

# Freedom to operate

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## 1. Introduction

Only the educated are free.  
*Epictetus* (55AD–135AD)

So far, this text has focused on capturing, acquiring and managing your own IP rights. Of course, your competitors and other third parties will be seeking to do the same. IP rights held by third parties represent a risk to your freedom to operate. This chapter focuses on patents.

Just like your own patents enable you to stop or threaten to stop others from doing what is covered by your patents, others may do the same to you. What is more, the fact that you may have covered your own product with patent claims only means that you have a right to exclude others from practising within your claims. It does not entitle you to practise yourself what is within your claims, for example, if doing so would infringe somebody else's patent. Whether you patent yourself or not, patent rights held by third parties will represent a potential risk to your freedom to operate.

It is never possible to fully prove a negative: the absence of conflicting rights. This is the case even with the most comprehensive searching and analysing. There is therefore, strictly speaking, no such thing as freedom to operate. Rather, the task is one of managing the risks to your freedom to operate represented by conflicting third-party patents. This is likely to involve looking for such patents. A number of approaches and strategies are possible, depending on a variety of factors such as your acceptance of risk, your market position and strengths, and the resources you are able or willing to commit to managing freedom-to-operate risks. However, it is critical to understand the risks and issues involved in relation to third-party rights, and your freedom to operate must be understood to enable rational decisions to be made.

Thus, even the well-informed can never be sure to be fully free to operate. However, by being educated about third-party rights and freedom-to-operate issues, the risks to your freedom to exploit your innovations can be understood and acted upon.

## 2. Reasons for engaging in freedom-to-operate risk management

If it is not possible to establish complete freedom to operate with full certainty, then the question is: why engage with this issue? While it is not possible ever to be certain

about your freedom to operate, it is only by engaging with the issue that rational decisions are possible. The level of engagement will very much depend on your specific circumstances, as will the possible actions taken as a result of any risks uncovered. How to arrive at a rational strategy, which factors to take account of, how to evaluate risks and how to mitigate them are discussed below.

While any amount of freedom-to-operate analysis cannot guarantee not being at the receiving end of a patent infringement suit – in particular, in technological areas where ‘patent thickets’ and non-practising entity (NPE) activity are prevalent – the downside risk of the expenditure of defending an infringement suit and potentially being unable to proceed with a given activity typically makes at least some investment in freedom-to-operate analysis worthwhile. Gaining information about freedom-to-operate risks allows mitigating actions to be taken or for a risky activity to be abandoned entirely before significant investment occurs.

**3. Developing a freedom-to-operate strategy – decision factors**

Developing a freedom-to-operate strategy requires a multi-factorial analysis specific to your business and the competitive and market environment in which you operate. Case studies illustrating how the factors discussed below may play out are provided at the end of this section.

Table 1 illustrates how internal and external factors may influence your strategy decisions about how much to do to assess your operating freedom.

**Table 1: Factors affecting FTO strategy**

	Do more	Do less
Internal	<ul style="list-style-type: none"> <li>• Risk averse</li> <li>• High stakes</li> <li>• Long time to market</li> <li>• Blockbuster product</li> </ul>	<ul style="list-style-type: none"> <li>• Limited resources</li> <li>• Insurance</li> <li>• Strong patent portfolio</li> <li>• Portfolio of products</li> </ul>
External	<ul style="list-style-type: none"> <li>• Litigious environment</li> <li>• Target large market share</li> <li>• Many patents in space/market</li> <li>• Fragmented ownership</li> </ul>	<ul style="list-style-type: none"> <li>• Patent backwater</li> <li>• Have large market share</li> <li>• Few patents in space/market</li> <li>• Known patent ownership</li> </ul>

**3.1 Internal factors**

A number of the relevant factors relate to your mindset, what you do and what resources are available.

**(a) Approach to risk**

At the outset, if your approach to risk is that even a high risk of being unable to proceed with a given activity is acceptable, or that the activity in question will be engaged in regardless of the outcome of any freedom-to-operate analysis, your

strategy should be a simple one: to proceed with the activity without carrying out any freedom-to-operate analysis. This saves the potentially substantial cost of engaging in such an analysis, which in any case would not affect your actions. Nevertheless, it is a bold approach rarely followed if all issues are considered.

A risk-taking approach to freedom-to-operate may sometimes be appropriate in circumstances where this will affect only a limited number of consenting people. However, in most settings – in particular, if third-party investment is involved – a more fine-grained approach is likely to be more appropriate. Even then, there will always be a trade-off between any residual risk remaining after a freedom-to-operate analysis and the cost of the analysis. The more resources invested in the analysis, the more confidence can be gained about the level of risk associated with a given activity. Thus, a very cautious approach may be investing large funds in searching for competitive patents, further funding to analyse carefully all search results, obtaining legal opinions where any doubt remains and so on. By accepting an overall higher risk (less confidence in knowing the risks involved), the analysis can be curtailed to a level where the cost is acceptable and in line with a level of risk that you are comfortable with.

