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Driving Revenue and Deal Flow: IP Strategies for Early-Stage and Smaller Life Science Companies

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For the life science industry, patents are more than just tools for restricting the commercial activities of direct competitors. Patents are being used more and more to generate substantial additional returns on research and development (R&D) investment costs through licensing. Early-stage and smaller companies can use out-licensing revenues as non-dilutive equity to fund and advertise their R&D programs. Unfortunately, early-stage and smaller companies rarely dedicate the resources necessary to set up an effective out-licensing program.

Early-stage partnering is now a vital component of business strategy for many life science companies.[1] Due to the fierce competition for late-stage life science assets, larger life science companies must look to early-stage life science companies to access new and promising compounds and technologies. For early-stage life science companies, entering into a partnership with a larger, more established company increases their visibility, validates their technology in the life science industry, and helps fund their R&D programs. Successful licensing transactions can also attract further private or public equity investments. However, because early-stage and smaller companies have fewer resources, experience, and leverage than the larger life science companies, negotiating with a larger life science company before making the necessary preparations may lead to suboptimal results.

A strong technology transfer program can help early-stage and smaller companies establish an intelligent IP strategy, placing companies in a more solid position for future negotiations with larger life science companies. Furthermore, there are ways to structure transactions that enable small and early-stage life science companies to effectively mitigate and manage the risks inherent in business transactions.

I. Creation of the Intellectual Property

When companies develop technologies and reduce them to practice, they can create intellectual property (IP). Owning valuable IP permits a life science company to consider a variety of business transactions, which in turn can validate the products and the company.

A company's technology must be well protected for the company to either achieve a significant technology transfer program or prepare for an eventual

acquisition. Several forms of IP protection are available. The most common is patent protection. Trade secrets can also be valuable for protecting some life science technologies, especially when the trade secrets are harmonized with the patent strategy. Despite the common misconception, patents and trade secrets are not mutually exclusive.[2] For example, a company with an algorithm for optimizing probes and primers for improved diagnostic PCR assays may patent the optimized probes and primers while keeping the algorithm a trade secret. Other forms of IP protection, such as copyrights and trademarks, should also be incorporated into a company's intellectual property whenever appropriate.

Building a patent portfolio can be a substantial financial commitment for small and early-stage companies with limited financial resources. A few suggestions to help create an intelligent, cost-effective IP strategy are provided below.

Provisional vs. Utility Patent Applications

Provisional patent applications have several advantages for small and early-stage companies.[3] First, the filing fees are substantially lower than for a utility application. Second, provisional patent applications are not published and are not examined. They automatically expire after one year unless they are converted into a regular utility application.[4] Therefore, a patent applicant can strategically capture subsequent developments of their invention during the year in second, third, ... provisional applications. The applicant can then convert all these provisional applications into one utility application at the first provisional application's one-year anniversary. This IP strategy is far more cost-effective than filing serial utility applications. Finally, and a significant advantage for life science companies, the 20-year patent term from the filing date does not include any provisional patent applications' filing date.[5] Therefore, provisional applications can effectively provide 21 years of protection. This advantage is important because most life science technologies require many years to be commercialized. For successful life science technologies, the revenues are often concentrated towards the end of the 20-year patent term.

Alternatively, filing a utility patent application from the outset can be a preferable strategy when the patent applicant has a shorter path to commercialization, needs to establish patentability quickly for a potential investor or collaborator, or needs a quicker route to an issued patent to assert against potential infringers.

Scope of the Patent Application

Life science companies frequently develop technologies with potential indications or uses outside of their business models. These companies could then face spending capital to secure patents with a scope of protection that covers substantially more or different from their core business model. Securing broader patents can be a worthwhile investment if the company also devotes resources to a significant technology transfer program. Otherwise, broader patents will be an unnecessary expense. And the IP strategy may appear unfocused to potential investors.

