Freedom to Operate, Public Sector Research, and Product-Development Partnerships: Strategies and Risk-Management Options

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ABSTRACT

Freedom to operate (FTO) is—first and foremost—a strategic management tool. It is the synthesis of scientific, legal, and business expertise coupled with strategic planning. Strictly speaking, however, FTO is a legal concept. It is a legal opinion by patent counsel on whether the making, using, selling, or importing of a specified product, in a given geographic market, at a given time, is free from the potential infringement of third-party intellectual property (IP) or tangible property rights. As such, it is one type of input among many that managers use to make strategic risk-management decisions in relation to R&D and product launch. For academic and public research institutions, bringing products to market is often not a main goal. However, as a portion of their research moves downstream into product development, FTO becomes—or should become—an integral component of their endeavors. This is particularly relevant for product-development partnerships (PDPs) in health and for various public–private partnerships (PPPs) in agriculture, as well as for the Consultative Group on International Agricultural Research (CGIAR) and national agricultural research systems (NARS), all of which are concerned about global access.

Research exemptions exist in many jurisdictions, so most university research does not generally need to be concerned with FTO unless product development takes place. But PDPs, such as the Malaria Vaccine Initiative or the TB Alliance, are in a different category since their purpose is directly related to the distribution of products in the developing world. This chapter discusses three main categories of options that are available to reduce risk and obtain a *manageable* level of FTO. In practice, a combination of two or more options will often be pursued concurrently. These are:

- Legal/IP management strategies: license-in, cross-license, oppose third-party patents, seek nonassert covenant, seek compulsory license
- R&D strategies: modify product, or invent around
- Business strategies: merge and/or acquire, wait and see, abandon project

Each option presents its own risks and opportunities. Any action—including the decision not to take action—carries risk. Delaying the licensing of third-party intellectual property, for example, could lead eventually to expensive licensing terms, the inability to obtain a license, or the possibility of being sued for patent infringement. But for some organizations, such as those developing genetically modified crops, the reverse may be the case. For the public sector, the challenge will be to balance the various types of risks that each option presents.

The chapter concludes by urging the public sector to judiciously evaluate whether and when FTO concerns should be considered, and to build in-house capacity to conduct patent searches and cursory FTO analysis (as opposed to legal opinions). This will lead to benefits like better competitive intelligence and culture change in public sector organizations engaged in product development. An FTO strategy, therefore, is a *plan* that begins with research and evolves into an *attitude* throughout a product's R&D and commercialization/distribution cycle.

1. INTRODUCTION: FTO AND RISK MANAGEMENT

Successful freedom to operate (FTO) strategies require forming partnerships, both within

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institutions and with third parties. Although FTO is often narrowly considered as only a legal issue, when approached from a more practical standpoint, FTO is a strategic risk-management tool; it relies on a synthesis of scientific and legal expertise, business development, and strategic planning. An FTO *opinion* is legal advice or input that managers use to make business decisions based on a full range of criteria (business goals, competitors' position, financial goals, and so forth).

FTO has two fundamental aspects. First, it is a legal concept: an FTO *opinion*, rendered by patent counsel, will advise senior management about whether the making, using, or selling of a specified product in a given geographic market would infringe a third-party's intellectual property (IP) or tangible property right. The legal opinion is based on a detailed analysis of the product or service under consideration, an analysis that primarily involves searching patents (though other forms of intellectual property, such as trademarks, will also be considered). The analysis also involves examining the claims of such patents, reviewing possible material transfer or contractual obligations, and providing a legal interpretation of the analysis.

Second, FTO indicates the nature of the business constraints imposed on the institution, such as whether regulatory approvals have been granted or import or export licenses have been obtained. Third, the word *freedom* in *freedom to operate* does not imply absolute freedom from the risk of infringing another party's intellectual property. It is a *relative* assessment based on the analysis and knowledge of IP landscapes for a given product, in a given jurisdiction, at a given point in time. This point underscores a critically important concept: there is no such thing as a risk-free decision. Whether an organization decides to perform an FTO or not, both options carry an element of risk. Not making a decision is itself a decision.