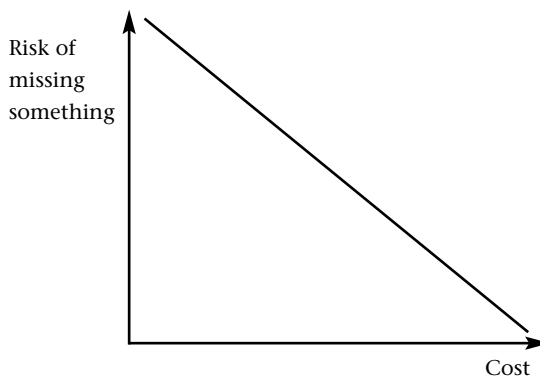
**(b) Available resources**

Even if your acceptance level for risk dictates a highly thorough freedom-to-operate analysis, this simply may not be feasible given the amount of resources available to carry out the analysis. Any freedom-to-operate analysis strategy must not only fit with the derived risk profile, but also be realistic in terms of affordability. Some resources that need to be considered are:

- funds for engaging external advisers;
- internal capacity and knowledge to carry out at least some of the tasks involved;
- management time; and
- time of technical personnel that may be involved in analysing third-party patents.

The trade off between risk and cost is illustrated in Figure 1 below.

**Figure 1: Risk v Cost take-off (general)**



(c) **Insurance**

There are several ways in which one can obtain 'insurance' against patent litigation. It is possible to underwrite patent litigation risks by taking out litigation insurance, but underwriters often require an amount of due diligence, which amounts to significant freedom-to-operate analysis. Other forms of non-traditional 'insurance' are also possible. New patent aggregator entities exist that aggregate patents to remove them as an infringement risk to their subscribers. Finally, having a significant patent portfolio covering some of a competitor's activities affords a certain degree of 'insurance' by providing negotiating chips if the competitor patent becomes a freedom-to-operate issue. In such circumstances, it can be possible to reach a settlement by cross-licensing or simply through the prospect of mutually assured destruction by patent infringement litigation. If a specific activity or product can be considered 'insured' to some extent, a strategy with higher risk levels may be acceptable.

(d) **Other circumstances**

Many other factors will influence how the question of freedom to operate is approached. Much will depend on your circumstances, for example, whether you are an individual entrepreneur, in partnership with a few like-minded individuals, a privately held company, a publicly traded company or dependent on third-party investment. A more cautious approach may be dictated by responsibility to investors or shareholders; but on the other hand, if there is a one-way street situation in which any result of a freedom-to-operate analysis will not affect the course of action taken, a light-touch or no analysis at all may be more rational.

(e) **The activity to be cleared**

The effort involved in clearing a product and elucidating freedom-to-operate risks will strongly depend on the complexity of the product and the number of features requiring analysis. For example, for a new drug the composition, excipient, medical use and dosage regime could individually infringe different patent claims. For a complex product, such as a car or a mobile phone, meanwhile, many components need to be considered (eg, software features, antennae, operating system, user interface features, engine, car body, suspension, control software, power steering). While the complexity of the task at hand is not in itself a reason to refrain from managing freedom-to-operate risks, in a universe of limited resources, the effort and cost involved in clearing a product will likely influence the degree and detail to which the product can be cleared.

Another important question involves the investment of resources and time in bringing a product or service to market. If a product takes years to develop and gain regulatory approval (as is typically the case in the pharma industry), the downside risk in potentially lost investment is relatively large. If a product can be developed and marketed in a comparatively short period of time, there is relatively less at stake. Thus, the downside of a freedom-to-operate problem blocking a development coming to market effectively is much higher in regulation and research-heavy industries than in industries where time to market is relatively short.

### 3.2 External factors

No enterprise operates in a vacuum and the environment in which you operate in will influence what freedom-to-operate strategy would be appropriate. In particular, it matters who your competitors are, the structure of the marketplace you operate in, how you are positioned in it and the nature of the patent landscape in which you operate.

#### (a) *Competitors and marketplace*

While there is a hypothetical freedom-to-operate risk based on the presence of a granted patent with an infringed claim, the risk is real only if there is also somebody who is willing to enforce the patent. Thus, if the marketplace you operate in is not active in patent litigation, the actual risk is likely to be lower than in circumstances where one or more competitors are actively enforcing patents in your field. Clearly, there is always the risk that a 'patent backwater' is suddenly hit by a storm, but a more relaxed approach may be justifiable if you know your competitors and patent litigation is not commonly engaged in your field. If, on the other hand, you operate in a territory where litigation is frequent and likely (eg, consumer electronics, in particular mobile phones; pharma), clearing the way for a new activity is more pressing. It all depends on the specific circumstances. For example, when a planned activity is likely to take significant market share from a competitor, taking a good look at the patents of that competitor would be prudent.

