CREATING A PRACTICAL AND USEFUL DUE DILIGENCE CHECKLIST

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The process of gathering information, verifying facts and assessing risks associated with a business transaction is called "due diligence". A key challenge in any due diligence is how to gather, verify and evaluate this information within the time and budgetary constraints of the transaction.

Prior to embarking on any due diligence with an intellectual property (IP) component, it is useful if not imperative to understand the following:

1. What is the nature of the transaction? Is it a license agreement, an acquisition, a merger, an investment or an IPO?
2. Is there specific technology considered key to the deal? Is access to specific technology or a product line driving this deal?
3. With respect to any key technology, where is it on the patent life cycle? Has it been patented? Is it an FDA approved product ? Is access to manufacturing key to the deal?
4. Is the owner of the technology a publicly-traded company subject to the Sarbanes-Oxley Act of 2002?
5. Is the market for the technology domestic or foreign, or both?

Key to creating a useful checklist is understanding the goal of the transaction particularly in terms of what is driving the deal. The "goal" of the transaction means more than the actual nature of the transaction, e.g. a license agreement or an acquisition, but why are the parties in this negotiation ? An underlying assumption here is that technology is a very important aspect of the transaction. In most transactions, a goal is access to one or two key products. Organization of the due diligence around these key products will economize time, effort and cost. Separate checklists for each product or technology is recommended and can be customized to suit the development stage of the product and its strategic value to the transaction.

Appended to this document are checklists organized by IP asset that identify common issues addressed in any transaction with an IP component. The checklists are comprehensive in scope to broadly apply to a variety of transactions, whether a joint development agreement, a merger, an acquisition, a marketing or license agreement or an initial public offering. They should be combined and tailored to the parties and the ultimate goals of the transaction.

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To that end, the following text attempts to place the items listed on the checklists into the broader context of an IP due diligence.

The Intellectual Property

Intellectual property includes patents, trademarks, copyrights, trade secrets and know how. Thus, an IP due diligence may include a review of all of these forms of IP. Patents and trade secrets are the forms of IP that are usually considered most important. Thus, the assessment of the patents, trade secrets and ancillary know-how will consume a lion's share of the resources allocated in the diligence. For transactions involving commercially available products or soon to be marketed products, the due diligence may extend to a review of regulatory filings and manufacturing facilities. Further complexity and analysis is required for publicly traded companies to ensure compliance with The Sarbanes-Oxley Act of 2002.

Patent due diligence typically involves two core inquiries: (a) the nature and strength of the patent filings as a right to exclude; and (b) whether any third party that can exclude the practice of the IP or the making or selling of a product.

Evaluating the Right to Exclude

Evaluation of the patent portfolio can be divided into three or more task-based segments: 1) cataloguing and verifying ownership of the IP; 2) assessment of the scope and validity of any patent claim; and 3) freedom to make, use or sell the technology without impeding on the valid rights of other patent holders.

An evaluation of the right to exclude necessarily requires a cataloging of the patent filings and an evaluation of the merits of those pending and issued patents. While it is useful to start with a patent status report provided by the patent owner or licensee, this information should be verified either by a review of the actual patent filings or by records available from publicly available databases.

Since the right to exclude is limited to the country in which each patent is granted, cataloging of the patent filings should verify the individual status of each patent application by country (e.g., is the patent pending, issued, or has it lapsed ?) and the claimed subject matter. Also, an evaluation of the patent claim as compared to any potential or present commercial product in the markets where the product is to be sold or made is key to ensuring that the patent provides the expected right to exclude.

Ownership of a patent resides by right in the inventor or inventors. Therefore, companies or universities can only obtain patent rights by assignment of these rights from the inventors. In most instances, the owner is the assignee of the patent rights either by an express patent assignment or by an implied obligation to assign those rights under an employment agreement.

Verification that a good faith effort was made to identify all inventors on the patent and the identification of potential inventorship challenges can start by searching for inventor-authored technical publications and confirming the contribution, if any, of any author who was not named in the patent filings as a joint inventor, or vice versa.