Life science companies often fall into the trap of trying to cover all these additional potential indications or uses by merely including them in a list embedded in the patent application. However, without sufficient support, claims to the unsupported indications or uses will likely be rejected due to insufficient written description or lack of enablement.[6] Therefore, if the company develops the empirical data as support and wants to file a later patent application to cover these indications or uses, the company's earlier published patent application will likely be cited as prior art to deprive the later, more extensive patent application of novelty. Accordingly, a prudent strategy is to either put an adequate written description and prophetic support in the original application or wait to file for patent protection on these additional indications when the company develops sufficient support.

Patent Cooperation Treaty (PCT) Applications

The Patent Cooperation Treaty (PCT)[7] is an international patent law treaty that provides a unified procedure for filing patent applications in each of the over 150 Contracting States.[8] By converting the provisional applications to an international patent application under the PCT, a life science company can simultaneously preserve patent protection in many countries for up to 30 months from the earliest priority filing date.[9] After 30 months, the life science company may need to enter the National/Regional Phase in the countries in which they wish to secure patent rights. This National/Regional Phase can get quite expensive, depending on the number of countries. As such, a PCT application beneficially delays costs associated with National/Regional patent protection until the life science company has secured financing, a licensee, or a strategic partner.[10]

The international application provides another important advantage. It is subjected to an "international search" carried out by one of the major patent offices appointed by the PCT Assembly as an International Searching Authority (ISA). The resulting

International Search Report (ISR) provides the applicant with a list of the published documents that might affect the patentability of the invention claimed in the international application. The ISA also provides a written opinion on patentability for the applicant. This Written Opinion provides valuable insight to the life science company about the strength and scope of patent protection likely to be obtained for their invention. A favorable ISR and Written Opinion can also provide comfort to any potential investor, licensee, or other party interested in acquiring rights to the invention.

Patent Prosecution Highway (PPH)

The Patent Prosecution Highway (PPH) was initially launched in 2014 to speed up the examination process for corresponding National/Regional Phase applications filed in the participating patent offices. Under the PPH in participating patent offices, a patent applicant who receives a final ruling from a first patent office that at least one claim is allowed may request a fast track examination of the corresponding claims in the corresponding patent application pending in a second patent office. The PPH procedure enables an applicant to reach a final disposition of the patent application more quickly and efficiently than the standard National/Regional examination process.

More than 20 patent offices participate in the PPH, including the U.S. (USPTO), the European Patent Office (EPO), Australia (IPAU), Canada (CIPO), China (CNIPA), and Japan (JPO).[11] These patent offices are jurisdictions in which patent protection is commonly sought by life science companies.

An often-overlooked strategy is using the PCT application (*i.e.*, a favorable Written Opinion of the ISA) as the basis for a PPH request. Issued patents reduce the risk and enhance valuation for any potential investor, licensee, or other party interested in acquiring rights to the invention. As such, an intelligent IP strategy is to submit claims in the PCT application that more narrowly cover the company's commercial embodiments to enhance the chance of receiving a positive Written Opinion. Filing a PPH request based on a positive Written Opinion accelerates the examination process and getting an issued patent. Filing a PPH request based on a positive Written Opinion also typically results in substantial savings in patent prosecution expenses. These results are important advantages for early-stage and smaller life science companies. Companies can pursue broader claims later in subsequent continuation applications.

Foreign Patent Coverage

Obtaining broad foreign patent coverage is very expensive, especially for cash-limited early-stage and smaller life science companies. However, when approaching the National/Regional Phase deadlines, patent applicants are reminded that they face the final opportunities to seek foreign protection for their inventions in all the PCT signatory countries. Early-stage and smaller life science companies often succumb to this pressure and file broadly in many foreign markets that they will never enter. The financial burden is further compounded when the company seeks protection for their second, third, fourth, ... invention.

Given the long path to commercialization for life science technologies, too many early-stage and smaller life science companies abandon patent protection in multiple countries after several years of costly patent prosecution to lower their expenses and burn rate. Abandoning patent applications after having spent tens or hundreds of thousands of dollars is not a sound use of financial resources.