#### (b) *Patent landscape*

A related but separate factor is the landscape of patents in the field you operate in. For example, clearing a product in a field in which patenting activity is high and patents are held by numerous entities and not necessarily only by a manageable number of main competitors, locating relevant patents and then dealing with them will be relatively more difficult. Generally, where patenting activity is high and there are many incremental patents covering similar concepts, establishing freedom-to-operate risks with any degree of certainty will be more difficult. This is not to say that in such circumstances a freedom-to-operate analysis should not be engaged in, but such an analysis is likely to be more of a general risk management exercise rather than being capable of elucidating freedom-to-operate risks with a degree of certainty.

### 3.3 Case studies

The ways in which the factors thus far discussed interact to inform strategy will always depend on the details of each case. Nevertheless, how this may play out can be illustrated by the following hypothetical examples, which are inspired by real-life scenarios.

#### (a) *Start-up 1: early stage*

Company A has developed a new internet-delivered service. The company has very few employees other than its directors and at this stage requires very little capital investment to operate. The main focus is on developing its own intellectual property (IP), which is considered the main asset. Limited resources and a high tolerance for risk suggest a light-touch freedom-to-operate clearance. Working with its technical

people and subject-matter experts, using an amount of in-house developed keyword searching and industry knowledge, a search is carried out and filtered to a shortlist of about 20 patents, in respect of which the company is not certain that they can be ruled out. A session is scheduled with the company's outside patent counsel to discuss potential issues connected to the identified families in an all-day meeting. The outcome finds at least one apparent differentiator for each considered patent, so that no immediate concerns are identified. A number of potential issues are identified that may become relevant with future developments and these are documented. A document detailing the findings and explaining the results in terms of risk management is produced for investors. Company A and its investors are aware that this outcome is based on a very limited amount of investigation, but they are happy with this in the context of the overall risk profile.

***(b) Start-up 2: investor demands***

Company B has been engaging in research and development (R&D) for some time and is in the process of arranging a further funding round to set up a proof of concept plant. Freedom to operate has not been considered a high priority, but investor demands for information on freedom-to-operate risk need to be addressed now. In an attempt to save costs, the company produces an in-house search using patent classifications, which retrieves a large number of documents. Discussing the approach with outside patent counsel, the potential pitfalls are explained and a search is commissioned. This search takes the in-house search as a starting point, but in reviewing the search strategy it becomes clear that important areas of classification have been missed. Working in collaboration with the searchers and patent counsel, a new strategy is developed with the searchers providing a retrieval-only search for manual filtering by technical experts in-house at the company. This results in a cost-effective update of the search, making use of technical resources available in-house. In the end, only a small number of documents are identified as potential concerns and passed to the patent counsel for further study, together with leads for potential invalidity attack. A report is produced that manages to classify all documents of concern as low risk based on a combination of infringement and validity analysis, but also consideration of the fact that the patentees in question are not competing in any field even vaguely related to the activities in which Company B is engaged.

***(c) Small- to medium-sized company: tool manufacturing***

Company C operates in a marketplace where there are a limited number of competitors well known to it. Patenting activity is mostly low, apart from one of the company's competitors. Historically, the company has not engaged in freedom-to-operate analysis, on the experience of operating in a market for decades without seeing any significant patent litigation activity by its competitors. However, in starting a new project, the company becomes concerned with a particular competitor having large market share in a field it would like to enter. The competitor's portfolio is analysed in detail and full legal opinions are

obtained where issues are detected. After several rounds of design changes to avoid potential infringement problems, market entry can be cleared.

**(d) Multinational corporate: electronic communication devices**

Company D is a large multinational corporation that manufactures and markets electronic devices. Increasingly, these devices are networked. While the company is actively developing its own patent portfolio, it is concerned that this is ineffective against patent threats in the communications area, in particular from NPEs. A process is put in place to consider freedom-to-operate issues early in the company's standardised development process, following proof of concept, with updates scheduled at all key process stages, with a final assessment and clearance prior to tooling. Freedom-to-operate analysis is focused on new features where there is no historical in-house experience of the patent landscape. For these features, the analysis is outsourced, but is managed by the company's in-house department.

#### 4. Evaluating freedom-to-operate risks

Having established a freedom-to-operate strategy, in particular regarding the trade-off between risk and cost, how should you go about establishing freedom-to-operate risks? The process can be broken down into four main components:

- searching for relevant third-party patents;
- analysing what is found;
- based on that analysis, evaluating risks; and
- deciding on any actions to be taken.