This chapter focuses on legal, research, and business strategies for resolving the legal aspects of patent infringement—in other words, on strategies for minimizing IP constraints. Companies deal with these challenges routinely. Early or cursory FTO reviews[1] are typically conducted during the conceptualization of research projects to indicate early on how to reduce IP/licensing constraints that may emerge further down the road. This makes it possible for a company to decide in advance which components, technologies, and processes are best incorporated into the product under development. Certain R&D projects may even be stopped fairly early—or may never be pursued—when the FTO situation seems too uncertain or too costly to resolve. Hence, with any FTO strategy there will be other business-related considerations, including market potential, geographic location, short- and long-term business opportunities, and the positions of competitors.

One of the big questions the public sector has struggled with is whether, when, and how to concern itself with FTO. University researchers generally do not need to be concerned with commercial FTO unless they are engaged in research that aims specifically at product development. This kind of engagement is becoming more prevalent in the public sector, not least through collaborations with product-development partnerships (PDPs), where the primary reason for funding the research is the development of products to help the poor. Such is the case for the research centers of the Consultative Group on International Agricultural Research (CGIAR) and for many national agricultural research systems (NARS). Universities, too, are shifting their research focus; some manage their innovations in novel ways. For example, Arizona Technology Enterprises LLC, the technology commercialization arm of Arizona State University (ASU), in-licenses (or assembles) IP to establish core technology platforms around ASU inventions, and then licenses the bundled IP as solutions, offering quicker market access and greater commercialization opportunities.[2]

These trends within the public sector require the building of various types of partnerships. Indeed, the very process of seeking and obtaining FTO, which requires myriad licenses and other forms of institutional arrangements, leads to partnership building. But partnerships carry risks—as does acting independently. Risk cannot be avoided completely. Instead, researchers and administrators must be aware of the different

types of risks and ask themselves how they can best be balanced.

2. FTO: FROM ANALYSIS TO STRATEGY

The approach to FTO follows a logical sequence (Figure 1). It begins with an FTO analysis, which is an investigation whereby the planned or existing product is dissected into its component parts. For each of these, a search is conducted for any intellectual and tangible property rights. The results of such an analysis allow patent counsel to provide an FTO opinion that discusses the likelihood that the product or process infringes identified IP rights or tangible property rights of others. The resulting FTO status becomes the baseline for formulating an FTO strategy, which then allows management to weigh different risks and make informed business decisions.

An FTO opinion usually divides third-party intellectual property into three classes (lawyers may not use the terminology used here):

1. Patents that have a high likelihood of being infringed and therefore require a license
2. Patents that *may* be infringed, depending on how claims are interpreted
3. Patents that are clearly outside the field of the product and require no license

Unfortunately, many patents will not have a clear status that would place them squarely in category 1 or 3. Many will instead fall into the more uncertain category 2. The classification is based in part on the analysis of the meaning and scope of the patent *claims*, the detailed portion of the patent text that specifically defines what the invention is and lays out a conceptual boundary or property line around the patented invention. Legal protection is awarded only to what is captured in the claims; anything outside the claims is open to the public.

Patent claims are analogous to the "metes and bounds" described in real estate deeds. As with a deed for land, claims delineate the limits (the dimensions and borders) of the invention. However, as distinguished from the tangible property rights to a deeded piece of real estate, patents deal with intangible property rights. Finding the precise limits of IP rights is thus not a quantitative activity; it is, therefore, open to interpretation, because one cannot see or touch the actual property in a patent (it is "intellectual," or of the mind). The boundaries can only be described with words, yet the meanings of words are not precise. They are always open to interpretation, especially given their context.[3] For these reasons, it is useful to further subdivide category 2 patents into subsets defined by the possible outcome of legal action:

2(a). It could be argued with some level of certainty that, if defendant were taken to court by plaintiff, defendant would probably ***lose*** a *patent infringement lawsuit*.

2(b). It could be argued with some level of certainty that, if defendant were taken to court by plaintiff, defendant would probably ***win*** a *patent infringement lawsuit*.

