Application Of Enterprise Risk Management (ERM) Principles To Patent Freedom-To-Operate (FTO) Analysis: A Novel "IP-RM" System

By Gillian M. Fenton

■ Gillian M. Fenton, Esq, CLP
Fenton IP Solutions LLC,
Managing Director,
Potomac, MD, USA
E-mail: gfenton@fentonipsolutios.com

Intellectual property (IP) is an integral component of business strategy in many industries, and for many types of enterprises ranging from startups, to emerging companies in growth phase, to mature companies that may be considered an attractive target for IP litigation. Certainly this is true in life science fields, particularly for biotechnology and pharmaceutical innovator companies, where IP is often a significant component of corporate value. A robust IP strategy should encompass at least three dimensions of activity:

1. Asset management, including capture or harvesting of newly created IP rights and portfolio development, maintenance and alignment to business objectives;
2. Freedom-to-operate (FTO), including the investigation, identification and management of third-party proprietary rights that present risks of blocking or hampering achievement of business objectives; and
3. Value extraction, or the use of IP assets to attract or secure investment in the form of financing, capital raises, licensing, and monetization.

There is, however, a wide variation in the skillfulness with which businesses harness the potential value of IP, and this is critically dependent on the abilities of in-house IP counsel to communicate complex and nuanced concepts of IP law to colleagues in other disciplines. This article proposes a framework for cross-disciplinary communication and management of FTO issues to better align IP strategy with overall business objectives. The present model system has been developed for use in the biotechnology and pharmaceutical industries, where product development typically takes years, sometimes even a decade or more, and commercialization is subject to licensure by a regulatory authority, such as the U.S. Food and Drug Administration (FDA). Nonetheless, many of the principles utilized will be relevant to other industries and other types of products.

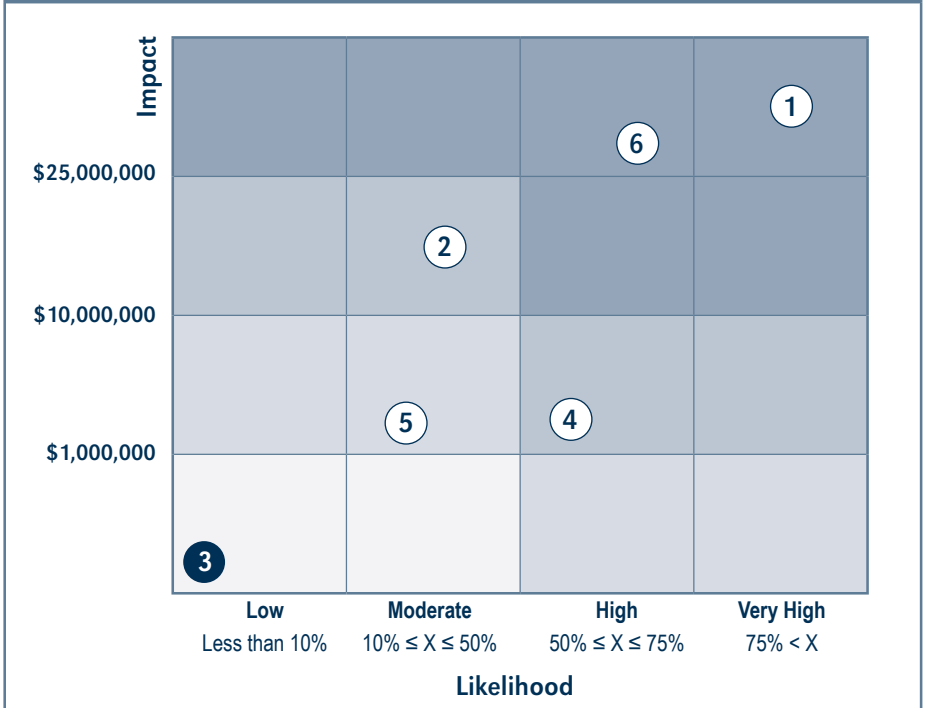
Need for a Systematic Framework

In-house IP counsels must be prepared to tackle a broad range of IP issues, and to communicate these in a meaningful manner to executive management, as well as to colleagues in different disciplines, ranging from research and development, to manufacturing, finance, marketing and compliance. It is particularly important to communicate meaningfully with C-suite level executive management, and with colleagues in corporate legal functions and corporate compliance. The objective in each case is to facilitate informed decision-making about IP issues, both opportunities and risks. It is not realistic for IP counsels to expect that colleagues from a broad diversity of other professions will become fluent in the language and concepts of IP; rather, IP counsels must learn to communicate using terms and concepts that are more broadly understood across business functions. One such conceptual system is Enterprise Risk Management (ERM).[1] ERM is a systematic approach to identifying, triaging, and managing all identified risks to a commercial enterprise and/or business strategy. In a typical ERM campaign, the organization conducts one or more workshops, to which managers in diverse business functions are invited and participate in identifying risks and concerns that affect their business activities. Workshop participants then vote on the relative magnitude of each risk, the likelihood of encountering the risk, and the urgency of addressing it before further executing on the business plan or corporate strategy. What emerges is a risk map, in which identified risks are plotted on a grid according to their likelihood of occurrence (the x-axis) and materiality; *i.e.*, the magnitude of potential harm (the y-axis). An example risk map is shown in Figure 1.[2] Risk maps enable the intelligent allocation of resources to address the most pressing threats to the business. Management of each risk, which may include proactive mitigation, a change in business practices, or simply periodic monitoring for a change in