##### 4.1 Clearance searching

The first step in evaluating freedom-to-operate risks is to search for third-party patents that may be relevant to the planned activity. Such a search is fundamentally different from the kind of prior art search that is carried out by patent offices when they search your own applications for patents (or when you search in advance of filing applications to establish whether a new idea may be patentable; or when you search for material to invalidate a competitor patent).

**Table 2: Different types of search**

Prior art search	Freedom to operate search
Looks for all documents published prior to a relevant date (today, the filing priority date of the application/patent in question)	Looks for granted patents that may yet be in force and, usually, pending applications
Looks for disclosures that may be relevant to the claims you wish to pursue	Looks for claims that may be relevant to the product that is subject of the freedom to operate search
Not necessarily only patents documents	Patents documents only

A frequent false assumption is that if you have a patent application covering the product to be cleared, a lack of relevant documents in a patent office search report indicates that there are no freedom-to-operate issues. While the patent office search may turn up a document which, on analysis, represents a freedom-to-operate risk, the converse is not true. For a thorough freedom-to-operate analysis, a separate search taking account of the above parameters must be carried out.

Patent searches (both prior art searches and freedom-to-operate searches) are best done by dedicated patent searchers or information experts with experience of searching for patents in the relevant field. This is because patent searches can be more complex than you might suppose. Keyword searches are rarely reliable enough for searching for certain subject matter and an experienced patent searcher will know how to navigate the subject-matter classification applied to patent applications and granted patents by patent office examiners (discussed below). Even when searching for identified competitor names, there are pitfalls. While it is important to use specialists with the right skill set to carry out the search, it is also important to understand the issues involved in order to be able to use the search in an informed way.

Engaging in a freedom-to-operate search is by definition a difficult proposition, as it sets out to prove a negative: the absence of relevant patents. It thus follows that a freedom-to-operate search will always be, to some extent, open-ended, as it is always possible to search more and in further detail. The right level of search, as a trade-off between the cost and comprehensiveness of the search, therefore needs to be developed in collaboration with the patents searcher and patent attorney involved.

What follows is intended to give a sense of the issues involved and how they affect the trade-off between cost and comprehensiveness. The following sections thus provide a brief summary of some detailed points about searching for freedom to operate.

**(a) Subject-matter search**

The most comprehensive kind of search is a search that looks for patents related to the subject matter of the product or activity to be cleared. This is consequently also the costliest kind. There are various ways in which technical subject matter can be searched, but common to all is a necessary preliminary step to define what needs to be searched. If a product contains a single new feature that has not previously been cleared, defining the subject matter to be searched is easy. If several features or aspects of a product need to be cleared, the search correspondingly will be more complicated. In fact, where a product contains several independent features, a comprehensive clearance may require a corresponding number of independent searches and subsequent analysis.

As mentioned above, there are various ways in which technical subject matter can be searched in patent documents – in particular, searching by patent office subject-matter classification, for example, International Patent Classification (IPC) or Cooperative Patent Classification (CPC) codes, or keyword searches. These are briefly discussed in turn.

A classification search makes use of the subject-matter organisation applied to patent documents by patent offices around the world, which effectively provides a subject-matter tree that can be used to identify collections of potentially relevant



patents. Since features of a product or activity may be classified in several classifications, and since the classifications are rarely perfect or can be inaccurate in places, expert knowledge of patent classifications in the relevant subject-matter field is essential. With expert knowledge, using the classification system, a body of patent documents can be identified for further analysis.

A keyword search does just what would be expected: the text of patents documents is scanned for search terms and it is designed to retrieve relevant documents. At first glance, this may seem a comprehensive approach, as it does not rely on (potentially false and misleading) classifications. In fact, designing keyword search strategies that are specific to a desired subject matter without risking excluding potentially relevant material is very difficult, if almost impossible. Therefore, searchers tend to employ keyword searches as a back-up strategy where a classification search would result in an unmanageable number of hits to be analysed.

Any search strategy – be it based on a classification search, a keyword search or a combination of the two – will involve an amount of manual searching through automatically retrieved hits. This is because any automatic search strategy that retrieves a sufficiently small number of documents to be analysed in detail would almost certainly miss potentially relevant results. In practice, then, the gold standard of a freedom-to-operate search employs a strategy that returns a broad collection of documents by retrieving results in classifications at a level of detail aimed to minimise the risk of missing relevant documents in related classifications. This should be followed by a manual search through the retrieved documents to narrow a typically large set of results to a manageable number of hits that can be analysed further. Given that the most time-intensive part of such a search is the manual review, this approach will be costly. Where the cost would be prohibitive or a manual search through the set of hits simply not practical, relatively broad keywords can be employed to reduce the amount of manual filtering required and therefore reduce costs.