A more intelligent IP strategy involves the life science company selecting a predetermined set of countries for patent protection based on the more important commercial markets for their technology. For a more sophisticated IP strategy, the company may have two sets of countries for patent filings: (i) a narrow list of foreign countries for most inventions; and (ii) a broader list of countries for the more valuable or cornerstone inventions.

For maximal valuation purposes, a patent portfolio with issued patents and consistent country filings across several patent families projects more favorably to any potential investor, licensee, or another party than a patent portfolio with inconsistent country filings across different families with dozens of intentionally-abandoned applications in too many countries.

II. Preparing for the Transaction

Establishing an intelligent IP strategy can place an early-stage or smaller life science company in a more solid position for future negotiations with larger life science or financial companies. However, several additional steps, discussed below, can further strengthen the early-stage or smaller company's position to effectively close a transaction.

Internal Due Diligence

Before entering into any business discussions with a prospective strategic partner or licensee, an early-stage or smaller life science company should evaluate and understand its own IP and corporate documents.

The principal objective of this exercise is for the life science company to identify and address any IP issues or corporate issues before submitting itself to external due diligence.

The internal due diligence should confirm that the company's patents or patent applications cover its research and development candidates and any commercial products. The internal due diligence should also assess the scope and strength of the patent coverage. The extent and scope of the internal due diligence should estimate and match the rigor of a future external due diligence. A prudent company will prefer to cure any potentially adverse issue before the transaction rather than have it pointed out by counsel representing the prospective strategic partner or licensee. Skipping a robust internal due diligence can be embarrassing, resulting in significant delays during negotiations, eroding the other party's confidence, adversely affecting the valuation of the company's IP assets, or possibly terminating negotiations.

The steps taken during internal due diligence will also provide comfort to the life science company later when it is required to provide representations, warranties, and indemnities about the strength of the life science company's IP in the resulting transaction agreement.

An internal due diligence should, at a minimum, identify and list the life sciences company's patents and patent applications, as well as identifying inventions that should become the subject of patent applications. The due diligence should ensure that the company owns all patents and patent applications, such as by having signed assignments from the inventors to the company. The due diligence should also identify and list the corporate documents, especially if the company has ever undergone any changes in name, ownership, or status, to ensure that the correct company owns all the patents and patent applications. This stage is also an excellent time to at least begin to assess the strengths and vulnerabilities of the company's patent portfolio. Additional patent filings can tighten up any gaps in coverage. The company should also review its other business consideration and file or perfect any needed trademark applications or other forms of IP registrations.

Identifying Potential Transaction Partners

The internal due diligence should next analyze the state of the life science industry, to identify potential transaction partners, assess their products and services, and prioritize their assets. Several technology platforms and databases are available for the patent landscape analyses required for this purpose.[12] The potential transaction partners' corresponding IP can also be identified by checking the company's website or searching IP databases such as the U.S. Patent and Trademark Office database[13] and the European Patent Office Espacenet database.[14]

The life science company must then assess the scope of protection provided by the company's own IP assets to learn how a transaction could provide synergies. This assessment should verify the "exploitability" of your company's IP assets from the potential transaction partner's perspective. To do this, the company conducts a non-infringement investigation on its patent portfolio, again from the potential transaction partner's perspective. If the potential transaction partner can easily design around your IP, then they are unlikely to spend much capital to obtain these rights. By the end of the internal due diligence, the company must establish a value for their IP assets, identify the issues that may be used to negotiate a valuation reduction, and prepare to address or counter such issues.

The purpose of any due diligence is to test the underlying business and IP assumptions in anticipated deal situations. The due diligence must assess how the IP reality corresponds with the rationale for the deal. The company should conduct any IP due diligence with that end in mind. Suppose the technologies from the life science company and the prospective transaction partner can be combined into a new product or a new indication for a known product. In that case, a prudent and inexpensive strategy for an early-stage or smaller life science company is to file a provisional application ***before*** approaching the transaction partner. Such a provisional application can establish that the life sciences company had an earlier conception of the combination. This prophetic provisional application could prevent the prospective transaction partner from making an overt or inadvertent taking of the idea for the combination, should the transaction not materialize.