1. For a general overview, see *https://en.wikipedia.org/wiki/Enterprise_risk_management* (last visited 22 May 2016). For a primer on the relevance of ERM to in-house legal practices, see "Enterprise Risk Management & Assessments Add to Legal Department Arsenal," by *Hilton and Jenkins, ACC Docket*, pp. 35-41 (January/February 2016).

2. Based on an Excel tool kindly provided by Core Risks Ltd. (*http://www.corerisksltd.com/* (last visited 22 May 2016).

Figure 1: Example 2-Dimensional Risk Map For A Hypothetical Biological Product Showing 6 Risks, One Of Which (Number 3) Has Been Mitigated



circumstances, is then assigned to a risk owner. In the case of IP FTO risks, in-house IP counsels are ideally suited to be risk owners. Risk owners report in regularly to executive management, which facilitates long term strategic planning and periodic reassessment. Because ERM is broadly cross functional and seeks to provide a commonly understood set of defined terms and concepts, it is a valuable tool for IP counsels to use in communicating across in-house business disciplines.

So how does ERM intersect with the FTO aspect of IP strategy? Broadly speaking, FTO should be understood to encompass two distinct types of activities: investigation and risk management. FTO investigative activities are conducted for the purpose of identifying third party patent rights that are potentially relevant as risks (threats) to the pursuit and realization of business goals for the commercialization of technologies and products. FTO risk management activities have the goal of reducing the likelihood and/or impact of the identified risks so that commercial goals can be achieved with little to no adverse impact being experienced from the assertion of third party patent rights. ERM principles and communication tools can be used to support both phases of FTO activities, but first become relevant when communicating the results of FTO searches to executive management. The ERM framework then assumes a central role throughout the risk management phase. In-house counsels should find that applying ERM principles and terminology will facilitate an understanding of IP strategy and in particular, foster alignment and approval by executive management of risk mitigation projects and expenditures that support key commercialization objectives.

Let's next consider the main activities of patent FTO strategy using the example of a biologic therapy that is subject to U.S. FDA licensure.

FTO Investigative Activities

The investigative phase of patent FTO is normally performed using applicable public and proprietary subscription databases of patent information. A variety of searching and data analytical platforms have been developed in recent years.[3] The goal, generally, is to identify third party patent rights that are relevant to the product or technology under investigation. There are practical benefits to separating the activities—and budgets—for conducting searches from the activities and investments needed to address the identified risks. FTO searching and FTO risk management should be separate line items in the in-house IP budget. This permits flexibility in the timing and handling of business investments to support IP strategy. For example, the business may enter into a collaborative development agreement in which part or all of the FTO investment may be shared, or assumed by the development partner. Also, tracking searching and risk management separately may help to "smooth out" year over year fluctuations, which may be useful in meeting internal financial expectations.

Many businesses seek to scale their investment in a particular product or technology in a manner reflective of its stage of development or prominence in the product pipeline. While this is not often feasible when investing in patent assets (for the obvious reason that

3. For a curated listing of available offerings, see *http://piug.org/vendors#Database_Producers* (last visited 22 May 2016).

U.S. and international patent laws strongly incentivize early patent filing, which then triggers a cascade of due dates for investment in foreign filing, etc.), it is both feasible and desirable to do so when conducting patent FTO strategies. Searching activities can be aligned in terms of scope and timing to the development stage and progress of the underlying product or technology. Ideally, management's decision to progress a product candidate through a development stage gate that calls for a significant discontinuity in investment in the product/technology should be informed by a current FTO search. Thus, a patent FTO investigation program should commence with a preliminary landscape search early in development, followed by a cascade of progressively more rigorous and comprehensive searches as the product progresses through the development pipeline. Spreading out patent FTO searching activities in time provides several benefits. First, it reflects the fact that not all aspects of a single pipeline product will be "ripe" for searching at the same time. Second, it addresses management's questions on why the business should invest in FTO searching on early stage products that may fail in development: the overall FTO search program is scaled in terms of scope, rigor, and timing such that major expenditures will only be made on successful pipeline products that have the greatest chance of surviving to achieve commercialization.