**(b) Name search**

As already discussed, a subject-matter search can be fairly open ended and possibly retrieve a large number of documents that need to be manually filtered. In situations where the competitive landscape is well known such that there are a limited number of possible competitors of concern, a less costly approach can often be to search for patents held by identified competitors. If a large number of patents is held by a competitor, this can be combined with a classification search, or an amount of competitor searching can be used to reduce the number of hits in a subject-matter search. As a further variation, where a particular field is associated with a number of limited inventors, a name search can be carried out by inventor names. This also has the advantage of capturing documents by the same inventor, irrespective of whether that inventor has moved jobs.

The clear risk associated with a name-limited search is that patents not associated with the searched names will be missed.

A name search can nevertheless provide a cost-effective alternative or addition to a subject-matter search. However, while searching by name seems straightforward, there are some subtleties in accounting for possible spellings and assignments of the

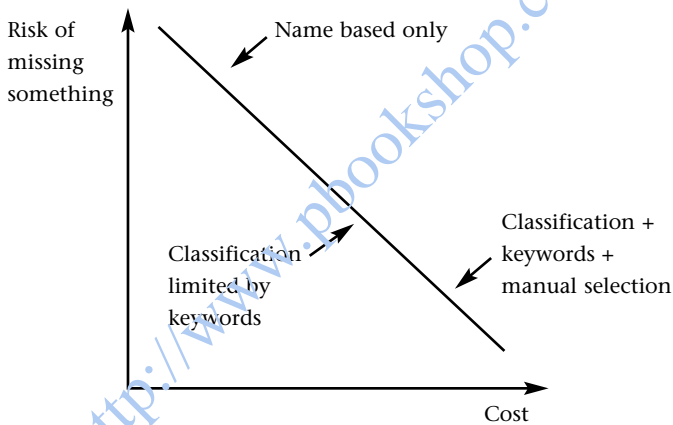
patents in question, so it is advisable to engage the services of an information expert even for a seemingly simple name search.

(c) **Geographical coverage**

As is discussed elsewhere in this book, patents are national rights and must be analysed jurisdiction by jurisdiction. This also means that if there are no activities to take place in a given jurisdiction; there is no need to search for and analyse patents in that jurisdiction. The number of search results retrieved can therefore be limited by focusing only on relevant jurisdictions. For example, if the main markets are, say, the United States and a selection of European countries, costs can be saved by limiting the search to these countries and not specifically searching in countries where activities are less significant.

The cost/risk graph is reprised here to illuminate how different approaches fit in with this from work.

Figure 2: Cost v Risk take-off (searching)



4.2 **Understanding search results**

Any professional searcher or information expert will provide a detailed outline of the search strategy employed together with the search results. While it is tempting to ignore this document, it is important to understand what has been done to be sure that the search is fit for purpose. Understanding how the search has been carried out is crucial to interpreting the results. Furthermore, there are a number of potential pitfalls to be wary of.

(a) **Patent families and abstracts**

A patent is a national right. Patentees rarely file in only one jurisdiction. They usually use a first filing in a home jurisdiction to file patents for the same matter abroad. Such a collection of patents (and patent applications) is referred to as a patent family. To make the amount of information manageable, search results are typically presented family by family, with a representative family member providing

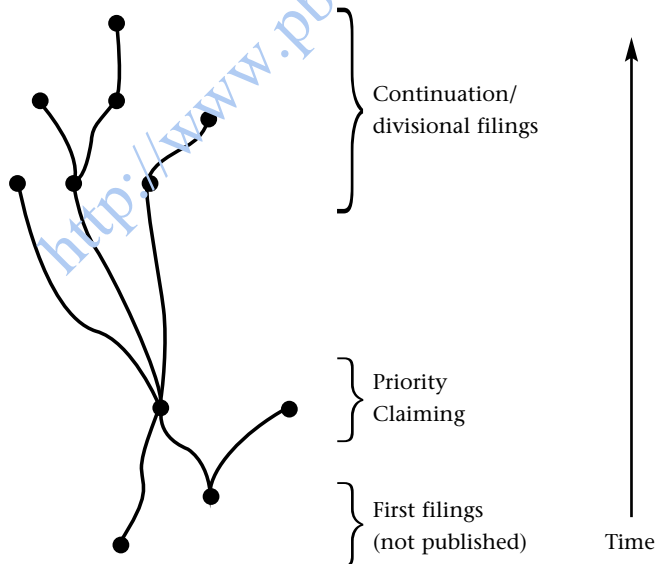
headline information and reference information only being provided for the remaining family members. In this respect, it is crucial to remember that the claims can vary between family members, even if the general disclosure is the same. Since the variation of even one word can have a significant impact on infringement and validity, one cannot fully rely on the representative family member being presented to rule out a whole family. On the other hand, as a matter of practicality, it is typically not possible to review all documents in detail.

As a practical solution, it is therefore often expedient to review patent families using a representative member and consider the family further if this information indicates that there is a possibility that the family could be relevant.