Note that this preliminary due diligence differs from the formal due diligence conducted during the transaction, where the company will examine in greater detail the strength, scope, and enforceability of the IP; the ownership rights surrounding the IP; and any legal concerns that may affect the value of the IP of the prospective transaction partner. The formal due diligence is only possible after the prospective transaction partner provides confidential information under a non-disclosure agreement (NDA) or confidentiality agreement (CDA), discussed below.

Term Sheets

An important early step in a successful transaction process is handling the term sheet. Term sheets are

common and expected before negotiations between startup companies (in any field) and their prospective transaction partners. A term sheet (also called a heads of agreement in some countries) is a document that outlines the expected key financial terms conditions for a partnership or transaction. The term sheet sets the expectations for the negotiations of the eventual agreement. Significant deviations from these expectations are usually resisted, barring any material issues discovered during the formal diligence process.

Accordingly, a small or early-stage life science company must be well prepared and must understand the value of their assets and contributions to be incorporated in the agreement. It must have a good understanding of the value or consideration that it expects from the transaction. The small or early-stage life science company should review prior agreements involving the prospective transaction partner to understand how the partner previously structured comparable deals and what terms the partner already deemed acceptable. Such information could be particularly useful in countering unreasonable positions that the prospective transaction partner might take during negotiations.

A term sheet usually is and should be a non-binding agreement. However, some life science companies later learn to their disappointment that their term sheet and subsequent behavior are interpreted as binding promises. [15,16] A prudent life sciences company will obtain legal advice to avoid this outcome.

A good term sheet will describe the important terms of the agreement to be negotiated. The parties to the agreement are named. The fundamental economic terms are set out, but not with finality or even clarity. Terms relating to each party's level of control in the agreement are also set out. Term sheets often outline the steps to be taken by each party before the definitive agreement.

Many companies assume that the most important parts of the term sheet are the financial terms. However, the other terms are equally important. They will set out the rights that the larger company receives or acquires in consideration for the financial offer and what risks and obligations are assumed by each party when they sign the formal agreement. The early-stage or smaller life science companies that underestimate the importance of the term sheet stage and assume that they can address issues during the subsequent negotiation of the formal agreement often find themselves in difficult negotiation positions, which result in unfavorable terms or lost opportunities.

Unfortunately, many small or early-stage life science companies allow the larger prospective transaction partner to take the lead on drafting the term sheet, perhaps assuming they will offer terms better than the early-stage or smaller company life science company would dare to request. The early-stage or smaller company should provide the first draft because it can advantageously set the stage for the negotiations. When the larger transaction partner takes the lead, the draft term sheet often is heavily slanted in their favor, making the negotiation process lengthier and more difficult. By taking the lead, the early-stage or smaller life science company can specify the crucial terms and parameters and define how detailed the term sheet will be before moving to contract negotiations. Moreover, the early-stage or smaller life science company establishes the timeline for the next step, potentially taking control of the process.

Non-Disclosure or Confidentiality Agreements

After the initial due diligence and the preparatory steps are completed, while the prospective transaction partner indicates interest, before ***any*** substantive business disclosures and discussions begin, the parties must negotiate and execute a non-disclosure agreement (NDA) or confidentiality agreement (CDA).

A good NDA or CDA will contain a provision exempting from confidentiality any information provided by the transaction partner that the life sciences company already knew before executing the agreement. It will also include a provision that such exempted information can be evidenced by written documentation. The filing of provisional patent applications before negotiations can help satisfy this criterion.

Larger transaction partners commonly insist that the early-stage or smaller life science company use "their standard" NDA or CDA. This is the time to be careful! These NDAs or CDAs are binding contracts. A prudent life science company will reject the notion that these agreements are easily invalidated in a legal proceeding because (a) they are not; (b) litigation is expensive; (c) litigation takes significant time and other resources; and (d) this kind of litigation inflicts an emotional burden that small or early-stage life sciences companies can ill afford.