Counsel can advise senior management about the number of patents that fall into each of these categories—1, 2(a), 2(b), and 3—and about the institutions that would have to be contacted to form a partnership or licensing deal. But counsel would not be able to tell which options made the most sense from an R&D, institutional, and business perspective. From a purely legal perspective, obtaining licenses for all the patents that fall into category 1 and 2 would minimize risk. Lawyers will tend, therefore, to identify licensing as the lowest risk option. To what extent this makes business, financial, and strategic sense, however, requires considering other options explained below.

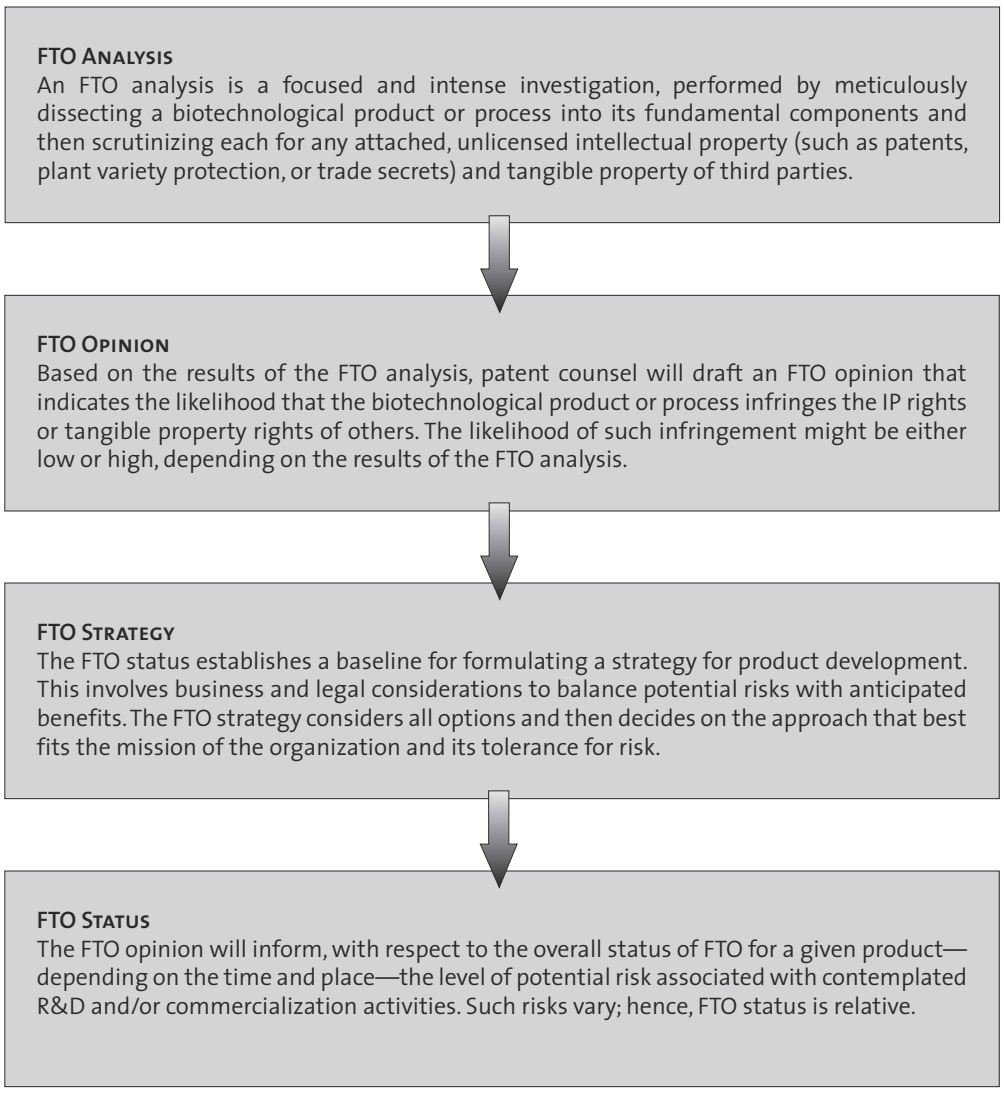
3. WHEN TO SEEK FTO

For ***companies***, FTO has to be considered very early in the product-development process. Once millions of dollars have been invested in the research, development, regulatory compliance/approval, formulation, and manufacture of a product, it would be difficult to obtain beneficial licensing terms from third parties. The more resources invested, the more difficult the bargaining position, though other factors may be equally important. For example, a company that has good marketing networks already in place might find it easier to negotiate licenses.