Often, it is expedient to make this initial triage based on the abstract of a representative family member, on the basis that this is a summary of what the family relates to. This is not without risk, since the abstract does not necessarily reflect that which is claimed. However, as a tool for initial triage, a brief look through the abstract and drawings of the representative family member can provide an indication of whether the family could potentially be relevant or is so unrelated that the likelihood of one of the family members having a relevant claim is sufficiently small to be ignored. As with most issues discussed here, there is a trade-off between costs and risk in this review.

By way of illustration, a complex patent family is shown in Figure 3.

Figure 3: A (complex) patent family



(b) *Patent applications*

Because pending patent applications may one day mature into a granted patent, a comprehensive freedom-to-operate search should also retrieve relevant pending

applications, not only granted patents (although excluding pending applications may be one way to control budgets). This raises a number of issues: although a pending application may eventually grant, it may not, so assessing the risk it poses also requires an assessment of the likelihood of grant, which may not be straightforward. Even if the application eventually grants, the claims are relatively likely to change during prosecution from the version as filed/published, which would be the version retrieved. Keeping in mind the concept of a patent family illustrated above, there is also the possibility that further applications (divisionals, continuations) will yet be filed.

Pending patent applications therefore represent a moving target, requiring analysis not only of what the claims are now, but also where they may end up. Counter-intuitively, the analysis of pending applications is thus more involved than the analysis of granted patents in a freedom-to-operate search.

(c) **Publication delay**

As discussed elsewhere in this book, a patent application typically does not publish until 18 months from when it is filed. This means that there will be 18 months' worth of patent applications pending when a search is carried out. Nothing can be done about this, but this is worthwhile bearing in mind. This is particularly so if you are aware of competitor activity and looking for competitive patenting activity that could, in time, become relevant to your freedom to operate. In this context, there will thus be an 18-month window of uncertainty.

(d) **Status information**

Status information for patent applications and granted patents is, in our age of information, relatively easy to get from patent office online databases. Clearly, a patent application which is no longer pending or a granted patent no longer in force (eg, because renewal fees have not been paid or the patent term is up) pose no risk to your freedom to operate. At first glance, it therefore seems effective to limit any search retrieval to pending/in force patents or applications. However, in practice, this information is not reliably integrated in search databases and retrieving it therefore involves a significant amount of manual work. It is thus often more efficient to have a first pass of triage to filter out clearly irrelevant patent families and only obtain status information for patents in families that remain.

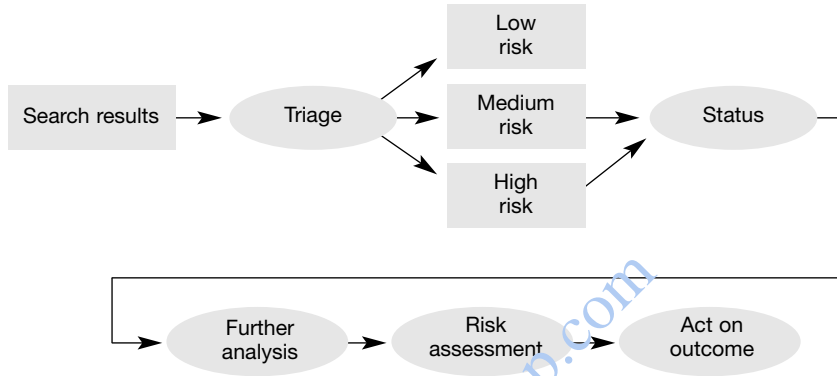
As an important caveat, the online status information mentioned may not always be reliable and it may be that seemingly lapsed applications or patents can still be revived under the respective local law. Therefore, relying on online databases is a useful tool, but it is not completely without risk. If a patent family of particular relevance is found, it would be advisable to confirm status information with local counsel.

#### 4.3 Infringement analysis

Once a set of search results is obtained, it becomes necessary to investigate whether any of the patents and applications found pose a potential threat. Conceptually, this can be broken up into one or more rounds of triage, followed by further analysis

where this may be necessary. What follows is not intended to be prescriptive, and different approaches may be appropriate or necessary depending on circumstances. However, approaches along the following limits have been found to work well in practice.

**Figure 4: A FTO process**



**(a) Triage**

Since any freedom-to-operate analysis is an exercise in risk management, rather than finding certainties, a first pass through the search results could classify each patent family into one of three categories: low risk, medium risk or high risk. This could be done on the basis that, for example, if a patent family is clearly unrelated on the face of it, it is classified as low risk. If, looking only at the family information, it seems that it could be relevant, it is initially classified as medium risk. If it appears that the family is likely to be relevant, it can be classified as high risk.