Risk and opportunity are two sides of the same coin. Although business transactions have an inherent risk of failure, strategic planning can mitigate risks to acceptable levels.

III. Choosing the Right Transaction

Understanding an underlying deal rationale is essential for an early-stage or smaller life science

company to determine which type of transaction should be pursued. A larger biopharmaceutical company (the prospective licensee or acquirer) will always have a deal rationale, *i.e.*, a business reason for entering into a license or acquisition, before concluding a license/acquisition transaction.

To successfully close a transaction, the early-stage or smaller life science company must evaluate the deal rationale from the prospective licensee/acquirer viewpoint. The early-stage or smaller company must be ready to convince the prospective licensee/acquirer that the deal provides a requisite commercial and industrial logic. A good deal rationale usually includes a business model for generating revenues from the target technology or target company post-acquisition. The business model can also include removing a perceived obstacle. Therefore, the deal rationale always has one or more underlying IP assumptions. For example, the power of patent rights to confer market exclusivity to the owner or licensee provides significant business advantages to a licensee or acquirer.[17]

Unfortunately, because early-stage or smaller companies have fewer resources, experience, and leverage than larger biopharmaceutical companies, negotiating with the larger company before understanding the deal rationale can lead to suboptimal results.

Three transaction types are discussed in turn below: (a) a license, (2) a strategic partnership, and (3) a merger/acquisition (M&A). Each has similarities, but each also has distinctive qualities. Some of the more significant factors that weigh in favor of each transaction are summarized in **Table I**.

Table l. Choosing the Right Transaction (factors favoring a particular transaction)

License
• Divergent business goals • Want to preserve operational independence • Earlier-stage technology platform that fits the research needs of the licensee • Multiple opportunities for related/similar products in various fields • IP doesn't have to be bullet-proof, as long as it's divisible • Pending or threatened litigation • Simply need freedom to operate
Strategic Partnership
• Common business goals as to a particular indication or research program • Expedite the process to achieve desired commercial results • Want to preserve operational independence but share the costs of R&D • Mid-Stage technology that solves a critical problem but needs collaborative input • Opportunities in complimentary fields are furthered by outside expertise • lP depends highly on know-how and can't be designed around • Prior art can be avoided under the lP safe harbor of 35 U.S.C.§ 103(c)
M&A
• Common business goals; one party wants to control all IP and commercialization decisions • Late-stage products with a good pipeline • Few opportunities for related/similar products • Target IP dominates the industry space or has posed a problem to the acquirer in the past • Target has no potential litigation problems • High upfront cost but lower overall cost • Help the controlling party reach a perceived leader status in the industry • Target is cash-poor

Licensing

A license is a transfer of rights to an intellectual property asset without transferring title. [18] Many kinds of IP licenses are available to the licensing parties, including a conveyance of exclusive rights, a transfer of sole rights, and a transfer of non-exclusive rights.[19] The variations on each kind of IP licenses are almost endless, involving such factors as retained rights, specificity as to particular fields, geography, or timeframes.

A license strategy is preferable when the companies want to preserve their independence, perhaps because of divergent business goals or pending litigation against one of the parties. Such a license strategy allows a company looking to acquire technology to be selective rather than taking the good with the bad. A license permits companies to take advantage of opportunities for obtaining related products where there may be a need for freedom to operate in a particular technology space. This provides a "win–win" situation for the licensor and licensee when the two companies do not compete for the same industry space or products. For an early-stage or smaller company, a licensing strategy is an excellent way to recover revenue from IP that is not core to its operations.

Deliberately creating potential freedom to operate issues for larger biopharmaceutical target companies through patent filings is an aggressive but effective way to create licensing opportunities for technology

invented and developed in an early-stage or smaller life science company.