The typical FTO search program for a novel biologic therapeutic agent will include the following types of searches:

Patent Landscape

A patent landscape search is a simple, subject matter specific query designed to identify clusters of innovative activity relevant to, for example, a research lead selected for exploratory development. Within the world of FTO searching, landscapes are suitable only for early-stage development, and may be carried out as soon as a meaningful search string can be formulated. Landscape search results can be used to help prioritize among different research leads or proposed development projects, and to optimize development strategies. At the early stage of development where landscapes are used, third parties active in patenting technology in the field may be as likely to be development partners (opportunities) as they are to be obstacles (risks). Only the most exceedingly risk averse companies will abandon promising research based upon the results of a landscape search.

Module One: Product Active Components

As noted above, not all aspects of a specific product candidate become ripe for FTO searching at the same time. The aspect(s) that are typically ready for searching at a particular time are, for convenience, referred to as modules. While there is no rigid definition of a specific module, or the number of modules needed to achieve overall FTO clearance of the product candidate, searches of biologic therapeutic agents are often grouped into four modules. Since the identity of the biologically active component(s) and of its structure and function are selected very early in the course of development, searches covering these aspects of the product will be referred to as "Module One." This module typically includes the active biologic or pharmaceutical ingredient(s), the biologic target or pathway that is affected by the active ingredient(s), the primary indication for use, any platform technology that was used to create the active ingredient, the general structural class to which the ingredient belongs, any ancillary active ingredients (*e.g.*, a vaccine adjuvant), and any other features, components, or methods that are envisioned to be practiced by the end-user of the product when commercialized. The scope of Module One should reflect the desired Target Product Profile used in defining the development project when proposed to executive management for approval of the investment in early stage development.

Module Two: Construction and Provenance

A second area of subject matter that can be defined early in development and forms a distinct module for search purposes encompasses source materials, research tools and construction methodologies that may have been used to create the product candidate but will not be actively practiced throughout development or commercialization. This Module Two may include, for example, proprietary source materials such as cell lines, viruses, bacteria; gene, transcript or protein sequences *e.g.*, of the biological target of the active ingredient(s); phage display or other libraries of biological materials or information; molecular biology tools and techniques; expression systems; assay technologies; in vitro and animal model systems, and the like. Ideally, Module Two covers all upstream obligations to providers of proprietary starting materials and research tools. There are several practical and legal reasons why it is useful to separate Module Two from Module One searches; for example, because statutory protections against patent infringement liability may not apply, or may apply differently, to subject matter within Module Two versus Module One. The safe harbor from patent infringement liability provided in 35 U.S.C. § 271(e)(1) will be discussed more fully below.

Module Three: Commercial Formulation and Presentation

Pharmaceutical and biologic formulations can be complex, and it is customary to design and test several in parallel for suitability with a particular active ingredient. Tests may include stability, solubility, bioavailability, biocompatibility and other desired properties, and may include a battery of in vitro and in vivo studies. While formulations may offer scope to 'design

around' third party patent rights, FTO searching can become unduly complex (and therefore expensive). Multiple components, combinations and recipes frequently require investigation, as do processes geared to produce different physical forms of the formulated composition. For example, a typical formulation search might include candidate excipients, stabilizers, liquid and lyophilized forms, spray or foam drying techniques, etc. The same is true of candidate drug presentations, which might include pills, capsules, lozenges, drinkable liquids, injectable or infusible liquids, injection devices, transdermal patches, inhalers, creams, or ointments. In the face of such complexity, it may be best to defer Module Three FTO searches until the formulations development team has selected the top three-five candidates for in-depth evaluation.

Module Four: Commercial Manufacturing Process

Normally the last module to be defined in biologic drug development is that covering all material aspects of the manufacturing process that is proposed for FDA approval. This Module Four should include all steps and processes required for manufacture of the commercial product, including if applicable, host cells, cell culture steps and conditions, downstream purification steps, and analytical techniques and criteria that will be used to support release of lots for commercial sale. As with drug formulation and presentation, early manufacturing development often involves testing a number of different approaches that may not be found suitable for the commercial process; thus, it is important to liaise closely with the manufacturing development team to understand the nature and status of decision making in selecting the final commercial process.

Pre-Launch Clearance Search

In the biopharmaceutical industry, risks associated with patent FTO are normally highest when a candidate biologic has reached late clinical development through regulatory approval, product launch and early adoption in the commercial marketplace. Several factors operate to magnify risk during this period: the innovator company has made significant financial investments in the product, which may by now be deemed material to enterprise value by investors and market analysts. If the innovator company is publicly traded, rules of the U.S. Securities Exchange Commission (SEC) or a foreign equivalent agency will require disclosure of certain information about the product, potentially attracting the interest of third party patentees. Information concerning the new product is typically also published at scientific and biomedical conferences and in scientific literature in order to develop a positive product reputation and facilitate future commercial adoption. Also, at this point in the regulatory approval process, FDA is unlikely to accept significant changes in the product, its manufacture, formulation, presentation and indication for use, without requiring substantial additional investment in clinical trials; thus, the innovator has little scope for using a 'design around' strategy to manage patent FTO risks. Finally, the innovator's risk exposure culminates upon receipt of regulatory approval by FDA as this event typically signals the end of applicability of 35 U.S.C.§ 271(e)(1), colloquially known as the Bolar Exemption,[4] which provides bio- and pharmaceutical drug developers with a Safe Harbor from patent infringement that accommodates the regulatory oversight and approval process by FDA.

