipelines-under-pressure-take-new-paths> (accessed August 18, 2012).

The assets are likely to be protected by one or more patents and possibly by trade secret protections afforded by state law.¹⁰ A threshold question is whether the divestiture is to be achieved by a license or by an assignment (or by a combination thereof) of the intellectual property.

A patent license is the grant, from one party to another, of permission to employ one or more sticks in the bundle of rights that come with a patent. Rather than providing affirmative rights to a patent holder, the United States Government actually grants a sort of negative right: the right to exclude or prevent other parties from making, using, selling, offering for sale and/or importing the subject invention.¹¹ Thus a patent license is exclusive or non-exclusive permission from the patent holder (i.e., the licensor) to the licensee of one or more of these rights *vis a vis* the subject patent. Licenses can last for specified periods of time, after which they expire. Also, licenses can terminate upon the occurrence of certain events such as uncured material breach of a material term of the license agreement.

In contrast, a patent assignment is the transfer (whether by sale or gift) from the assignor to the assignee of the entire ownership interest in a patent or a patent estate. While assignment agreements may have a reversion clause which can be triggered by certain events, an assignment is often viewed as a permanent transfer of all the sticks in the bundle of rights. The concept of reversion is discussed in greater depth below.

A patent license and a patent assignment each has complementary advantages and disadvantages. Some of these complementary properties may be better suited to divestiture of a pharmaceutical asset to a small NewCo as opposed to a large receiving party. For example, because ownership is not formally transferred in a patent license, it is easier than in the case of an assignment for a licensor to regain control of a subject patent estate in the event of failure of the NewCo to follow the terms of the agreement or to be diligent in its development efforts.

Furthermore, a license agreement can retain control of the patent estate by the licensor or can require that the licensee obtain consent of the licensor before taking certain actions which affect the patent estate. This restriction would make it more difficult (as compared with assignment) for a licensee to game the royalty structure by purposely abandoning patents in some territories. Also, a remedy for failure to pay royalties could be loss of the license; this is a remedy out of reach of the licensor if the patents are assigned. Therefore, a license agreement is quite appropriate if the goal of the transaction is to establish a running royalty stream.

A patent assignment agreement allows the assignor to get the subject patent estate entirely off of its books and dockets, thus greatly simplifying the assignor's operations relative to the situation with a license agreement. An additional plus for patent assignment is that there is significantly reduced liability of the assignor for on-going patent prosecution and maintenance issues. In the case of a patent license agreement, if the licensor (as owner of the patent) takes an

¹⁰ Another intellectual property right that can be important to a product is product trademark. However, it is most often too early to be overly concerned about trademark selection for the drug product when the pharmaceutical is still in Phase 2 clinical trials.

¹¹ 35 U.S.C. §271.

action or fails to take an action which results in the loss of a patent, it could mean loss or limitation of market exclusivity for a product and could cause considerable liability for the licensor.

Often for patent assignment agreements, up-front payments (i.e., payments owed to the assignor upon execution of the agreement) are much larger than for license agreements and royalties are much smaller or non-existent.¹² This is because the divesting party has essentially no control of the patent estate after assignment and royalties are usually dependent upon the existence of valid patent claims. Therefore, the divesting party will prefer to take the bulk of its consideration up-front rather than accepting later-term risks which are out of its control.

The choice of whether to license or assign a patent estate can be based on the size and resources of the acquiring company. A large acquiring pharmaceutical company may have adequate resources to provide a large up-front payment while a smaller NewCo will prefer to preserve its cash for product development. In addition, a larger pharmaceutical company may prefer to have complete control over the subject patent estate. Sometimes a cash-strapped NewCo may have a risk of bankruptcy. In this situation, it is easier for the divesting company to regain control of a licensed asset than an assigned asset.¹³ For all of these reasons, it is often logical to use a patent license agreement when divesting a program to the small NewCo and to use an assignment agreement when divesting to the larger pharmaceutical company.

What to Look For in a Small NewCo Partner

When a larger divesting party is considering a small NewCo as a partner in a divestiture, that NewCo may not have actually been incorporated as of the time discussions begin. A threshold question is: Who is the licensee? Formally, the licensee may be a NewCo, which may not even exist as of the time of the due diligence. But at the nucleus of the nascent NewCo will usually be a lead scientist (who may become CEO or CSO), a business lead, transactions or mergers & acquisitions attorney, and a syndicate of venture capitalists. The divesting company needs to perform its own due diligence on each of these persons prior to deciding whether to begin negotiations.