No matter what the scope of the diligence, it is imperative that the claims of any patent filings be compared against the commercial embodiment or product. While "broad" claims provide an extra layer of protection against competitors and copiers, concisely drafted claims that protect the commercial embodiment(s), especially if present in published applications, are more likely to withstand challenge and may provide the basis for added damages if and when the patent is enforced. Therefore, it is useful at the onset to identify each claim that covers specifically and generically any commercial product and how the product is made and used. Where the technology has been commercialized, evaluation of patent markings on the product and accompanying packaging must also be investigated and confirmed.

The substance of the examination of any patent filing should be reviewed for obvious omissions and missteps, such as failure to timely file an application prior to publication, disclosure or sale of the invention, failure to timely file an international application to obtain the benefit of the Paris Convention, failure to cite to the patent office(s) prior art, especially that cited by patent offices, and the timely payment of maintenance fees and annuities. While there is a one year grace period for disclosing one's own invention prior to filing the patent application in the United States, most foreign countries do not have such a grace period and adhere to a strict novelty standard. Stated another way, in such countries, any application that claims the invention must be filed prior to any non-confidential publication of that invention. Therefore, a public disclosure of the invention prior to filing of the patent application negates the patent rights in most foreign countries.[1]

Invention disclosures should also be obtained and reviewed to determine if the inventors have identified what they consider to be the most relevant prior art. Communication of this information to the patent offices that have an disclosure obligation should be confirmed when reviewing the file history of any patent family.

Third-party and post-grant challenges to patent validity, if any, should also be identified and evaluated for merit. This information may be obtained from commercial databases but is typically obtained by interviewing the attorney or agent who is responsible for filing, prosecuting and maintaining the patents.

While it would be ideal to evaluate the validity of every claim of every patent in the portfolio, in most instances such an undertaking would exceed the budget allocated to the diligence. Thus,

[1] Note that electronic disclosures are treated the same as paper disclosures so pre-publication transmittals over the internet to the public will also impede the ability to obtain patent protection.

the patent claims considered to most cover the commercial embodiments should be reviewed for novelty, obviousness and support for meeting the written description requirement. This involves a search and review of the "prior art" (prior patents, publications, public disclosures, etc.) to determine if the patent claims are novel and non-obvious in each country where an application has been filed. Priority should be given to those countries of greatest commercial interest to conserve time and resources.

The patent claims also should be evaluated in light of the evolving case law in the United States and foreign countries. For example, the concept of whether a claim is "novel" is not always straightforward in the biological sciences where properties of a prior art composition may inherently anticipate later filed patent claims. Moreover, the obviousness standard applied in the United States, while similar to the concept of inventive step in foreign jurisdictions; is not necessarily its equivalent. Thus, where foreign patent rights are key to the transaction, it may be prudent to engage foreign patent counsel for a validity search and opinion that independently considers the most recent applicable law in that country.

The requirement that patent claims be adequately enabled throughout their scope and be adequately described in the patent specification, including any priority patent application, is evolving and of more concern to patent practitioners in the United States and abroad than it has been in the past. Thus, the evaluation of the patent specification and the number of working examples in support of the claims should be separately reviewed and analyzed.

The U.S. patent system is unique in requiring that each patent holder identify the best mode to practice an invention claimed in a patent. This additional requirement may create a trap for the unwary foreign patent applicant if the U.S. patent application was prepared only to meet non-U.S. standards. Thus, the patent claims and supporting specification should be analyzed to determine if the best mode has been disclosed.

Prior to delving into any specific FDA or other regulatory issue, whether or not patent term extension was applied for and obtained should be investigated and confirmed for patents covering an approved product or device.

Freedom to Operate

The "freedom to operate" analysis is an assessment of whether the making, using, sale or importation of a product will infringe third party patents. The inquiry is more complex when pending claims are published yet not issued, so the inquiry not only requires construction of the claims and infringement analysis, but also estimation of whether the published claim(s) will issue. Evolving application of infringement under the doctrine of equivalents only adds to the complexity and cost of this analysis.

