

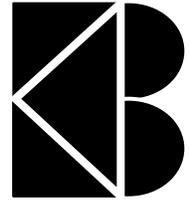
# DUE DILIGENCE PLAN

Validity and Freedom to Operate  
Analysis of Patents Applicable  
to a Specific Product

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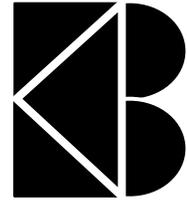
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When introducing a product into the marketplace, it may be wise to conduct a freedom to operate study. While there is no formal duty to conduct such a study if you are not aware of intellectual property barriers to product introduction, the downside risk of finding your company in a patent litigation, with potential forced withdrawal from the marketplace in addition to damages, may dictate that at least some form of study should be undertaken. The degree of rigor of search for unknown patents that is actually executed is determined by the value of the product and the damage to the company if a surprise patent does surface. Once a patent is identified as raising a potential issue, a process needs to be conducted to manage the related risks.

A useful first step in conducting an efficient freedom to operate and validity study is to identify tasks and potential issues to be considered for a comprehensive and meaningful analysis of intellectual property landscape of the technology to be analyzed. It is helpful to list these tasks and issues in outline form to understand the potential scope of the project and to efficiently plan the steps to be carried out.

The following mock project analysis outline is a typical analysis format that is used at Kagan Binder as a tool to explain the freedom to operate study process to the client, and to work with the client in arriving at an agreed-upon estimate of the cost of the analysis process prior to incurring expenses.



**-SAMPLE-**

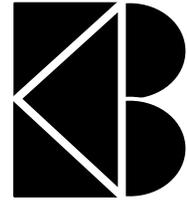
**Proposed Initial Task List for Blood Glucose Monitor Project**

**Phase 1 Tasks.** The objective of this phase is to determine whether we can develop theories of noninfringement and/or invalidity.

<b>Task</b>	<b>Authorized</b>	<b>Completed</b>
Preliminary study, including initial review and study of OTHERCO patents, internet searches to uncover relevant background art, study of the same, draft agenda for technical discussion, and prepare initial task list and budget	?	!
Ongoing business and technical discussions.	?	?
Title search of patent(s) at issue.	?	?
Order remaining OTHERCO file wrappers, but only one with references.	?	?
Review all file wrappers.	?	?
Analyze IDS consistency among the 5 OTHERCO patents.	?	?
Legal research and analysis of case law governing claim construction.	?	?
Develop theory of noninfringement and list design around options.	?	?
Develop theory of invalidity based upon known information, including the prior art blood glucose monitor product.	?	?

**Phase 2 Tasks.** The objective of this phase is to document our analysis in writing.

<b>Task</b>	<b>Authorized</b>	<b>Completed</b>
Draft one or more responsive letters to OTHERCO explaining our noninfringement/invalidity position(s).	?	?
Prepare a written opinion of noninfringement for the OTHERCO patent.	?	?
We may also desire to draft noninfringement opinions for the remaining OTHERCO patents.	?	?



**-SAMPLE-**

**Phase 3 Tasks.** The objective of this **OPTIONAL** phase is to uncover prior art that would demonstrate the invalidity of the Widget Patent Claims and document this in writing. Validity studies can be expensive and time consuming. We may not need to do this Phase at all.

<b>Task</b>	<b>Authorized</b>	<b>Completed</b>
Conduct technical and patent literature search for other documents authored by Jones, et al.	?	?
Conduct technical and patent literature invalidity search.	?	?
Review results of searches and assess impact upon validity of OTHERCO claims.	?	?
Discuss results of invalidity analysis with Susan Doe.	?	?
If authorized, prepare written opinion of invalidity.	?	?

**Phase 4 tasks.** The purpose of this phase is to monitor the position of the OTHERCO patent portfolio over time. Specifically, beginning in June 2004, it may be desirable to monitor patent literature on a bi-monthly or quarterly basis to uncover any patent documents owned by OTHERCO or its inventors. In-house personnel could easily do this, so there would be no outside counsel expense.

**The foregoing is intended to provide you with helpful suggestions in protecting your organization from avoidable liability concerns in intellectual property matters. Each matter is different, and the advice of competent counsel in each situation should be obtained.**