In practice, performing a detailed FTO analysis on every product or process early in the pipeline would be impractical and prohibitively expensive. Therefore, even the early decision on whether or not to commit resources to perform an FTO analysis for a given project or product candidate must itself be based on a preliminary, or cursory, assessment. Such a preliminary assessment can help determine when to perform a more-detailed FTO analysis and at what level of sophistication and depth.

For ***public sector*** entities, the same *principles* usually apply to FTO but with important differences. For universities the organization's primary mission or focus is research, teaching, and sharing knowledge. The freedom to engage in these endeavors derives from the norms of academic freedom and, in some countries, is codified as academic research and fair-use exemptions under IP law. Downstream business development considerations are often a secondary or derivative focus.

Figure 1: FTO Strategy in Context



Source: SP Kowalski, personal communication.

This is why university technology transfer offices typically license inventions (patents) and, in some cases, trademarks and plant varieties, but do not develop and sell finished products. However, for PDPs and many nonprofit organizations, product distribution and access often are their main purpose, even if they may not be the party that will actually produce and distribute the products. Their missions focus on the development of products for the marketplace (whether considered nonprofit or for humanitarian purposes). The main questions, therefore, are simply when to initiate the examination of FTO and when to begin the process of assembling the necessary intellectual property.

Should the assembly[4] of intellectual property be done early or late in the product-development process? Timing the licensing of third-party intellectual property is an important strategic decision, and like any decision carries certain risks. By deciding to delay, an institution accepts the following possibilities:

- that higher licensing terms will be extracted (Once an institution invested years and millions of dollars into R&D, its bargaining power is often reduced.)
- that no license will be obtained
- that a lawsuit will be filed for patent infringement

Conversely, by seeking to in-license early on, an institution accepts other risks. In agricultural biotechnology, for example, one of the biggest obstacles for public sector institutions in obtaining IP licenses from companies is their lack of trust and confidence in the public sector's ability to produce a high-quality product and to be a responsible steward of the technology and product. Few public sector entities have experience in developing biotechnology products. Understandably, companies may therefore be reluctant to grant licenses—especially those for humanitarian purposes—to entities that have not demonstrated credible product-development plans and that lack the requisite resources for product stewardship throughout the product's life span. Public sector entities may therefore find it easier to obtain licenses on preferential terms once they have demonstrated a product's quality and their overall institutional capacities, especially their capacity in IP management, regulatory management, and high-quality productions. Demonstrated capability generates confidence and trust, which translates into a greater willingness by companies to provide licenses and to enter into partnerships. This is one reason for the creation of AATF: the stewardship of agricultural applications.[5]

In sum, there is no textbook strategy. Each case must be reviewed and evaluated, and the best strategy—or strategies—will depend on many factors, including:

- the mission of the organization
- the range of existing partnerships
- the ease with which the organization interfaces with companies
- the type of product under consideration
- the degree of overlap between public and private sector interests related to the specific product.

4. COMPLEMENTARY STRATEGIES TO OBTAIN FTO

Companies determine their overall FTO strategies, generally speaking, through a combination of decisions by boards, senior executives, business managers, marketing executives, R&D managers, and legal counsel. Although this chapter has so far stated that most IP issues related to FTO are about deal making, in-licensing, and partnership building, such deals are the *results* of choosing from among a combination of ten main options (Table 1).

To be sure, not all of the options apply equally well to public sector research institutions. Bringing products to market is not their major concern, but to the extent that their research is used downstream, such as in collaboration with the private sector, FTO is becoming more integral to their endeavors.