It is important at the outset of the diligence to request the results of any pre-existing infringement or freedom to operate opinions, and to determine whether the potential partner has received notice from a patent holder that they may be at risk of infringing another's patent.

Freedom to operate or product clearance searches may have been conducted that identify potential blocking patents. It is not uncommon for companies to have obtained opinions that identify and address the potentially blocking patents. If possible, copies of these opinions should be obtained and evaluated in terms of continuing evolving case law.

With respect to the infringement of an issued U.S. Patent, all subsections of 35 U.S.C. § 271 should be considered, e.g., direct infringement, contributory infringement and inducement to infringe. Importation of a product made by a process patented in the United States also can be an act of infringement and the analysis of what is a "product" for the purposes of infringement should also be considered and analyzed. A search of relevant databases should be conducted to determine if the patents have been the subject of any litigation.

One should not assume that every patent holder will file a corresponding U.S. patent. Thus, a separate search for patents and published applications should be conducted for each country where the technology will be practiced. A separate review of non-English patent literature may be the ounce of prevention that justifies the cost of hiring foreign patent counsel to conduct a separate patent search in non-English jurisdictions.

If blocking IP is identified, it may be possible to change the product or process so that it no longer infringes the third party patent, commonly called a "design around." If a meaningful design around is not possible, then it may be possible to also license the potential blocking technology or alternatively, to invalidate the third party patent in a court or at the patent office.

The freedom to operate search and evaluation should also consider whether the practice of the technology requires acquiring rights to ancillary or enabling technology. For example, while a recombinant protein may be adequately protected by a patent claim on the gene and recombinant expression product, the actual making of the protein may require compositions such as growth media and/or culture that are not covered by the underlying patent.

If a license to technology has been obtained, copies of the licenses should be obtained and evaluated to assess whether the licensed patents generically and specifically cover the product or any enabling technology. License fees and royalty rates should be evaluated and noted. Unduly burdensome rates and the need for multiple licenses to commercialize a product should be highlighted.

Although not a common freedom to operate issue, whether an application was supported in whole or in part by a federal grant should be noted since they are subject to additional restrictions and

reporting obligations as set forth in 35 U.S.C. §§ 200-212. For example, the federal agency funding the application has the right to at least a non-exclusive license (see 35 U.S.C. § 203 also known as "March-in Rights") and the statute imposes a preference for U.S. manufacturing of any products falling under the claims (35 U.S.C. § 204).

Trademarks, Copyrights and Trade Secrets

Trademarks and trade dress identify the source of a good or service. The value of a trademark depends on the strength of the mark. For U.S. trademarks, whether the mark has been federally registered should also be noted. Similar to patents, trademarks are limited to the country in which they are obtained and therefore, the mark in each country should be reviewed. In general, a review of these assets follows the guidelines set forth for patents.

Also similar to patents, trademark registrations require the payment of renewal fees and the timely payment of these fees should be confirmed. All assertions of trademark or trade dress infringement should be reviewed and assessed for risk, especially when protection for the mark has not been obtained in that country or region.

Trademark protection should not be overlooked. For products that may be manufactured abroad, strong trademark protection for the product may be the first line of defense against counterfeiters and the importation of gray market goods. U.S. and other courts provide trademark owners with powerful remedies against counterfeiters such as ex parte seizures of products and related assets.

Copyrights prevent others from copying and claiming authorship of original works that have some fixed and tangible form of expression. Ownership of key copyrights should be confirmed by reviewing employment agreements with employees and independent contractors.

Trade secrets protect information that the owner has no intention of making public, as well as the research and development that has the potential for future patent protection. Prior to the enactment of the Sarbanes-Oxley Act of 2002, trade secrets were typically viewed as an amorphous asset of no concrete valuation. It was not unusual for top corporate management to be ignorant of the actual value of these assets and their inter-relation to product lines and other IP. The implications for publicly traded companies is addressed below.

For privately-held companies, trade secrets are valuable only as long as they remain secret and the holder has procedures in place to ensure continued non-publication or disclosure. To that end, the company or holder of the trade secret should have appropriate confidentiality provisions in all employment and contractor agreements.