In an ideal world, the licensor company has issued patents. Unfortunately, the patent examination process is typically very slow. Several years can elapse between the original filing of a patent application and the issuing of a patent.[20] Nonetheless, an early-stage or smaller company can design a successful technology transfer program using patent applications—even provisional applications. As shown above, the value of an issued patent to a license arrangement is its ability to exclude competitors from the market. The value of a pending patent application to a license arrangement is its potential ability to exclude competitors. When a patent application is far enough along in prosecution to have received a favorable International Search Report or Written Opinion, or a favorable domestic Office Action, the potential licensor can demonstrate a potential ability to exclude competitors. The licensee's apparent risk will be reduced, so the value of the patent application should increase. There will be a clear relationship between the value and the "newness" of the application, with the value appreciating as the probability of issuance increases (although the value curve is not necessarily linear).

Utility patent applications filed with the USPTO publish 18 months after the first patent filing, the "priority" date.[21] After publication, an applicant accrues provisional rights that permit (in limited circumstances), the applicant to obtain for infringement of any patent issuing from the application, reasonable royalties retroactive up to the application's publication date.[22]

To maximize licensing opportunities, the early-stage or smaller company should create its IP to be as complete and divisible as possible. Ideally, a patent portfolio should include one or more "composition of matter" patents, with several "method of use" patents covering planned activities for each field to be licensed. Broad patents should be backed up with other related patents having specific and narrow claims. Patents with broad claims are often challenged for failure to meet the written description and enablement requirements of the patent laws.[23] But it is harder for challengers to invalidate narrow patents.[24]

Strategic Partnerships

Strategic collaborations continue to be a popular business strategy in the life science and pharmaceutical industries.[25] Because of the fierce competition for good late-stage life science assets, larger biopharmaceutical companies must look to early-stage life science companies to access new and promising pharmaceutical compounds and therapeutic technologies. For early-stage and smaller companies with less mature or developing technologies, collaborating with a larger biopharmaceutical company can be a sensible way to access greater knowledge, experience, and resources. A strategic partnership can also help the early-stage or smaller company increase their visibility, validate its technology in the life science industry, help fund their R&D programs. Entering into a successful strategic collaboration with a respected biopharmaceutical partner can also attract further private or public equity investments.

Collaborations are particularly suitable when one company has a "platform technology" that fits into the pipeline of another company, when the technology platform is highly dependent on Know-How, when the platform can benefit other initiatives in the larger company, or when the business goals are common as to a particular indication or research program. Instead, a company should consider a license—rather than a collaboration—when its products are mature or when the company has truly dominant IP positions.

Collaborations allow companies to preserve their independence while sharing the costs and research burdens. Collaborations are appropriate when both companies want some control or input into the decision-making processes while maintaining independence. Each party must bring something to the partnership. An early-stage or smaller company's goal during the early negotiations for structuring any collaboration is to show the people on the other side of the table that they need you and that they cannot appropriate your research or otherwise design around your intellectual property.[26] As discussed above, provisional patent application filings should be in place before the parties exchange any information. The early-stage or smaller company should also hold back some critical Know-How from patents after the initial filing.[27] The IP used by an early-stage or smaller company to drive a collaboration should overcome a critical problem for the larger company. But the final collaboration arrangement should force the larger company to go to people in the early-stage or smaller company—not documents—for the solution.

Contract research is a variation on the strategic partnership model. This contract research structure is dominated by one party that will generally own the research results and any resulting intellectual property. A failure to properly structure such a transaction type has often jeopardized IP ownership in process improvements and testing methods. The contractual ownership of any IP should be clear before commencing any actual work. Never assume that the obligation

to pay for the work will automatically provide ownership in any resultant IP. In cross-border deals, this problem can be magnified.

Mergers and Acquisitions (M&A)

M&A has recently become an attractive exit strategy for early-stage and smaller life science companies. An acquisition deal requires a high upfront cost for the acquirer but lower costs overall than licensing transactions, where a long-term obligation to pay milestone payments and on-going royalties can eventually become expensive.