In a second round, status information can be obtained from medium- and high-risk families and the risk level updated accordingly. Starting with any remaining high-risk families, live family members are then looked at individually to see whether the product or activity can be distinguished from the respective claims – that is, the claims recite at least one feature clearly not present in the product or activity. If the difference is significant, it may be possible to reclassify the document in question as low risk; if in doubt, it can be reclassified as medium risk and if no differences are found it remains as high risk. Medium-risk families can be reclassified document by document in a similar manner.

At the end of the triage, there will be one pile of low-risk documents, not to be analysed further; one pile of medium-risk documents that may need to be looked at further with a view to reclassifying as low or high risk, possibly with the aid of outside counsel; and a hopefully small or non-existent pile of high-risk documents.

In summary, the purpose of a triage along the lines described above is to identify those search results which are clearly unlikely to be of concern, those for which further clarification is necessary and those which are clearly of concern and need to be dealt with further.

**(b) Further infringement analysis**

Given the number of results that are typically found in a freedom-to-operate search, a full legal opinion analysis of all search results is clearly neither practical nor appropriate in the context of a risk management exercise. However, where a patent application is perceived to represent a potential threat of significance following triage, further detailed legal analysis may be necessary, potentially including an investigation of the validity of the claims in question, in order to elucidate whether the risk perceived at first pass is real.

Whether a patent claim is held to be infringed depends on whether the adjudicating court believes that all elements of the claim are present in the alleged infringement. This is straightforward only in a few cases and is often a question with significant interpretative leeway. While some claims can be dismissed if a claimed feature clearly is not there, for others the analysis needs to assess whether a court would be more likely or not to hold a claim infringed. The closer an alleged infringement is to what is claimed, the less certain a finding of likely non-infringement.

As already established, patents are national rights. While patent systems around the world have much in common, there are significant differences. For increased certainty, again at increased cost, it may be advisable to consult local patent counsel for any high-risk patents found if the budget and commercial importance warrants this. Thus, the disparity between national patent systems is in effect another risk factor that can be reduced by spending resources to elucidate the infringement risk specific to the country in question. In practice, this may not need to take the form of a formal opinion, but an initial view from local counsel can often be helpful and provide some comfort without the expense of a fully worked-out legal opinion.

**4.4 Risk analysis**

The previous sections were concerned with infringement risks – that is, the legal question as to how likely a court in a relevant country would find a patent to be infringed by the proposed activity or product. Without suggesting that a patent that is clearly infringed should be wilfully ignored, the business risk is also clearly determined by the commercial context. A higher risk of an infringement finding might be acceptable where the likelihood of patentee bringing an action is low, for example, where the patentee is not a competitor and is operating in a completely different field. For instance, a white goods manufacturer is more likely to enforce (and not accept a licence) against another white goods manufacturer than against a company making refrigeration units for scientific research only.

If the risk is found to be real and significant at the end of this stage, a decision as to how to deal with this situation is needed, the extreme outcomes being to knowingly take the risk or to abandon the product or activity at risk. Between these positions there are ways in which freedom-to-operate risks can be mitigated and these are discussed below.

**5. When to evaluate risks**

To state the obvious, it makes sense to engage in a freedom-to-operate analysis only

if the outcome can still affect future actions. It is therefore imperative that if you to decide that a freedom-to-operate analysis to manage third-party rights risks is appropriate, the analysis be carried out at a point in time where you are not yet fully committed to the product or activity in question, so that if the worst comes to the worst, all options can be considered. Thus, it makes sense to consider freedom-to-operate analysis at a stage where the project is not yet fully engaged. On the other hand, the project must have progressed sufficiently far so that reliable information about what the product or activity will end up like is available, since the freedom-to-operate analysis would otherwise chase a moving target. Therefore, an appropriate time to engage in freedom-to-operate analysis could be subsequent to design freeze, before significant tooling and production resources are invested in the case of a manufacturing business. Other milestones may be appropriate triggers for a freedom-to-operate analysis, depending on the circumstances. Perhaps an amount of freedom-to-operate risk analysis may have to be carried out in order to complete an investment round.

The initial timing when to carry out freedom-to-operate analysis is clearly important. Further, neither the patent landscape nor, usually, the product or activity in question will stay the same forever. Therefore, the best freedom-to-operate analysis will eventually become outdated and it is good practice to schedule a periodic update of any freedom-to-operate analysis, depending on the speed with which changes are anticipated. Of course, there may be freedom-to-operate projects that are one-off, such as in the context of due diligence for a potential acquisition. However, if one is concerned with freedom to operate over a longer timeframe, periodically updating the analysis will ensure that changes can be managed.

## **6. How to mitigate risks**

Between the two extremes of ignoring any risks and seizing all activity in question, a number of measures can be taken to mitigate freedom-to-operate risks. The presence of possible mitigation strategies effectively lowers the risk profile. Even if not engaged proactively now, they may be available later on in the event that any risks materialise.