For these reasons, it is considered customary best practice to conduct a thorough patent FTO investigation prior to commercial launch of a new drug or biologic. This pre-launch clearance search is typically the most rigorous and comprehensive search carried out on the candidate drug or biologic, and encompasses all subject matter previously explored in the modular searches carried out earlier during development. Indeed, many firms will outsource the searching responsibility to a professional searcher who has not previously conducted the modular searches in hopes that a 'fresh pair of eyes' will uncover any FTO risks that may have been missed. The pre-launch clearance search is conducted prior to encountering the first anticipated commercial activity with the new product, *i.e.*, the first event that is reasonably believed to fall outside the scope of the Bolar Exemption. The pre-launch search should encompass each key feature or component of the product (active and inactive ingredients), key starting materials, manufacturing technologies and intermediates, release assays, research tools, clinical indications and methods of use, formulation and presentation, probable combinations with other drugs or biologics, and the like. This search should also cover key competitors, collaborators, prominent investigators in the field, and potentially dominant technologies. The patent assertion/litigation histories and prior licensing practices of key third party patentees should also be investigated. Assignment history and maintenance fee payment records should be checked for the most significant identified patent risks. These factors are representative, not exhaustive, as every drug/biologic candidate and its circumstances are unique.

Timing and Updating FTO Searches

Patent counsel will find that it is important to communicate to business leaders and decision makers that establishing patent FTO for a new drug or biologic is not a 'one and done' type of exercise; rather, it is an ongoing activity that requires vigilance throughout the arc of new product development and commercialization. Once a specific FTO search has been performed

4. From *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 221 USPQ 937 (C.A.Fed., 1984).

for the first time, it should be periodically updated until superseded or until the corresponding product is no longer of interest to the business. Thus, landscape searches should be updated at regular intervals until superseded by one or more of the modular searches described above. Each modular search should be updated throughout development, until superseded by a comprehensive pre-launch clearance search. Even after an initial product launch, commercial expansion into new indications for use, use in new combination therapies, and geographic expansion into new markets will likely require supplemental FTO searching. The frequency of updates may vary depending on the speed of development, competitive pressure, prominence of the product in the company's portfolio, maturity of the market, and other factors. Annual updates may be sufficient for most circumstances where the subject drug or biologic candidate is in the company's active pipeline. Flagship products may merit more frequent updates, *e.g.*, every six months.

When managing FTO investigative activities for a diversified product pipeline, it is important to consider the timing (and therefore cost) for each search activity. It is conventional for project managers in biopharmaceutical product development to define 'stage gates' at significant decision-points throughout the development process. While it may be appealing to simply use product development stage gates as due dates for conducting FTO searches, this approach can be unduly rigid and result in uneven spending year-over-year, which may be inconsistent with the innovator company's goals for steady-state or predictable general and administrative (G&A) expenses over time. A better approach is to define windows of time throughout product development in which it should be acceptable, from a risk management perspective, to carry out landscape, modular and pre-launch searches. Passage through a first product development stage gate opens a search window, and passage through a later stage gate closes the window. The window-opening event should coincide with the earliest point at which a meaningful search strategy can be formulated. The window-closing event should be the latest point in development at which a reasonably prudent innovator company would continue developing the product 'at risk' of patent infringement liability.[5] Ideally, the window-opening and window-closing events are separated by a longer period than that actually required to carry out the search activities, and occur in different fiscal years. This permits in-house counsel discretion to conduct some searches early in the corresponding windows while deferring other searches. In this manner, establishing patent FTO for product candidates that are of greater importance or prominence in the pipeline can be prioritized, while smaller-market or strategically marginal products can be deferred. This also allows counsel scope for managing FTO costs to a consistent, predictable level over consecutive annual budgets. The search windows can even be included in product management GANTT charts, which facilitates interactions with project management, as well as with the product, formulations and manufacturing development teams.

Table 1 sets out an example set of FTO search window-opening and window-closing events for a novel biologic being developed under FDA's normal path for a Biologic License Approval (BLA). Also shown are exemplary alternative window-opening and -closing events. Alternative events can be used, for example, if an accelerated FTO strategy is required for a flagship product, or for a product to be developed in collaboration with a business partner (*e.g.*, under a license or JV) for which the innovator expects the partner to conduct due diligence. Defensively accelerating some or all FTO searches can enhance a licensor's (or licensee's) negotiating position. Alternative events will also be required for product candidates that are subject to nontraditional development trajectories, such as FDA's Animal Rule,[6] an alternative development path applicable to products for which it would be unethical to conduct efficacy tests via randomized, controlled human clinical trials. Such products are often developed for government procurement in anticipation of emergency preparedness needs, *e.g.*, vaccines or therapeutics for emerging infectious diseases, countermeasures for health impacts of CBRN[7] threats, etc.