Part of the divesting company's due diligence is to determine whether the NewCo and its principals have the financial wherewithal to progress the asset through a desired stage of development. The divesting company will need to request and review documentation such as financial statements, equity documents, debt documents, and the corporate charter. Again, this is in contrast to the situation in which the acquiring company is a large pharmaceutical company for which much of the required information is part of the public record.

Another key piece is the reputation of the principals. It is helpful if the NewCo's principals are well-known in their respective fields and have a track record of involvement with successful start-ups. It is critical that no person or entity involved with the NewCo has been

¹² See, Mendes, Philip, *To License a Patent- or, to Assign It: Factors Influencing the Choice*, World Intellectual Property Organization. Accessible at http://www.wipo.int/sme/en/documents/license_assign_patent.htm

¹³ For example, a licensing agreement may include a clause which terminates the license in the event of bankruptcy or insolvency of the NewCo.

debarred by the FDA from the development or approval of drug products can be allowed to participate in the NewCo.¹⁴ Most importantly, the divesting company needs to assure itself that the principals of the NewCo understand and embrace principles of business and medical ethics and patient safety.

As part of selecting the optimum small NewCo partner, the large divesting company needs to perform a collation of internal knowledge about the NewCo and its principals. Particularly, the divesting company needs to determine if its internal functional areas (e.g., general litigation, patent litigation, R&D leadership, privacy, global security, patents and trademarks) are aware of any issues with the individuals or entities.

The CEO and CSO of NewCo must have adequate business acumen and experience to operate the company and the CSO must have scientific experience and management skills suitable for the particular project. This includes a detailed understanding of the drug development and drug approval processes. Usually the Licensor will require the startup principals to make a confidential presentation of their capabilities and their development plans for the asset.

Life of the Asset

The asset is not getting younger as due diligence and negotiations progress. In the United States as well as in most foreign jurisdictions, the term of a patent claim expires 20 years from the filing date of the earliest non-provisional patent application. In the US, the Uruguay Round Agreements Act (Public Law 103-465) became effective on June 8, 1995. Before June 8, 1995, US patents typically had a patent life of 17 years from the date the patent was issued. However, for US patents granted after this date, the term is 20 years from the date of the first filing of the non-provisional patent application.¹⁵

Subsequent to the enactment of the Uruguay Round Agreements Act, the United States Congress enacted the Patent Term Guarantee Act of 1999, a portion of the American Inventors Protection Act (Public Law 106-113). The Patent Term Guarantee Act affected the patent term duration of a US patent by adding day-for-day credits or adjustments to the 20 year term. Since this time, the US patent office is required to make a Patent Term Adjustment (“PTA”) determination for each and every allowed patent application.¹⁶ The PTA is calculated by the patent office via a computer program, and is then provided on the notice of allowance. Once this determination is made, the applicant has a single opportunity to file a request for reconsideration

¹⁴ 21 U.S.C. §§ 335(a) and (b).

¹⁵ Provisional patent application filings are available in the United States. The provisional patent application provides a means to establish an early filing date and priority rights in and to an invention without the need for a formal specification or claims. The later filed non-provisional patent application can establish priority rights in the invention based on the provisional application filing. When this type of filing is made, the patent term is in essence 21 years from the provisional application filing date (the priority date).

¹⁶ The rules controlling PTA are codified at 35 U.S.C. § 154 and 37 C.F.R. §§ 702-705.

of the PTA. Such a request must be filed no later than at the time of the issue fee payment.¹⁷ Alternatively, the PTA determination by the USPTO can be contested by the patent owner judicially up to 180 days after the patent issues. The PTA is derived from specific dilatory application examination or processing events by the USPTO (such as secrecy orders), events caused by the applicant (such as requests for extension of time, etc...) and/or patent application pendency when it is greater than three years.