In some cases, a merger can be the end-stage of an M&A acquisition deal, where the target company is merged into the operation of the acquiring company. After the merger, some product lines can be assimilated, and other assets can be sold off. This is where understanding the deal rationale is of paramount importance. IP usually becomes a principal asset for a merger. Therefore, the smaller life sciences target company should take all necessary steps to perfect its IP, lest defects reduce the final company valuation. For example, when the smaller life science target company will be ceasing operations due to lack of funds, getting the IP in good shape will maximize the sale price, even when the acquirer is otherwise getting a bargain.

In another model, the merger is essentially a marriage of two companies. In a "consented-to" transaction, both companies usually have common business goals, but the acquirer wants to control all IP and business decisions.

In more aggressive merger deals, the acquirer may be motivated solely by the target company's IP. When the smaller company's target IP dominates the industry space or has posed a problem to the acquirer in the past, or when few opportunities exist in the market for similar products, a larger company may acquire an early-stage or smaller target company solely to obtain the IP assets, with little interest in the other assets.

The optimal acquisition target companies have late-stage products with a good pipeline and no litigation problems. Early-stage or smaller target company IP should dominate the particular industry space-or at least the part most significant to the larger acquirer company—but must also be defensible. To position a smaller company for acquisition, the IP portfolio must be complete. The objective is to generate maximum value for the IP assets for the eventual sale.

1. U.S. Department of Justice and the Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property, January 12, 2017, § 2.3 Procompetitive Benefits of Licensing.
2. *See*, *On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1141 (Fed. Cir. 2004) (quoting RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 39 cmt. f (1995)).
3. 35 U.S.C. § 111(b)(1) (2011).
4. 35 U.S.C. § 111(b)(5) (2011).
5. 35 U.S.C. § 154(a)(2)-(3) (2011).
6. A patent application must disclose enough information to satisfy the requirements of 35 U.S.C. § 112. *See*, *e.g., Ariad Pharmaceuticals et al. v. Eli Lilly and Company,* 598 F.3d 1336 (Fed. Cir. 2010) (en banc) (defining the written description requirement) and In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) (defining the enablement requirement). Both the *Ariad* case and the *Wands* case concerned life science patents. The information that a patent discloses is not protectable as a trade secret.
7. The PCT was concluded in 1970, amended in 1979, and modified in 1984 and 2001. *See*, The PCT Applicant's Guide, *https://www.wipo.int/pct/en/guide/*.
8. The PCT currently has 153 Contracting States. *See, https://www.wipo.int/pct/en/pct_contracting_states.html*.
9. The earliest priority date is usually the filing date of the first provisional patent application. Some Contracting States permit national stage entry at 31-months or later. *See, https://www.wipo.int/pct/en/texts/time_limits.html*.
10. *See*, The PCT Applicant's Guide - International Phase, CHAPTER 4: USEFULNESS OF THE PCT FOR APPLICANTS, *https://www.wipo.int/pct/en/guide/ip04.html#_chapt4*.
11. For the U.S. Patent & Trademark Office's PPH procedure, *see* M.P.E.P § 708.02(c) Patent Prosecution Highway Program.
12. A patent landscape is an analysis of patent data that reveals business, scientific and technological trends. Landscape reports typically focus on a single industry, technology, or geographic region. Additional information on creating and using patent landscapes is available in the following sources:

    Bubela, T., *et al*. (2013) "*Patent landscaping for life sciences innovation: Toward consistent and transparent practices*." Nature Biotechnology, 31(3): 202–07.

    Intellectual Property Office (2015) "*The Patent Guide - A Handbook on How to Analyse and Interpret Patent Data*." Newport, UK: Intellectual Property Office.

    Trippe, A.J. (2015) "*Guidelines for Preparing Patent Landscape Reports*." Geneva: World Intellectual Property Organization.

    Singh, V.K. (2019) "*Patent Analysis, Mapping, and Visualization Tools*." *https://wiki.piug.org/display/PIUG/Patent+Analysis%2C+Mapping%2C+and+Visualization+Tools*.