4.1 *Legal/IP Management Strategies*

4.1.1 *License-in*

All FTO issues can be resolved by acquiring (individually or through consortia) a commercial

Table 1: The Ten Strategic FTO Options

Option	Pros	Cons	Key challenge for the public sector
1. Legal/IP Management Strategies			
License-in	Is relatively straightforward	May not foster in-house R&D initiatives and may be costly	Determining the right time to initiate licensing discussions/ negotiations
Cross-license	Involves give and take	In certain cases, antitrust issues may arise	Requires alignment of institutional strategy
Oppose third-party patents	Can be cost effective	Can be expensive and result might be undesirable (stronger and/or broader patent)	Policies of public sector rarely allow for such measures; cost may be prohibitive
Seek nonassertion covenant	Is cheap and effective	Rarely allows for the in-licensing of valuable know-how	Might require lobbying by lead scientist and head of institution
Seek compulsory license	Allowed under TRIPS under certain circumstances	Will not allow for the in-licensing of know-how and brings many constraints and complexities with it	Many conditions need to be fulfilled for compulsory licensing to be feasible
2. R&D Strategies			
Modify product	Can be fairly simple if planned early in R&D stage	May not be possible due to lack of readily available alternatives; incurs opportunity costs	Requires early FTO review and business-driven R&D strategy
Invent around	Could lead to cross-licensing position	Could lead to delays in product launch and might be costly; incurs opportunity costs	IP/licensing department would need to drive, or at least influence, researchers and the direction of research
3. Business Strategies			
Wait and see	Gives time for strategic positioning	Could lead to litigation and jeopardize investment already made	Generally undesirable
Abandon project	Is simple and effective	May be costly (need to write off R&D investments already made, incurs opportunity costs)	Difficult to determine when, how, and by whom such a decision is made (unless the financial donor has a clear IP policy)
Merge and/or acquire	Is highly effective	May distract from main business focus	Not generally feasible
→ In Practice **A combination of several options implemented concurrently**			Requires strategic mindset

Source: A Krattiger

license from the certified owners/assignees for each IP right that the product under study is likely to infringe. Negotiating a license is the most common option and perhaps the most logical. It may be broad—a grant to make, have made, use, have used, import, export, offer to see, sell, or have sold all products and product parts and all related products and processes—or it may be more restrictive.

Licenses are agreed to every day, and in many circumstances entering into licensing agreements is almost a mechanical matter.[6] However, we hear of special cases when licenses have been difficult to obtain, when licenses were refused, or even when license disputes have ended up in court. Considering the number of licenses executed each year, these special cases are rare, but they seem to receive an inordinate amount of attention. The main question is not *whether* to license, but *when* to initiate licensing discussions/negotiations (or when and how to pursue other options discussed here). But, to reemphasize, licensing is just one of many options.

4.1.2 *Cross-license*

Cross-licensing occurs when two IP holders license intellectual property to each other: "A" licenses a set of patents to "B," and in exchange B licenses a set of patents to A. This approach is often adopted when one entity holds a patent on an invention and another has an improvement on it. For example, assume that A holds the rights to a promoter that is only effective in cereal species. B, however, has modified the gene so that it is now also useful for dicotyledonous species (which are non-cereal species). A can continue to practice its invention on cereals but could not use it in beans (since they are dicotyledonous species). Yet B cannot use its improvement in beans because it would require a license from A. Cross-licensing inventions in this case allows both A and B to both apply their inventions in beans.

Some companies have entire teams of researchers conducting research to place the company in a stronger cross-licensing position with certain competitors. Due to costs, public sector institutions are probably not in a position to do this; nonetheless, cross-licensing should not be dismissed outright.