Patent term restorations are also available for drug products where market term was lost because of the duration of the FDA approval process. To compensate patentees for certain regulatory delays associated with the FDA's approval of drug product, since 1984, a patent term extension ("PTE") are available based on the time consumed by the FDA during regulatory review. While PTA and PTE both serve to extend patent term, the PTE applies only to delays that occur at the FDA.

Furthermore, notwithstanding these opportunities to reclaim patent term, the effective patent term is frequently much less than 20 years because a patent is often granted before market launch. For example, while the maximum term adjustment provided by the PTE is 5 years, the total patent life for a product granted a patent term extension cannot exceed 14 years from the product's approval date. Similarly, for PTA determinations, the total duration of all adjustments to the patent term shall not exceed five years.¹⁸ So, the timing of when a patent application is filed is critical to maximizing the amount of patent term available. However, licensed-in or assigned patent applications often issue before the market launch of a product. If the patent application has been filed, or has already issued into a patent when licensed or assigned, the life of this asset is already limited.

Steps Leading to Negotiations

The process by which a divesting company seeks a divestiture partner usually begins with distribution of a non-confidential disclosure describing the asset. This disclosure usually contains published or otherwise non-confidential information about the asset, such as therapeutic target, therapeutic indication, clinical stage, and the like. Usually the disclosure will not disclose the chemical structure or sequence, or details of the clinical results, pharmacokinetics, pharmacodynamics or business plans.

Once potentially interested parties are identified, each will be asked to execute a confidentiality agreement which will allow deeper disclosures and, possibly, access to the data room (see below).¹⁹ At this stage, some principals are reluctant to sign a CDA, or at least reluctant to sign one which has confidentiality and non-use obligations of greater than one to two years in duration. Often such principals feel that longer obligations place a significant constraint

¹⁷ An applicant may also file a request for reconsideration of PTA no later than two months from the issue date of the patent. However, this second request can only be used to correct an error related to the issue date estimate.

¹⁸ 35 U.S.C § 154.

¹⁹ Holmes, Mark S., *Patent Licensing: Strategy, Negotiation, Forms*, PLIPress, New York (2001) at 13-1.

on their ability to seek collaborations with other parties on similar subjects. The perspective of the larger divesting company, however, is that it would be disastrous for the obligations to be weakened by an unacceptably short confidentiality term, and thereby damage the value of the asset. This often becomes the main issue of disagreement in the negotiation of the confidentiality agreement, and another point distinguishing the case of a small entity acquirer compared with a large entity acquirer. The large entity acquirer will usually and readily accept a longer term of confidentiality and non-use, in the range of five years or more.

Eventually the divesting company and a group of acquiring principals may become sufficiently comfortable with each other that they decide to progress into full due diligence. This will require the divesting company to assemble a data room. The data room may be an actual physical room or, more likely today, a secure electronic room to which scanned copies of the relevant documents are uploaded. Included in the data room will be the key and confidential information relevant to making the decisions about an acquisition or in-license of the program: marketing information, sales information, supplier agreements, product characterization, clinical study reports, manufacturing processes, PK reports, PD reports, the investigational new drug application (the "IND"), toxicology studies, communications with FDA, the investigators' brochure, relevant agreements (including assignments, license agreements, distribution agreements, option agreements and service agreements), and other legal information such as patent application files (e.g., file histories), and if any of the patents or patent applications have been subject to ex parte or inter parte proceedings, copies of such papers. Likewise, any disputes, actual or potential, regarding inventorship, ownership, or in-licensing of related technology used to make, use or sell the product, should be identified by the divesting company. Also, information as to whether the divesting company has received any third-party infringement charge or allegation should be requested and obtained by the buyer.

At this point, complete description of the product(s) including both the active component(s) and proposed or final formulation should be made available. Clinical study protocols, adverse event reports, and post marketing surveillance records, if applicable, should be available and reviewed. If the product is already on the market or about to go to market, a description of the facility or facilities in which the product(s) will be manufactured, finished, packaged and stored and a list of the licenses and permits issued for such facilities should be made available. Also, if available, copies of FDA and other inspection reports should be reviewed for at least the past three years. Other items of importance include quality control protocols and quality control specification for release of product. Further, one should check whether the product already on the market has been subject to recall and if so, a description of the circumstances and resolution be examined. Any notices, allegations, claims, demands or lawsuits alleging wrongful death or personal injury from use of the products should be identified and made available.