Results of the FTO Investigation

A well-conducted campaign of patent FTO investigations permits the innovator to discover and identify potential third-party patent risks to its novel biopharmaceutical product well in advance of commercialization. "Commercialization" for present purposes means any activity that could, unless authorized by law or by the patentee, result in exposure to patent infringement liability. Commercial acts thus include making, using, importing, offering for sale, or selling a patented product in the U.S. or importing a product made abroad

5. For purposes of selecting the window-closing event, in-house counsel should disregard the artificial risk-suppressing effect of the Bolar Exemption, codified at 35 U.S.C. § 271(e)(1). Instead, counsel should consider the amount of investment made by the innovator company cumulatively up to the selected event, the future amount of investment to be made after that event and up to the point of first commercial sale, the potential consequences of ceasing further development (in terms of reputation, opportunity cost, and the like), and the innovator's overall level of risk tolerance.

6. For an overview, see *http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMRegulatoryScience/ucm391604.htm* (last visited 22 May 2016).

7. Chemical, biological, radiological or nuclear weapons.

Table 1: Exemplary Correspondence Between Product Development Stage-gates And FTO Search Windows

Event	Landscape	Module One	Module Two	Module Three	Module Four	Pre-Launch Clearance
Definition/ Scope	Preliminary View	Biologically Active Ingredients	Provenance, Tools & Construction	Formulation & Presentation	Commercial Manufacture	Comprehensive Search
Window Opens	Target Identified	Pre-IND Meeting	Concurrent with Module One	Identification of formulation to be used in Pivotal Trial	One year prior to Engineering Lot manufacture	Upon last subject, first dose in Pivotal Trial
Window Opens (alternatives)	Decision to Collaborate	IND Submission	Decision to Collaborate	–	One year prior to manufacture of Phase III Material	One year prior to eligibility for Emergency or Compassionate Use Authorization;
Window Closes	Commence Animal Model for Proof of Concept	IND Submission	Concurrent with Module One	Use of formulation in manufacture of material for Pivotal Trial	Commencement of manufacture of Consistency Lots	Pre-BLA Meeting with FDA
Window Closes (alternatives)	–	Release of Phase I Trial Study Report; Release of Animal Proof of Concept Study Report	Decision to Collaborate	–	—	Filing of BLA or EUA/CUA if applicable

using a process patented in the U.S.[8] While the Bolar Exemption[9] immunizes development activities that are relevant to the FDA approval process, there has been uncertainty around exactly when a novel product exits the safe harbor provided by this exemption. In the biopharmaceutical industry, the first commercial activity may be product launch, manufacture or stockpiling of product for commercial sale, sale of product under a procurement contract, award of an advance market commitment for sales, or pre-launch sales under an emergency use or compassionate use authorization. It behooves in-house counsel to consider all potentially relevant candidates for the first commercial act and to complete all patent FTO investigative activities in good time for that first commercial act to take place in a risk environment that is acceptable to the innovator.

In accordance with ERM principles, each third party patent or patent application that is identified as being sufficiently relevant to commercialization to merit further action should be assigned a short, unique identifier. The identifier is used for plotting the results on a risk map and for long-term tracking and reporting purposes, *e.g.*, in status tables, spreadsheets, dashboards and other reports. To avoid confusion and facilitate the tracking and reporting processes, the same identifier should be used for a particular patent throughout the FTO campaign. It is usually sufficient (and efficient) to group a simple patent family under one identifier where an FTO investigation uncovers a significant number of third party patents. Consecutive numbering may be sufficient (1, 2, 3, etc.) or if desired a short reference to the search module may be included (1m1, 2m1, 3m4, etc.). Whatever convention is developed should be short enough to enable the production of clear risk maps. It goes without saying that any table, spreadsheet, dashboard or other report listing FTO search results will constitute attorney-client and work-product privileged information. Access and distribution should be limited in accordance with established principles.

Creating and Using Risk Maps

As emphasized earlier, communication between in-house IP counsel and decision-making executives is key to the success of an IP FTO strategy. An important communication tool for this purpose is the ERM-style risk map, in which identified risks are plotted according to their potential materiality (magnitude) and likelihood of occurrence (probability). An example risk map for a hypothetical pipeline product is

8. 35 U.S.C. § 271(a).
9. 35 U.S.C. § 271(e)(1).