4.1.3 *Oppose third-party patents*

It is generally presumed that, after issuance, a patent is valid. But patents can be challenged. Essentially, there are three components to patent validity under U.S. law: novelty, utility, and nonobviousness. A successful challenge on any of these grounds will annul a patent claim, and sometimes the entire patent. A patent claim can also be declared invalid if it can be shown that the written description requirement was inadequate. When considering litigation, two certainties must be kept in mind: the cost of litigation is high, and the outcome is uncertain. Furthermore, preparation for a patent-invalidity challenge will involve research and analysis that is comparable to, if not greater than, that involved in an FTO analysis. Cost must be carefully considered when thinking about this option. Other possible drawbacks are that the assignee/inventor comes back with additional claims (as happened with the Enola bean case at first).[7]

4.1.4 *Seek nonassertion covenant*

Many companies are, in principle, willing to license their valuable intellectual property for developing country and humanitarian uses. But quite naturally, they are reluctant to take on risks for activities that do not generate cash flow or profits. One way for them to manage some of the risks is through nonassert covenants, or nonassert agreements, through which an IP rights holder essentially assures the IP rights user that it will not enforce the IP right. These are fairly simple agreements to execute and may be in the form of public statements or bilateral or multilateral agreements.[8]

In this new era of "humanitarian" licensing, the international community is struggling to develop and distribute new products and to extend the benefits of those the developed world already enjoys. Dealing with all of the FTO issues, however, can be daunting. Just obtaining licenses can be complex, time consuming, or impossible. Companies may be reluctant to license due to liability issues. This is especially so with agricultural

biotechnology applications (partly brought about by the Cartagena Protocol's ongoing international negotiations on liability and redress) and with vaccine technology. Fortunately, many of these complexities can be circumvented with a simple nonassert covenant.

4.1.5 *Seek compulsory license*

Most countries have provisions for the issuing of compulsory licenses to national producers in national emergencies, provided that certain conditions are met according to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The country must have the manufacturing capacity to produce the patented invention and must also have attempted to negotiate a license in good faith (although the World Trade Organization's Council recently instituted a waiver to the original TRIPS Agreement that allows developing countries without manufacturing capabilities to import patented drugs from sources other than the originator company). Compulsory licensing has to be initiated by governments for public non-commercial uses and may take one or more years to complete: it is a complex process and requires significant government resources and experience.[9]

Production under compulsory licenses presents several operational challenges. Patent holders are unlikely to license and transfer their know-how under compulsory licenses, so companies in developing countries will need to develop know-how internally. Exports, moreover, may only be made to certain countries under specific conditions, which limits economies of scale and potentially increases production costs significantly. But compulsory licensing can also be a beneficial tool (for example, as a negotiation strategy). Furthermore, international IP standards mandated by TRIPS already allow member nations considerable discretion to enact laws and provisions that not only meet treaty obligations, but also support national innovation policies, development priorities, and cultural values. This includes voluntary pricing and licensing arrangements. Other options primarily relate to national policies and laws beyond the purview of this chapter (for example, permitting and regulating the government use of patented inventions, taking actions through patent courts to protect public interests, and the judicious framing of competition law and policy). Importantly, when compulsory licenses are issued, the licensor has no obligation to transfer know-how/trade secrets or any safety, efficacy, or clinical data. In other words, the compulsory license may be limited to the information disclosed in a patent specification, which frequently represents only an invention's early best mode. It will not include subsequently developed and/or ancillary technical know-how or related show-how.

Given the range of necessary licenses and the time required to issue a compulsory license, this option might not permit a developing country to quickly develop a product. That especially applies to licensing vaccines, for which know-how is a major component of the intellectual property. Moreover, even raising the possibility of compulsory licensing would significantly deter future investments. A "false alarm scenario," in which a national emergency is proclaimed to justify compulsory licensing when the conditions may not fully warrant such a proclamation, might be a harmful approach, since such compulsory licensing could act as disincentive for future investments. Granted, the threat of a compulsory license can prompt an early licensing agreement, but seeking a commercial license early is probably more effective in most circumstances.

4.2 *R&D Strategies*

4.2.1 *Modify product*

An alternative to licensing is to change the product specifications. In agriculture, for example, instead of using a certain (patented) promoter that would require a license, the vector design would include a different type of promoter unencumbered with intellectual property.

Such a strategy will succeed only if (1) there are alternatives in the public domain that would work at least as well as the encumbered promoter and (2) an FTO analysis is performed relatively early during the R&D stage (preemptive FTO analysis). Otherwise, many years of work would be lost, and a license might suddenly seem quite appealing, if not necessary, in order to gain FTO.