Typically, the principals of the NewCo access the data room on-line, allowing for access tracking and limited ability to download documents. This is less secure than the old days in which data rooms were real rather than virtual. Yet the on-line data rooms are hugely more convenient because they do not require cross-country travel of a large group of people, and they provide clear evidence of what documents were accessed and by whom.

The success of a life science company depends not only on continued innovation and business discernment, but on the strength of its intellectual property portfolio. Any party acquiring interest in intellectual property rights should carry out a due diligence investigation to ensure that the technology underlying the transaction has its purported value and the products and/or services adequately protected. For intellectual property rights covering pharmaceutical products and other biotechnology related devices, this is particularly critical as these rights can have a direct and significant effect on predicted cash flow, product development and income.

A due diligence investigation first includes a review of patent claims and/or claims pending in patent applications. The scope and breath of a patent claim is a function a claim language, the written description (patent specification) and the prior art. Even when literal language of the claim seems broad, if the disclosure is minimal, the claims will be construed narrowly by a court of competent jurisdiction. Further, protections afforded by the patent claim can be narrowed by changes made to the claims during patent prosecution and by arguments advanced by the applicant. For example, during prosecution, if the claim was limited because of the teaching of a prior art reference uncovered and cited, then the later patentee will be precluded from capturing back subject matter ceded by way of amendment. Also, an applicant can be subsequently precluded from taking a position inconsistent with the position it took to get the claim allowed.

If patent claims can be narrowly construed, it might be easy for competitors to create a design around product and then entered the market while avoiding infringement of the patent. An investor must understand whether the patent claims are broad enough to cover the commercial product and to keep competitors out of the market. This type of assessment often requires input from technical persons with substantial knowledge in the field.

Because of these considerations, the acquiring entity may request from the seller during the diligence investigation whether the divesting company has obtained any patentability, validity, infringement or non-infringement opinions. The seller will usually decline to produce those opinions, even if an opinion exists. Production of such opinions risks a waiver of the attorney-client privilege associated with the opinion. In some circumstances, it may be possible to engage in a common interest agreement to allow the sharing of legal opinions without waiving privilege. However, interpretation of such agreements varies widely among jurisdictions and depends on the facts involved. Moreover, if the common interest agreement has any effect at all, it may inadvertently create a new and unintended attorney-client relationship between the divesting company's attorney and the acquiring company. Hence, common interest agreements should be avoided.

The due diligence investigation involves an assessment of both the benefits and risks of the transaction, especially the risks that may undermine the value of the technology. As noted above, patents make up the predominant form of intellectual property rights in the life science industry. Hence, the due diligence inquiry must ascertain who owns the technology. Assignments, licenses or any other agreements, currently in force, or once in force but now terminated or otherwise have expired, that concerns the patents and patent applications covering the product(s) should be made available and reviewed. Indeed, common problem issues arising in the transfer of patent rights are associated with inventor assignments. Therefore, these issues should be carefully considered in reviewing assignments. For example, when multiple inventors

are named in a patent application, one or more assignments may be executed. If one of the inventors has not assigned his or her rights in the claimed invention, he or she may be considered a joint owner and could grant a separate license without the company's consent. Moreover, the chain of title in and to the patents and/or patent applications should not have a gap.

The strength of the IP portfolio should be examined when entering a market defined by established or pending IP assets. The general inquiry is whether the rights to be transferred to the buyer can withstand a challenge. One or more basis can be applied to challenge a patent claim including lack of novelty, obviousness, lack of enablement, or insufficient written description. As noted above, when examining the patent claims (or the pending patent claims of a patent application if the application has not issued), these and certain other issues should be considered in light of the scope of the claim(s), the patent specification and the prior art cited or otherwise known.

Furthermore, in the life science industry, licensing strategies can maximize income and leverage competitive market penetration. However, the licensee must have satisfied the terms of the agreement and provided sufficient rights in the technology. For example, if technology has been in-licensed for freedom to operate or other reasons, a key inquiry is whether the conditions of any agreements have been satisfied. If certain terms are not satisfied, an otherwise valid license could be limited or even terminated. Also, license agreements previously made by the divesting company must be reviewed to determine whether the rights can be transferred. Therefore, careful review of the terms of the license agreement must be made to ensure that the licensee has the ability to transfer the rights to the buyer. Furthermore, the technology licensee must provide sufficient rights in and to the product technology so that the owner can generate second and third generation product(s). Here, the inquiry is whether the agreement provides all rights in and to improvements to the licensor or the licensee. Finally, careful considerations should be made to the scope of any licensee as a license in and to patent rights can be restricted to a specified field of use, geographic territory or other similar terms.