shown in Figure 1. The first step in setting up a risk map is to calibrate the scales to be used for the x-axis (probability or likelihood of occurrence) and y-axis (materiality). In a standard ERM risk assessment exercise, it is customary and of practical value to also select the risk planning period, *i.e.*, the period running forward from the present time in which likelihood is estimated. Depending on the needs of the business (in our example, an innovator biopharmaceutical company), this may be one, three, five, or ten years. Positions along the x-axis thus represent likelihood that the risk will materialize before the end of the planning period, ranging from near 0% (impossibility) to near 100% (certainty). While this works well for most risks envisioned by an innovative business, it is confounded by the effects of the Bolar Exemption, which provides a Safe Harbor from patent infringement, especially when the development trajectory from discovery to regulatory licensure under a BLA is longer than the risk planning period. Because the Safe Harbor protects products that are subject to FDA approval from patent infringement litigation until the regulatory process is complete, the likelihood of encountering an IP FTO risk is legally zero if the ERM planning period is too short to include the projected date of licensure, and it suddenly jumps up in a subsequent ERM planning cycle that includes time and activities that are not within the Bolar Exemption. In other words, the effect of the Bolar Exemption is to artificially suppress the likelihood of encountering an identified risk within the applicable planning period. This effect can be compensated for by including a third dimension in the ERM risk map for IP risks: "time to impact," which can be shown as a z-axis or another means of introducing depth to standard ERM graphic tools. The true position of each risk along the x-axis can then be assessed as of the date of first commercial activity using other relevant measures of probability of patent assertion, such as whether the patent holder is a competitor, a startup, a business partner, a university, or a patent assertion entity. One can also consider whether the patent holder has granted prior licenses, engaged in litigation, etc. The "time to impact" indicator is then useful to show the time period available for mitigating the risk. Depending on one's graphic preferences and ease of comprehension for the audience, this can be a z-axis or a change in size, shape or color of the icons used for each risk identifier.

Turning to the y-axis—materiality—the standard ERM approach is to assess impact of the risk, if encountered, on the innovator business as a whole. The maximum y-value would thus correspond to a level of harm sufficient to consume the entire business. Many types of harm can be envisaged, even if the focus is limited to IP risks: an award of infringement or other damages, a permanent injunction, prohibitive cost/terms required by the patent owner to license its technology, cost or difficulty of moving operations to a non-patent jurisdiction, designing around a technology, opportunity cost to abandoning the product, etc. Each of these can be translated into a financial impact scale. For risk mapping purposes, a correspondence is set up between the different impact scales so that a single relative scale can be used for plotting the specific identified FTO risks. An example impact scale is shown in Table 2. The standard

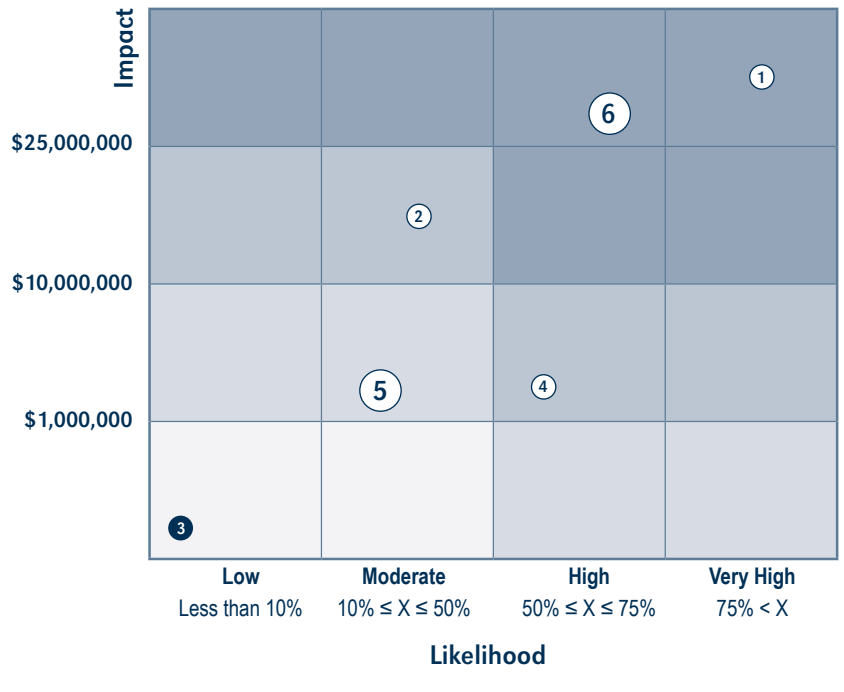
Table 2: Corresponding Scales Of Materiality (Impact Of Encountering An FTO) Risk)

Type of Impact	Low	Medium	High	Extreme
Claim for Infringement Damages	< $1M	$1 – 10M	$10-25M	> $25M
Injunction	TRO only	Preliminary Injunction Only	Permanent Injunction in an Important Market	Permanent Injunction in two or more Major Markets
Cost to Design Around	< $1M	$1 – 3M	$3-5M	> $5M
Abandonment (Opportunity Cost)	< $25M	$25 – 50M	$50-100M	> $100M
Cost of Business Solution (License)	No impact on NPV	Acceptable impact on NPV	NPV Negative in an Important Market	Product not Commercially Viable (NPV Negative)
Other Impact Factors -Related Legal Claims -Regulatory Body Investigation -Business Reputation/ Public Image -Employee Retention/ Morale	TBD (varies)	TBD (varies)	TBD (varies)	TBD (varies)

ERM approach of calibrating impact against enterprise value is useful when assessing FTO risks to an entire business, or to an entire product pipeline. However, it is also possible to use a smaller scale when analyzing risks to a specific candidate product. In this case, the maximum impact should correspond to a "product killing" event—one that extinguishes the value thesis for developing and commercializing the product. It is important to be very clear, when communicating IP FTO risks, to alert the audience to the impact scale being used.