FDA Regulatory and Compliance Issues

An added layer of complexity is imposed when a regulated product is part of the transaction. Any review of products in the approval pipeline should verify the completeness and integrity of the approval process.

Requests for documents and interviews with key personnel can be organized by region and status of the review, e.g., preclinical testing versus clinical testing and type of approval, e.g., orphan drug status, investigation new drug (IND), abbreviated new drug application (ANDA) or 510(k) clearances.

With respect to requesting documents from the target or potential partner, the requests should be broadly defined to include any correspondence (including meeting minutes or telephone conference memoranda) to and from the regulatory agency which relates to the products, licensors, sellers or manufacturers of the product (including key components of the product) and the identity of the manufacturing facilities. Pre-clinical documentation should include protocols, reports and other documents relating to in vitro, animal or mechanical or chemical tests, and toxicity data. Some of this information may only be available in laboratory notebooks and data analyses.

A review of clinically relevant documents should include: 1) regulatory application files; 2) information on adverse events or lack of clinical efficacy; 3) clinical trial reports; 4) reports to the FDA or institutional review board (IRB) concerning the trials; and 5) results of audits of the study sites or any contract research organization (CRO).

Exposure to liability as it applies to quality assurance and manufacturing issues should be investigated. To that end, a review of any FDA or regulatory-type inspection observations and responses, internal and external audits, FDA warning letters relating to manufacturing or other compliance issues should be obtained and evaluated.

Sarbanes-Oxley Act of 2002

Sarbanes-Oxley was enacted to create more transparent financial disclosures and reporting in publicly-traded companies by requiring greater internal controls and audits. A company's management team is subject to civil and criminal liability for noncompliance. Sections 302, 404 and 409 are germane to the due diligence.

Section 302 of Sarbanes-Oxley requires CEOs and CFOs to certify the accuracy of annual and quarterly reports filed with the Securities and Exchange Commission (SEC). Accordingly, after a review and analysis of the relevant IP in a transactional due diligence, the results should be

compared to the company's annual and quarterly reports to ensure that these reports adequately reflect the status of the company's IP assets.

Section 404 of Sarbanes-Oxley requires management to document and certify the scope, adequacy and effectiveness of internal financial reporting procedures and procedures for internal controls. In practical terms, publicly traded companies are now required to include an annual report on these internal controls.

Section 409 requires the company to deliver real-time reports to shareholders on "material events" that could impact the company's finances or business operations and include "material events" involving IP such as litigation involving an IP asset. Thus, to the extent that lawsuits or other actions that affect the value of IP have been uncovered in the due diligence, timely reporting of these events to shareholders should be confirmed.

DUE DILIGENCE CHECK LISTS

	PATENTS			
#	**Subject**	**Date Requested**	**Date Received**	**Comments for follow-up**
1.	Obtain schedule and copies of all U.S. and foreign issued patents and pending applications, both utility and design, used in or associated with the target company ("target").			
2.	List maintenance and annuity fee status for each patent application.			
3.	Obtain copies of all ownership and assignment records for patents and applications. Confirm recordation with U.S. and other patent offices.			
4.	Confirm whether foreign patents been "worked" in countries requiring working.			
5.	Identify all opposition, reexamination, interference, reissue, confirmation of scope, nullity, inter parties and post grant proceedings and status or disposition of each. Provide information and documents.			
6.	Identify R&D which may be appropriate for future patent protection. Confirm trade secret status of each.			
7.	Identify patent claims that correspond to product(s).			
8.	Identify key patents and their respective inventors. Identify employment status of each inventor. Confirm assignment of patent rights.			
9.	Obtain and review copies of all agreements dealing with patents, e.g., licenses or interference settlement agreements, and identify revenue streams or royalty obligations associated with each agreement.			