Due diligence does not end, however, when it is established that the company owns the patents and patent applications covering the products. Risks of infringement of the rights of a third party should be evaluated to avoid being sued as soon as the technology is commercialized. To evaluate this risk, a freedom to operate search and review can be performed. This review serves to confirm the lack of unlicensed third party rights which may exist that might hinder or prevent making, using or selling the product. These assessments can vary in the depth of review. However, the product or methods that the life sciences company plans to commercialize must be clear and free of another's rights. The freedom to operate search and review aids in minimizing the risk of launching an infringing product.

Moreover, if third party patent rights are uncovered that appear to affect product commercialization, the next inquiry can be whether those claims are valid. Often patent claims are invalid or unenforceable due to the existence of prior art not before the examiner during prosecution of the patent application. Now, under the American Invents Act ("AIA"), several new US patent office post grant proceedings have been established to challenge the validity of issued patent claims and changes to existing proceedings have been introduced.²⁰ These

²⁰ Public Law 112-29 enacted September 16, 2012

proceedings are designed at least in part in an effort to reduce the number of invalidity challenges brought in the Federal Courts. Therefore, if relevant third party patent rights are uncovered in the freedom to operate search, a prior art search can be conducted directed to the validity of those third party patent claims to further assess the impact these rights have on freedom to operate. Alternatively, an inquiry can be made to the third party as to whether the rights are available for licensing.

Selection of a Negotiation Partner and the Term Sheet

Preliminary non-binding term sheets may be requested of bidders if divesting company has not narrowed the field to a single bidder. These preliminary term sheets will be evaluated by the divesting company as part of the equation for partner selection. As guidance in the preparation of the preliminary term sheet, the divesting company may provide the bidders with some thoughts on what the minimum expectations are with respect to finances and development.

Based upon the non-binding term sheets, the divesting company may narrow the field to one to two bidders and begin drafting a more detailed term sheet. Typically the term sheet will include a disclaimer or “Yogi Clause”²¹ such as:

This Term Sheet is prepared and exchanged for discussion purposes only and does not constitute or reflect an offer, acceptance or an agreement of any kind. Neither this Term Sheet nor any related discussions shall create any obligation or right for either Party; such rights and obligations shall only arise out of written, definitive agreements that are mutually negotiated, executed and delivered by both Parties. This Term Sheet does not purport to contain or address all of the elements of a potential transaction, which would remain subject to various conditions, including management approval of each Party. Each Party may withdraw from and terminate discussions at any time.

The Yogi Clause helps to remind the parties that negotiations are preliminary and non-binding and that either party may be in negotiations with other parties.

The term sheet is perhaps most conveniently prepared in tabular form. A typical form of term sheet for a license agreement negotiation is reproduced in Table 1 provided immediately below.

²¹ “It ain’t over ‘till it’s over.” -- Lawrence Peter Berra, 1973.