A license may also come with regulatory know-how/trade secrets, data, and trademarks. Of course, it is critical that this approach include analyses of any viable alternatives so that their likelihoods of FTO can also be assessed. One does not want to exchange a sick pony for an even sicker burro!

4.2.2 *Invent around*

Choosing the invent-around option would require a research team to search for alternative ways to develop the product in question. Taking again the example of a promoter, the team would seek to isolate a new, unknown promoter and concurrently seek patent protection. This option would delay product development but could lead to significant benefits in terms of new inventions, new intellectual property for cross-licensing, and perhaps even better products. The main downside is that costs would be high, so in many cases the option might not be feasible for public sector organizations. The costs of licensing versus the costs of an all-out development of a new product should be weighed using a risk/benefit analysis. Given the frequent open-ended cost structure of research and development, licensing might be more feasible. In industry, inventing around is often a strategy pursued in parallel with licensing negotiations.

4.3 *Business Strategies*

4.3.1 *Wait-and-see*

The simplest option is to commercialize the product under question and wait to see if the IP holder contacts you for a license. If and when that happens, it would still be possible, perhaps, to come to a licensing arrangement (discussed in Section 4.1.1). Alternatively, the option of opposing a third-party patent (discussed in Section 4.1.3) could be pursued as a form of defense. In addition, a cross-license (discussed in Section 4.1.2) might be offered in return. However, in the United States, the potential downside is that if it can be proven that the infringer willfully infringed the particular IP rights of the other party, then a court may assess damages as high as three times the IP owner's lost revenue. In exceptional cases, the court may also award reasonable attorney fees to the prevailing party (that is, the owner of the IP rights).

4.3.2 *Abandon project*

If all else fails, a project may simply have to be abandoned, freeing investments for safer and less-risky ventures. Naturally, the best time to decide to abandon a project is before initiating any research and development. For this reason, companies typically hold regular project/product planning meetings that include scientists, business-development managers, and legal counsel.

Public sector institutions often find it difficult to abandon projects since promises to donors have often been made for several years. Scientists in the public sector also often have a lot of autonomy compared to their corporate counterparts. That is why a donor's IP policy is so important for determining when, how, and by whom such a decision is made (unless the financial donor has a clear IP policy).[10] The requirement of the Bill and Melinda Gates Foundation (as well as other donors) for a global access strategy is particularly welcome and important in this context.

4.3.3 *Merge and/or acquire*

Any company, regardless of its size, may acquire, through mergers and acquisitions, a number of smaller companies, just to expand its IP portfolio. Although not a feasible option for academic institutions, in the private sector this practice is an important step in obtaining FTO.

Nonprofit PDPs and other nongovernmental organizations (NGOs), moreover, might gain by considering mergers, perhaps not so much as a strategy to obtain FTO, but as a way to increase the potential for innovation. For example, in the 1990s, when the world around the centers of the CGIAR became more complex, with many more actors and spheres of influence, rather than regroup and focus, the CGIAR expanded (with a constant or reduced budget in nominal terms) and has since become an increasingly diffuse entity. This is particularly problematic because the work of this group is conceivably more important than ever from strategic and humanitarian points of view. Paradoxically, over the same

period, the private sector undertook mergers and acquisitions, reducing the number of key players from more than 20 to a mere five or so. This happened during a time when development agencies, NGOs, and a plethora of other service organizations increased and multiplied.[11]

5. CONCLUSIONS

For public sector institutions, planning for FTO early in the research phase is neither necessarily appropriate nor feasible. Indeed, since much of the research conducted in academic institutions is not directly intended for commercial use, there is and indeed should be little concern over FTO. But public sector institutions, particularly the NARS and CGIAR in agriculture, and the PDPs in health, are increasingly dealing with the complex interface of proprietary science and the public domain. Moreover, donors such as the Bill and Melinda Gates Foundation are requiring them to develop global access strategies that spell out how intellectual property will be managed to make the products from the grants available to the poor. This will increasingly require FTO considerations as products are moving downstream.[12] Significantly, however, while the steps involved in an FTO are straightforward, their execution is complex and time consuming, and the implications of an FTO are difficult to translate into a product-development strategy.[13] As mentioned in the introduction, FTO opinions provide only snapshots of the intellectual property related to a product at a given point in time. For example, the patent landscape changes daily as the specifications of the product become modified and improved, as the legal landscape evolves (for instance, rules are issued for what type of invention is patentable), and as patent applications are filed and patents issue, expire, or are invalidated.