#	Subject	Date Requested	Date Received	Comments for follow-up
10.	Obtain copies of all prior art searches, conclusions, reports and opinions, whether internal or external, that target possesses concerning the validity of its patents, the infringement of its patents by others, the infringement of third party patents by its products and the validity of such third party patents. Confirm that material prior art has been cited to patent offices that have duty of disclosure.			
11.	Obtain copies of all correspondence relating to patent disputes, cease and desist letters, letters alleging infringement, warning letters, service of notice, letters threatening lawsuits or other legal notices received or sent by target.			
12.	Does target conduct product clearances? Provide copies of clearance procedures and any results and/or opinions.			
13.	Obtain all correspondence to or from target inquiring about a possible license or the status of a patent or patent application.			
14.	Schedule any action to be taken during the transition or due diligence periods to protect the patents, e.g., paying maintenance fees or responding to Office Actions?			
15.	Will bar dates or disclosures of new products necessitate imminent filings in order to avoid loss of rights?			
16.	Have patent term extensions been applied for and obtained for where appropriate?			
17.	Have reporting requirements been met for applications supported with federal grants?			
18.	Obtain copies of any valuation analysis.			
19.	Obtain copies of all patent term extension applications for U.S. and foreign marketed devices and drugs.			

	TRADEMARKS			
#	**Subject**	**Date Requested**	**Date Received**	**Comments for follow-up**
1.	Obtain schedule of all federal, state and foreign trademark registrations and pending applications used in or associated with the target and their renewal fee due dates.			
2.	Obtain copies of all ownership, assignment, and lien records for trademarks and applications.			
3.	Obtain copies of all Section 8 and 15 filings.			
4.	Obtain copies of all opposition, cancellation, inter parties, concurrent use and registration proceedings.			
5.	Cross-reference products on which each trademark is used.			
6.	Identify any non-use of any trademarks. For what periods of time?			
7.	List and schedule all non-registered trademarks, the products on which these trademarks are used, and the breadth of such trademarks. Are these trademarks used in interstate commerce?			
8.	Obtain copies of all agreements dealing with trademarks, e.g., consent letters, mutual use agreements, licenses or opposition settlement agreements, identify whether target is licensee of licensor, and identify revenue streams or payment obligations associated with each agreement.			
9.	Obtain copies of all searches, conclusions, reports and opinions, whether internal or external, that target possesses concerning the validity of its trademark registrations, the scope of rights, geographical limitations, expansion restrictions, the infringement of its trademarks by others, and infringement of third party trademarks by its activities.			

#	Subject	Date Requested	Date Received	Comments for follow-up
10.	Obtain copies of all correspondence relating to trademark disputes, cease and desist letters, letters alleging infringement, letters threatening lawsuits, or other legal notices received or sent by target.			
11.	Obtain copies of all correspondence to or from target inquiring about a possible license or the status of a trademark registration or application.			
12.	Does any action need to be taken during the transition or due diligence periods to protect the trademarks, e.g. paying renewal fees or responding to Trademark Office correspondence.			
13.	Obtain copies of any valuation analysis.			

	COPYRIGHTS			
#	**Subject**	**Date Requested**	**Date Received**	**Comments for follow-up**
1.	Schedule all copyrighted materials, particularly software and mask works, used in or associated with the acquired business. Provide copies of applications and registrations, assignment documents, and security agreements.			
2.	Schedule and copies of all agreements dealing with copyrights, e.g., licenses, identify whether target is licensor or licensee, and identify revenue streams or payment obligations associated with each agreement.			
3.	Obtain copies of all searches, conclusions, reports and opinions, whether internal or external, that target possesses concerning the validity of its copyright registrations, the scope of rights, the infringement of its copyrights by others, and infringement of third party copyrights by its activities.			
4.	Obtain copies of all correspondence relating to copyright disputes, cease and desist letters, letters alleging infringement, letters threatening lawsuits and other legal notices received or sent by the target.			
5.	Schedule any action that needs to be taken during the transition or due diligence periods to protect copyrights.			
6.	Obtain copies of any valuation analysis.			