Table 1
Example Term Sheet

SCOPE	Worldwide research, development, manufacture and commercialization of Licensed Products in the Licensed Field.
IP	All scheduled US and non-US patents and patent applications owned or controlled by Company or licensed to Company as of the Effective Date or acquired during the Term of this Agreement relating solely to the Asset, including any addition, continuation, continuation-in-part or division thereof or any substitute application thereof; any patent issued with respect to such patent application, any reissue, extension or patent term extension of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent (altogether, the “IP”)
LICENSED FIELD	All therapeutic, prophylactic and diagnostic uses of the Asset in humans and animals.
TERRITORY	Every country in the world.
LICENSE GRANT	Company will grant to NewCo an exclusive (even as to Company) license, with the right to sublicense, under the IP for all purposes in the Licensed Field to make, use, sell, offer for sale, import and export Licensed Products in the Territory.
LICENSED PRODUCTS	Any and all pharmaceutical, diagnostic or veterinary products that contain the Asset.
PATENT PROSECUTION	NewCo will take responsibility for prosecution and maintenance worldwide of the IP and will pay for all costs of such prosecution and maintenance .
TRANSFER OF INFORMATION AND DOCUMENTS	A schedule of the documents and information to be transferred from Company to NewCo will be appended to the Agreement.
DEVELOPMENT	NewCo will become solely responsible for funding and conducting all development activities for the Licensed Products for the Licensed Field in the Territory as of the Effective Date of the License Agreement.
MANUFACTURING	NewCo shall have the sole right to manufacture, or have manufactured, Licensed Products, and it shall be entitled to use, and to sublicense rights to the manufacturing aspects of the IP for such purposes.
MARKETING AND PROMOTION	NewCo will be responsible for marketing and promotion of Licensed Products in the Territory.
REGULATORY	NewCo will be responsible for all regulatory activities concerning Licensed Products in the Territory, including filings to conduct clinical trials and for marketing approval. NewCo will hold all marketing authorizations in the Territory.

LICENSE FEE AND MILESTONES	
<i>Upfront</i>	Promptly upon execution of the License Agreement, NewCo shall pay Company an up-front license fee of [insert sum] .
<i>Equity</i>	[Insert proposed equity terms, if applicable]
<i>Clinical Milestone</i>	[Insert one or more clinical milestone payments, if applicable]
<i>US Launch</i>	NewCo will pay to Company [insert sum] US dollars upon [receiving regulatory approval or upon first commercial sale, as appropriate] of the first Licensed Product in the United States.
<i>EU Launch</i>	NewCo will pay to Company [insert sum] US dollars upon [receiving regulatory approval or upon first commercial sale, as appropriate] of the first Licensed Product in the any European Union country.
<i>Japan Launch</i>	NewCo will pay to Company [insert sum] US dollars upon [receiving regulatory approval or upon first commercial sale, as appropriate] of the first Licensed Product in Japan.
ROYALTIES	NewCo will pay Company a fixed royalty rate of [insert number] percent of the Net Sales of Licensed Products, subject to any applicable reductions. [Note: the parties may elect tiered royalties, tied to the total Net Sales in a given year.]
TERM:	The term of the License Agreement shall expire on a country-by-country basis upon expiration of the Royalty Term in each country.

The Agreement

There is a difference in the type of consideration to be expected when the acquiring company is a large entity compared with a small NewCo.

As discussed above, the large entity would typically be expected to have more cash on hand than would a NewCo, so consideration from a NewCo would likely be back-ended, or more tied to equity in the NewCo. The term “back-ended” refers to the trade-off between a smaller up-front payment and larger royalties and late-term milestone payments that might be expected from a NewCo versus a larger up-front payment that might be expected from a large entity.

Often if the asset comprises a significant piece (or all) of the NewCo’s product portfolio, the divesting company will take equity in the NewCo, frequently as preferred B stock or common stock , although occasionally as preferred A stock. Usually the other investors will push for the divesting company’s equity interest to be subordinate to theirs. But granting an equity position instead of making an up-front cash payment often helps the cash-strapped

NewCo deliver the feel of up-front value to the divesting company while retaining cash for operating expenses.

Other considerations in divesting to a small NewCo include:

Claw-back rights: A claw-back is a way for the divesting company to re-acquire a product under terms which are amenable to all of the parties. A claw-back can often take the form of an option to license, but may be as mild as a right of first negotiation. A claw-back is difficult for many NewCos to accept, however, because it limits the exit strategies for the cash investors.

Reversion. This is different from a claw-back. If the NewCo fails to show diligence, for example, the asset might revert to the divesting company. A reversion is easier for a NewCo to accept than for a large-pharma licensee, but still can be a point of contention during negotiations. Nonetheless, it is very important for the divesting company to seek this right.

Diligence. The divesting company must require that the NewCo show some reasonable level of diligence in the development and commercialization of a product, otherwise the milestones and royalties are meaningless. In many ways, this is the flip-side of back-end loading of the consideration for a program. For the back-end loading to have value to the divesting company, there must be significant incentive for the NewCo to carry the project forward. One standard of diligence to consider is that of “Commercially Reasonable Efforts”, under which a party is obligated to use those reasonable, good faith efforts and resources that a pharmaceutical company of similar size and means to the NewCo would use when developing or commercializing its own products that are of similar stage and market potential as the acquired asset.