Once the x- and y-axis scales are selected, and a convention chosen to illustrate "time to impact," risk mapping becomes a fairly straightforward exercise: each of the third party patent risks identified in the course of FTO investigations is plotted according to its estimated likelihood and impact. The resulting scatter plot is a compelling "at a glance" view of the overall field of FTO risks under consideration. For an example IP FTO risk map illustrating "time to impact," see Figure 2. It becomes a relatively easy exercise for executive management, together with in-house IP counsel, to use IP risk maps to prioritize the most pressing risks to be addressed prior to the innovator's engaging in its first commercial activity. The goal of the in-house IP counsel(s) as FTO risk owner(s) will be to take actions intended to cause the prioritized risks to shift away from their starting positions on the risk map, toward more acceptable, lower levels of materiality and/or likelihood prior to the expected date of "impact." Ideally, all of the risk icons should become clustered in the lower left quadrant of the risk plot (low materiality, low likelihood) in advance of the first commercial activity.

Figure 2: Example 3-Dimensional Risk Map Showing Relative "Time To Impact": The Hypothetical Product Is In Early Clinical Development, And Risk 3 Has Been Mitigated By Taking A License. Risks 5 And 6 Are Platform Patents Shared With A More Mature Product.



IP Risk Mitigation Activities

Once all identified FTO risks have been calibrated in a risk map, the next logical question is to consider whether whatever is being done already is sufficient to address the potential impact of the risk on the innovator's business, or on the commercial prospects for the specific product. In ERM parlance, an activity undertaken to address a risk is termed a 'control.' If current controls are sufficient, the risk in question is said to be 'in retention' and no active steps should be required to change its position on the risk map. If current controls are not sufficient, the identified risk is subject to 'mitigation' or active steps undertaken with the goal of driving the risk's position lower along the scales of materiality and likelihood of occurrence. An example of an FTO risk that is in retention is a patent or application for which the innovator has already entered into a license agreement with the patent owner, and the license agreement is in good standing. Another example is an automated patent monitor of a pending application: the monitor alerts the risk owner to changes in prosecution status, which enables him or her to decide whether to keep the risk in retention, or institute any active risk mitigation activities.

The menu of potential IP FTO risk mitigation activities (controls) is large and diverse. As IP counsels well understand, the choice of which risk mitigation measures to take varies widely with the circumstances and the ends to be achieved. Specific strategies are out-

side the scope of this article. In general, in-house counsel risk owners can choose an avoidance or 'design-around' strategy, a variety of business resolutions, litigation, or one of the relatively new U.S. Patent and Trademark Office administrative law proceedings.[10] There are many options within each category:

Avoidance Strategies and Business Solutions

An FTO risk may be avoided by adopting an alternative technology if the alternative is acceptable technically and economically (considering, for example, the changeover cost and terms of access). Avoidance can also be accomplished geographically, by moving commercial operations to a non-patent jurisdiction and/or by targeting non-patent markets. Likewise, there are many potential strategies within the category of business resolution: the innovator may negotiate access via a license from the patent owner, acquire the desired technology rights, or if applicable, rely upon an indemnification clause in a separate licensing or collaboration agreement with another third party having the resources to reach accommodation with the patent owner. Of course, the ultimate avoidance strategy and business solution is to adjust the organization's goals and objectives based on an understanding of the risk (and opportunity) landscape. This may involve a shift in emphasis within a product pipeline, or a new initiative to explore additional or different development opportunities. Conversely, even a significant patent risk may be tolerated if it is offset by opportunities outside of the scope of IP freedom-to-operate, leading to an exploration of litigation and/or administrative law measures to reduce—even partially—the potential magnitude or probability of harm to the business.

Litigation Based Strategies

Turning to litigation approaches, the innovator may seek relief via declaratory judgement (DJ) of non-infringement, invalidity or unenforceability. If the innovator does not desire to take proactive action, or if the jurisdictional requirements for DJ action are not (yet) fulfilled, the innovator may instead prepare itself for defending against future litigation by the owner of the FTO risk. Often the first step in such a defensive strategy is to procure an opinion of counsel as to invalidity, unenforceability or non-infringement of the identified FTO risk. It is important to remember that opinions of counsel, taken alone, are not risk mitigation strategies; rather, they are valuable tools for developing the overall mitigation strategy and in assessing available options.