### **6.1 Design around**

A patent represents a potential freedom-to-operate risk if there is a threat that a court would find that all features of at least one claim of the patent are all present in the product or activity in question. Should such a risk be present, if the product or activity can be changed so as to be clearly outside the scope of the claim, the risk has been mitigated. This may be relatively easy where the feature in question is not central to the commercial value or can be replaced or changed without significantly affecting the value, and when the change can be carried out relatively easily. For example, a smartphone app that can be changed simply by issuing an updated version may readily be changed if a threat materialises. On the other hand, a design around may be more consequential – for example, if there is a need to change tooling or manufacturing processes.

## 6.2 Negotiate

If the patentee is not a direct competitor with a vital interest of excluding you from the market, the option of obtaining a licence can be a risk-mitigating strategy. This may be applicable in particular where the patent in question is a standards-related patent for which a licence on fair, reasonable and non-discriminatory terms is available. Whether the licence should be sought proactively or whether the potential availability of a licence is taken into account in evaluating risk will depend on the commercial circumstances and the perceived magnitude of the infringement risk.

## 6.3 Attack (or be prepared to attack)

A granted patent will represent a freedom-to-operate threat only if it has a claim which is not only infringed, but also valid. Therefore, one way to mitigate a freedom-to-operate risk is to attack the patent or prepare for such an attack. This can be done by researching potential prior art that can be used to invalidate the patent – for example, using a combination of in-house technical expertise and third-party searchers. If prior art is found which clearly invalidates the patent in question, the risk is to a large extent mitigated (however, see further on this below). Even if prior art is found on the basis of which the validity case is more balanced, this changes the balance of power.

The question of what then to do with any uncovered attack or attacks does not have a straightforward answer. On the one hand, clearing the way proactively, if successful, provides certainty, even if it brings legal costs forward, by definition. On the other hand, being well prepared also has advantages. Legal costs are deferred or possibly not incurred if the validity attack can be used successfully as leverage in future negotiations. Further, a patent that is judged as low risk due to its vulnerability will still look like an obstacle to competitors. Being fully prepared for any eventuality by not immediately acting on the identified attacks keeps the benefit of the information gained to yourself. Actively clearing the way, while possibly giving you legal certainty, benefits everybody but the patentee in question and therefore shares the benefit of investing in an invalidity attack with your competitors.

The answer to the question of when information gained should be used thus involves a trade-off between legal certainty (including for other competitors) and competitive advantage. Many specific factors will determine the answer to the question to defer or not to defer, but a universal factor will be how the relevant patent systems concerned treat infringement and validity questions. Where the courts hear validity and infringement together (eg, in the US and the UK), the case for being fully prepared is stronger because no effective decision on infringement will be reached by a court before a validity defence has been considered. In other jurisdictions, notably Germany, infringement and validity are heard by separate tribunals and it is common for defendants to be faced with an enforceable decision on infringement long before a decision on validity is reached. Such circumstances mitigate in favour of clearing the way.

While at first glance it seems advantageous to keep the investment in developing invalidity attacks to oneself rather than to clear the way (not only for oneself, but for everybody), detailed tactical considerations, in particular regarding the constraints



imposed by how patent disputes are dealt with in a particular jurisdiction, will have to be taken into account.

#### 6.4 Stockpile

Inspired by cold-war doctrine, the threat of attack can often be an effective defence. Thus, building an effective patent portfolio that can be used against competitors if needed will provide negotiating chips in case of attack. Having an effective patent portfolio can thus also mitigate for freedom-to-operate risks where competitors are concerned. However, the threat of counterattack is ineffective if the patentee in question does not engage in significant activities that can be covered by your portfolio, *in extremis* if the patentee is an NPE which engages in no other activity besides monetisation of a patent portfolio.

### 7. Chapter summary

- Others enforcing their patent rights against you is a risk to your freedom to operate – just as you may seek to enforce your patents against others, so may they.
- You can take measures to understand and manage this risk, but never fully exclude it – proving a negative is always hard.
- There is no one right approach to dealing with this risk – the more resources invested in clearing risks, the higher the likelihood that any problem will be uncovered. Depending on your circumstances, there will be a level that is right for you.
- The key is to understand the risks associated with any problem found, as well as the risk of missing something relevant. The right strategy will enable informed decision making based on an understanding of the risk.
- Having defined a strategy and understood the risk, you should act on the results: if all is clear, go forth. If problems are found, be prepared to deal with them – or you will need to make an informed decision to take the risk.
- Timing is important: it only makes sense to clear risks if you can/will still act on the results. Again, risk management needs to be an ongoing process as part of your IP strategy.
- Investigating risks not only allows you to plan and allow for any risks uncovered but also to take mitigating action.

Risks associated with patent rights of others cannot be eliminated; but they can be managed. Understanding of these risks enables decision-making and, if necessary, mitigation.

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