	TRADE SECRETS			
#	**Subject**	**Date Requested**	**Date Received**	**Comments for follow-up**
1.	Schedule all trade secrets and know-how used in or associated with the acquired business. Identify confidential information that target licensed or otherwise acquired from a third party.			
2.	Obtain copies of all agreements dealing with trade secrets, e.g., license, secrecy, or non-analysis agreements, identify whether target is licensor or licensee, and identify revenue streams or payment obligations associated with each agreement.			
3.	Obtain copies of all correspondence relating to trade secret disputes, cease and desist letters, letters alleging misappropriation, letters threatening lawsuits and other legal notices received or sent by target.			
4.	Obtain copies of any valuation analysis.			

	IP GENERAL			
#	**Subject**	**Date Requested**	**Date Received**	**Comments for follow-up**
1.	Obtain copies of all litigation and claims threatened or asserted against the target involving any alleged infringement by the target of any patent, trademark, copyright, trade secret or other proprietary right of any other party.			
2.	Obtain copies of all litigation and claims threatened or asserted by the target involving any alleged infringement by any third party for violation of any patent, trademark, copyright, trade secret or other proprietary right of the target.			
3.	Obtain copies of all agreements with directors, officers, employees and agents of the target and independent consultants relative to non-disclosure of trade secrets, development and assignment of inventions, non-compete and similar matters.			
4.	Obtain copies of all joint venture and joint development agreements or any other agreements that contain intellectual property clauses.			
5.	List prospective agreements currently in negotiation that contain intellectual property clauses.			
6.	Obtain copies of all sales, distributor, or other agreements that contain general or special warranties and/or indemnifications against any form of intellectual property infringement.			
7.	Schedule and describe products manufactured and/or sold by the target and the geographical market where each is made or sold.			

FDA AND GMP REGULATORY COMPLIANCE DUE DILIGENCE CHECKLIST

#	Subject	Date Requested	Date Received	Comments for follow-up
1.	Obtain copies of publicly available press releases and product announcements.			
2.	Obtain publicly available SEC filings concerning product development.			
3.	Obtain target organizational chart to determine personnel involved in regulatory or GMP compliance.			
4.	Obtain drafts of NDA, BLA 510(k) or PMA.			
5.	Obtain preclinical development protocols, reports and other documents relating to in vitro, animal or mechanical or chemical tests and previous toxicity data.			
6.	Obtain preclinical development laboratory notebooks and data analyses.			
7.	Obtain preclinical GLP audits (if any) including those of contracting suppliers and manufacturers activities relevant to the product development.			
8.	Investigate who sponsored clinical trials and whether there were conflicts with outside CRO's, any other factors that would call into question the integrity of preclinical or clinical trial data?			
9.	Obtain copies of ANDA, IND or other FDA drug or device applications and related correspondence.			
10.	Investigate and obtain information on adverse events or lack of clinical efficacy.			
11.	Obtain clinical trial reports to the FDA or institutional review board (IRB) concerning the trials.			
12.	Obtain target's records of audits of the study sites or contract research organization (CRO).			
13.	Obtain copies of promotional and advertising materials for the product.			
14.	Obtain copies of correspondence to and from the FDA, e.g., those that impact range of potential claims or liability.			

#	Subject	Date Requested	Date Received	Comments for follow-up
15.	Obtain copies of documents pertaining to FDA inspection observations and responses, EIRs (FDA establishment inspection reports).			
17.	Obtain copies of any FDA warning letters such as those related to manufacturing or marketing practices.			
18.	Obtain copies of all correspondence: involving foreign product development related to regulatory agencies (if any).			
19.	Obtain copies of correspondence: correspondence related to orphan drug status.			
20.	Obtain correspondence related to special, priority or fast track designations in FDA approval process.			

REPORTING ISSUES UNDER SARBANES-OXLEY

#	Subject	Date Requested	Date Received	Comments for follow-up
1.	Do annual and quarterly SEC filings accurately and timely report on IP assets, including a valuation of trade secrets ?			
2.	Have periodic and compliant audits been conducted to ensure compliance with IP-related license agreements?			
3.	Have appropriate IP-related freedom to operate searches been conducted?			
4.	Does the target have internal controls to account and monitor IP? Are internal controls in place to monitory infringement of its rights and the infringement of third parties rights?			
5.	Have material events been timely reported to shareholders ?			