Administrative Law Strategies

Administrative law remedies have recently been expanded considerably as a result of the America Invents Act[11] and the formation of the U.S. Patents Trial and Appeals Board (PTAB).[12] The innovator facing a patent FTO risk may now elect to file an inter partes review (IPR), post-grant review (PGR), or covered business method review (CBM) proceeding, depending on the technology presenting the FTO risk and the age (priority date) of the third party patent in question. Even before grant of a patent on a third party patent application (again, depending on priority date), the innovator may consider making a submission of third party observations in accordance with current USPTO rules.[13] Of course, administrative law remedies have long been available in other commercially important jurisdictions, the primary example being the availability of third party observations and post-grant opposition proceedings in the European Patent Office.[14]

Considerations Influencing Risk Mitigation Strategies

Just as with identifying search windows, there are a number of factors to be considered when selecting control strategies. One factor is whether the strategy in question requires action to be taken at a specific time, or in light of a specific event. For administrative law strategies in particular, it is necessary to monitor and docket key dates by which action must be taken in order to deploy a desired risk mitigation strategy. European patent oppositions and U.S. post-grant reviews must be initiated within nine months of the date of issue of a third party patent; thus, the risk owner must monitor third party patent prosecution for issuances and docket opposition due dates accordingly. Similarly, one can only file third party observations at specific points in prosecution, again necessitating proactive monitoring and docketing of due dates. It follows that control strategies that rely on triggering events arising from the third party's progress through patent prosecution cannot be deferred for convenience, or for purposes of managing costs and expenses.

Other types of IP FTO control strategies can be deferred, or initiated when desired by executive management of the innovator company. For these strategies, a prime consideration for the in-house IP counsel as risk owner is to understand the anticipated date of the innovator company's first arguably commercial activity (the critical date) and how long one should expect a desired control activity to take for implementation

10. For a comprehensive overview, see Patent Office Litigation, *http://www.skgf.com/book* (last visited 22 May 2016).

11. Public Law 112—29, the Leahy-Smith America Invents Act (effective September 16, 2012).

12. *http://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board-0* (last visited 22 May 2016).

13. *http://www.uspto.gov/patent/initiatives/third-party-preissuance-submissions* (last visited 22 May 2016).

14. *https://www.epo.org/applying/european/oppositions.html* (last visited 22 May 2016).

and/or completion. For example, the PTAB must decide whether to initiate a U.S. *inter partes* review (IPR) proceeding within six months after a petition has been filed, and once instituted, the IPR must be concluded within 12 months. The latest date for filing a petition is therefore 18 months prior to the critical date, assuming that the innovator's risk appetite is such that an appeal can be pending once commercial activity commences. It is important to engage executive management early in discussions concerning what level of certainty of IP freedom to operate constitutes an acceptable risk environment: final resolution of all prioritized risks? Including appeals? The outcome of this discussion informs not only the time frames for initiating specific control measures, but also the budget and other resources necessary to achieve the desired outcomes. Maintaining a dashboard showing current progress and investments made versus anticipated in the risk mitigation activities for each identified FTO risk facilitates management's understanding of the process. IP counsel should, of course, also liaise with finance colleagues to keep abreast of the potential impact of control activities on overall development costs and economic attractiveness of the product.

Beyond the investment of resources and time frame for implementing a desired control strategy, it is also necessary to consider the geographic scope of the desired solution. Litigation and administrative law proceedings will be by definition limited to specific countries or regional jurisdictions (*e.g.*, in the case of the European Patent Convention). However, the innovator may desire access to a broad regional or global market, and IP FTO risks may exist in multiple countries within the desired market. It may be necessary to work toward achieving a global business solution in the form of a license, cross-license, acquisition of IP rights, or settlement with the third party owner of the IP FTO risks in question. Litigation and administrative law activities in specific countries may be viewed as tactics or leverage for achieving a robust global solution.

Additional Uses of the IP-Risk Management Framework

The foregoing discussion illustrates the utility of adapting enterprise risk management concepts and communication tools for use in IP freedom-to-operate planning, activities and investments for a specific candidate product in development. Creative in-house IP counsels will see that there are other uses for such an IP risk management framework: rather than generating a risk map of specific third party IP FTO risks to a specific product, one can, for example visualize the overall IP FTO risk of different products in a pipeline by summing or averaging individual risks to create a risk score for each product. Executive management may find this a useful tool in deciding which among several product candidates is the more desirable investment prospect. Or, rather than considering candidate products, a risk map may be applied to a platform technology or to the choice of different platform technologies for designing a desired new product.

Overall, the management and strategy of achieving IP freedom to operate benefits from the application of enterprise risk management tools and concepts. It is hoped that in-house IP counsels will find these concepts useful in facilitating interactions with executive management and in demonstrating the business value of IP strategies.[15] ■

Available at Social Science Research Network (SSRN): *https://ssrn.com/abstract=2855189*

15. The author wishes to thank Kenneth Piña and Andrew Tait of Core Risks Ltd., and Colleen Larson of Emergent BioSolutions Inc., for their helpful comments and suggestions on the manuscript.