A sound strategy for obtaining FTO for a given product or process should consider all options and an assessment of the risks of each in relation to the institutional context, the product type, and market dynamics. In practice, several options are pursued concurrently. Strategies will need to be regularly revised and tactics adapted in response to changing circumstances. In practice, some options may be more feasible during the R&D stages (such as inventing around), whereas others may become the only option if all else fails (such as litigation or abandonment of a product).

All of the options outlined in this chapter require, in some way, the formation of partnerships, both internal and external. First, managing potential IP infringement requires cooperation and partnerships between and among R&D personnel and professionals in business development, finance, strategy, law, and even governance. Moreover, translating this coordinated, focused, and informed risk management into a solid, reliable, and thorough FTO strategy should be a shared goal for all involved. Indeed, everything in the end is driven by relationships, both internal and with third parties outside the organization seeking FTO. If a decision is made to passively manage such risks, unexpected problems could arise and opportunities could be missed.

Above all, as with any strategic issue, the key is not so much to *have* an FTO strategy—but to *execute* it. Strategy is not so much a plan but an attitude. Take a positive attitude to facing problems, view them as opportunities, chart the best course action, and then implement it. ■

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1 Fenton et al call such searches "level one" searches that are more cursory than "level two" investigations where legal FTO opinions are typically given in a confidential document under attorney-client privilege (see, also in this *Handbook*, chapter 14.4 by GM Fenton, C Chi-Ham and S Boettiger).

2 See, also in this *Handbook*, chapter 17.8 by PJ Slate and M Crow.

3 In addition to the interpretation of claims, an analysis of patents must also include embodiments of inventions.

4 *Assembly* essentially means to have gathered the relevant pieces of intellectual property.

5 See, also in this *Handbook*, chapter 17.17 by RY Boadi and M Bokanga.

6 See, also in this *Handbook*, Section 11 on Technology and Product Licensing.

7 Rattray GN. 2005. The Enola Bean Patent Controversy: Biopiracy, Novelty and Fish-and-Chips. *Duke L. & Tech Rev* 0008 (3 June).

8 See, also in this *Handbook,* chapter 7.6 by A Krattiger.

9 See, also in this *Handbook*, chapter 3.10 by CM Correa.

10 See, also in this *Handbook,* chapter 5.2 by Z Ballantyne and D Nelki.

11 For this, and other reasons, it has been proposed to restructure the CGIAR and FAO, for a consortium of developing countries to purchase Monsanto, and for the creation of an agricultural investment service (see Krattiger AF. 2003. Technology transfer to developing countries and technology diffusion: The future role of institutions in capacity building, regulations, IPRs and funding. In *Handbook of Plant Biotechnology* eds. P Christou and H Klee. John Wiley & Sons, London. pp. 987–1010. http://www.wiley.com/WileyCDA/WileyTitle/productCd-047185199X,descCd-tableOfContents.html).

12 One of the first major FTOs conducted for a public sector consortium was for GoldenRice. It was commissioned by the Rockefeller Foundation on behalf of the International Rice Research Institute (IRRI) and the Humanitarian Board for GoldenRice (see Kryder D, SP Kowalski and AF Krattiger. 2000. *The Intellectual and Technical Property Components of pro-Vitamin A Rice* (*Golden*Rice™): A Preliminary Freedom-to-Operate Review. *ISAAA Briefs* No 20. ISAAA: Ithaca, NY. www.isaaa.org/kc/bin/isaaa_briefs/index.htm. See also www.goldenrice.org/Content2-How/how9_IP.html.

13 See, also in this *Handbook,* chapter 14.2 by SP Kowalski, and *supra* note 1.