Technology Transfer

Once the agreement is executed, there must be a transfer of the subject technology from the divesting company to NewCo. Some level of detail about this transfer should be addressed in the agreement. Depending on the clinical stage of the asset, the items for transfer may include product (GLP or non-GLP), the IND, other regulatory documents (e.g., applications, registrations, licenses, authorizations, approvals and correspondence), pharmaceutical sciences reports and procedures, toxicology reports, laboratory notebooks, patent files, third party agreements, clinical protocols, study reports, adverse event reports, and clinical study raw data. This list is non-exhaustive and will vary significantly depending on the asset program.

Whether the receiving party is a large entity or a small NewCo influences the timeline of the transfer and the precautions which must be taken. A large entity will be expected to have regulatory, archival, business compliance and pharmaceutical sciences resources in place to handle receipt of these materials. This is not necessarily true for a small NewCo, and the extent to which the NewCo can receive and handle the technology transfer must be judged before the agreement is executed.

Transfer of intellectual property rights is carried out by assignment. For patent rights, the assignment would list each and every patent and patent application assigned. Once the

assignment has been executed, the assignment should be recorded in the US patent office against each US and PCT application and US patent transferred.

Furthermore, as part of the purchase agreement and upon its execution, the assignee could seek to obtain the attorney files of the seller's attorney who has handled the patent prosecution. It is generally understood that an attorney file belongs to its client. So the prosecuting attorney who has worked for the seller must turn of his or her files to the new owner if requested by the divesting company. Yet, there are at least two issues arise with this request. First, what contents of the file are to be transferred? Second, what happens to the attorney client privilege associated with the privileged documents contained with the attorney's file that are transferred to the buyer?

Certain states take the position that except for client-owned property, the entire file belongs to the lawyer. Sometimes this is referred to as the "end product" or "work product" model of file ownership.²² Here, the inquiry then becomes whether the attorney notes or other documents "are related to and necessary for the client to continue his or her representation."²³ For example, administrative notes such as conflict checks or assignments of projects by a partner would not be considered as documents that would be presented to a client or its new counsel. On the other hand, notes related to legal theories and strategies might be considered part of the attorney file if necessary to continue representation on the matter. Conversely, some states such as Texas, in their desire to guard and protect the client, have adopted the entire file rule. If this is the applicable law, all of the documents in a file belong to the client. If the NewCo desires the attorney's files, it is best to understand the applicable state law when handing over the file.

Most importantly, however, is regardless of the jurisdiction, once the attorney's patent prosecution file is given to the buyer and/or its counsel, to the extent the file is privileged or contains documents that are subject to the attorney-client privilege, the privilege is then waived by the divesting company. Hence, the file can and will be produced in its entirety upon request in related litigation. For these reasons, most divesting companies typically decline a request of the acquiring company to produce the attorney files (other than file histories which are available to the public upon publication of the patent application).

Post-Deal Support

The divesting company will need to provide some post-execution support to the receiving company, but the amount of support must be clearly limited so that it does not become a multi-year drag on the divesting company's resources. It is useful in the agreement to have a mechanism for the Newco to request additional documentation which may have been forgotten or overlooked during the initial transfer or due diligence. However, it is in the divesting company's interest to have clear limits set on how much support can be reasonably provided. It is important to clearly identify in the divesting agreement what technology is to be transferred, what the timeline for the transfer will be, whether there will be any on-going technical consulting, and how that technical consulting will be limited in scope and duration.

²² Brill, James E., *Ownership and Disposition of Client Files*, Texas Bar Journal, April 2008 at 318.

²³ Dietrich, Dean R., *What Comprises a Client File?* Wisconsin Lawyer, Vol. 83, No. 8, August 2010.

Summary

The expectations of the parties in the transfer of a pharmaceutical asset to a receiving company clearly vary depending on whether that receiving company is a large pharmaceutical entity or a startup NewCo. Significant considerations include the basic deal structure (license or assignment), due diligence of the receiving company, due diligence of the asset, tailoring the deal terms to the specific capabilities and needs of the parties, technology transfer and post-execution support.