13. *http://patft.uspto.gov*.
14. *https://worldwide.espacenet.com*.
15. *SIGA Techs. Inc. v. PharmAthene, Inc.*, 67 A.3d 330 (Del. 2013) [SIGA I]. The Delaware Supreme Court found that SIGA, in bad faith, breached its contractual obligation to negotiate a license agreement consistent with the parties' license agreement term sheet.
16. Contrast the result of the SIGA I decision with the New York case of *Prospect St. Ventures v. Eclipsys Solutions*, 800 N.Y.Supp.2d 131 (N.Y.A.D. 2005), where the court found a letter agreement was an unenforceable "agreement to agree" because it included a clear expression of intention not to be bound until both parties sign "a definitive agreement satisfactory in form and substance to both sides." *Id.* at 213. In this case, the court found no obligation to negotiate in good faith because of the written expression of intent not to be bound. *See also R. G. Group, Inc. v. Horn & Hardart Company,* 751 F.2d. 69 (2d Cir. 1984), where there was a clear understanding between the parties that they intended to be bound only by a written agreement when no agreement was ever signed.
17. "[A] patent grant is a legal right to exclude, not a commercial product in a competitive market." *Intergraph Corp. Intel Corp.*, 195 F.3d 1346, 1355 (Fed. Cir. 1999). "Implicit in the right to exclude is the ability to waive that right, *i.e.,* to license activities that would otherwise be excluded, such as making, using and selling the patented invention in the United States." *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1379 (Fed. Cir. 2000).
18. A license is a contract governed by the ordinary principles of state contract law. *State Contr. & Engineering Corp. v. Florida*, 258 F.3d 1329 (Fed. Cir. 2001).
19. When drafting patent licenses, the licensing parties should be careful to accurately describe what kind of patent rights are being licensed. If the description of the rights is ambiguous in the license document, unfortunate difficulties in enforcing the transferred patent rights can results. *See, TM Patents L.P. v. International Business Machines Corp.*, 121 F.Supp.2d. 349, 58 U.S.P.Q.2d 1171 (S.D.N.Y. 2000); *Mars Inc. v. Coin Acceptors Inc.*, 527 F. 3d 1359, 87 U.S.P.Q.2d 1076 (Fed. Cir. 2008); and many other cases.

20. "The time to obtain a patent depends greatly on the technology area of the invention, the amount of negotiation that is required with the patent office to obtain the patent, and on other factors ... In the computer, electrical, internet, and business method arts, this time can range from 18 months to nearly three years, just to get a first examination. "Leonard Hope, How Long does it take to get a patent? The Patent Prosecution Law Blog, *http://www.patentprosecutionblogcom/ archives /patent-prosecution-basics-24-how-long-does-it-take-to-get-a-patent.html* (posted October 9, 2005).
21. 35 U.S.C. § 122(b)(1)(A) (2011).
22. 35 U.S.C. § 154(d)(1) (2011). However, the patent that ultimately issues must cover "substantially identical" inventions as published in the provisional applications, *Id.* § 154(d)(2), and the action must be brought within six years of the issuance, *id.* § (d)(3).
23. 35 U.S.C. § 112 (2011).
24. *See*, *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 2005 U.S. App. LEXIS 21434, *31 (Fed. Cir. 2005) (holding that a specification that clearly describes one narrow embodiment of the invention did not support a broad claim).
25. U.S. Department of Justice and the Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property, January 12, 2017, § 2.3 Procompetitive Benefits of Licensing.
26. Many small companies have learned, to their dismay, that patent applications must be on file before beginning negotiations with potential transaction partners, even when they believe that the negotiations are confidential. *See, e.g., Group One Ltd. v. Hallmark Cards Inc.*, 254 F.3d 1041, 59 U.S.P.Q.2d 1121 (Fed. Cir. 2001).
27. *See*, *e.g., Bayer AG & Bayer Corp. v. Schein Pharms., Inc.*, 301 F.3d 1306, 1314 (Fed. Cir. 2002) ("Unlike enablement, the existence of a best mode is a purely subjective matter depending upon what the inventor actually believed at the time the application was filed."); *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955, 963 (Fed. Cir. 2001) ("[T]he factfinder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention.")