

## Freedom to Operate and Risk Management

Freedom to operate (FTO), a simple and straightforward concept, means that for a given product or service, at a given point in time, with respect to a given market or geography, no intellectual property (IP) from any third party is infringed. But to translate this concept into a productive strategy for companies and for public sector institutions alike is not so straightforward.

For public sector organizations, the **opportunities presented by incorporating FTO considerations** into product development strategies are numerous. These may include benefits through higher competitive intelligence, the ability to bring about culture change, and the forging of strong partnerships with providers of intellectual property and technology. An FTO strategy, therefore, is a *plan* that begins with research into the IP landscape of a potential product and evolves into an *attitude* through a product's R&D and commercialization/distribution cycle. Krattiger discusses these policy and strategy elements in detail.<sup>1</sup> It is useful, however, to first consider how FTO analyses are conducted before reviewing the principal FTO strategies.

At the beginning of a research project, a company would typically consider scientific feasibility, the effect of the research on the organization's business position (whether or not the research and the product would eventually strengthen its competitive position), the project's impact on financial status in terms of costs and potential

rewards, and legal aspects (such as infringement risks). That is where an FTO analysis comes in as an initial, cursory, or quite possibly detailed, overview of the patent landscape and competitors' positions. Hence an **FTO analysis need not be a costly legal FTO opinion** (note that an FTO opinion is rendered by patent counsel whereas an FTO review can have any level of legal review, or none). Rather, an FTO analysis is an assessment of the set of patents and other IP rights that are or would be connected to the product and/or method under consideration. Kowalski<sup>2</sup> outlines in detail how different levels of FTO analyses are conducted in practice. Addressing scientists, business people, and legal staff, he describes how products and/or methods are broken down into fundamental components, processes, and combinations thereof, and then how each component is carefully analyzed for attached IP rights of third parties. An FTO analysis, irrespective of the level of detail, requires good preparation, systematic review, and rigorous record keeping.

Although FTO is often viewed as simply a legal issue, when approached from a more practical product-development perspective, **FTO is a strategic risk-management tool**; it relies on a synthesis of scientific and legal expertise, business development, and strategic planning. FTO for a given product in a given market is difficult to achieve because it can never conclusively be established. Obtaining FTO, therefore, becomes a

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Krattiger A, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez, and SP Kowalski. 2007. 14: Freedom to Operate and Risk Management. In *Executive Guide to Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (Krattiger A, RT Mahoney, L Nelsen et al.). MIHR (Oxford, UK), PIPRA (Davis, USA), Oswaldo Cruz Foundation (Fiocruz, Rio de Janeiro, Brazil), and bioDevelopments-International Institute (Ithaca, USA). Available online at [www.ipHandbook.org](http://www.ipHandbook.org).

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strategy, or even a position, mindset, or culture. This is because the patent landscape is dynamic: new patents issue; old patents expire; some patents are abandoned. Therefore, *freedom to operate* does not imply absolute freedom from the risk of infringing another party's intellectual property. Whether or not FTO exists is an 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 statement underscores a critically important principle: there can be no risk-free decision.

FTO is thus a concern that remains throughout the R&D process, to commercialization and even afterward. By setting a goal of having *reasonable* FTO, a set of ten FTO strategies for managing potential IP infringement are proposed and discussed in detail by Krattiger in Chapter 14.1 (Table 1). In practice, typically two or more of these strategies will be adopted, with the specific mix of strategies varying. Which strategies will be appropriate depend on, for example, how advanced the product is, the type of organization that develops the product, and relevant market dynamics. And not all of the listed strategies are feasible for public sector institutions.

**How much attention should a public sector organization give to FTO?** Since some public sector research is not directly intended for commercial use, the answer is sometimes quite simple: Not much. This condition certainly applies to a great deal of university research. However, if the project is specifically aimed at product development, a goal that is becoming more prevalent in the public sector, then FTO becomes a concern. For example, through collaborations with product-development partnerships (PDPs), the primary reason for funding the research is to develop products to help the poor. Such is the case also 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 and aim to bundle technologies and intellectual property in order to license “solutions” rather than individual patents.

A relevant example of the importance of the public sector managing FTO is the development of **Golden Rice**.<sup>4</sup> No attention was given to FTO until the first material was nearly ready for transfer to developing countries. The Rockefeller Foundation then commissioned an FTO analysis that demonstrated, first of all, how many inventions from scientists around the world enabled—or accelerated—the development of Golden Rice. Although a large number of patents—and patent applications—were identified, the FTO analysis also demonstrated that licenses to only a few would be required for the transfer to and use of Golden Rice in developing countries. The FTO analysis provided a list of primary owners of patents (and of materials that went into Golden Rice under material transfer agreements) for which licenses were needed. With the leadership of the Rockefeller Foundation and Syngenta, a large agro-chemical company headquartered in Switzerland, the relevant intellectual property was quickly assembled (or in-licensed) into a package. That package then was licensed, essentially royalty-free, to public sector institutions in developing countries. This approach, in essence, represents the various aspects of FTO, from analysis to strategy, to action.

Each of the ten strategic approaches to obtain FTO listed in Table 1 presents certain 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. For some organizations, such as those developing genetically modified crops (GMOs), the opposite may be the case (where it might be advantageous to delay in-licensing) due to stewardship issues that are the main concern with biotechnology crops. Krattiger concludes his discussion, in Chapter 14.1, by urging the public sector to:

- judiciously evaluate whether and when FTO concerns should be considered
- build in-house capacity to conduct patent searches and cursory FTO analyses (as opposed to legal opinions)

**TABLE 1: THE TEN STRATEGIC FTO OPTIONS**

OPTION	PROS	CONS
<b>LEGAL/IP MANAGEMENT STRATEGIES</b>		
1. License-in	Is relatively straightforward	May not foster in-house R&D initiatives and may be costly
2. Cross-license	Involves give and take	In certain cases, antitrust issues may arise
3. Oppose third-party patents	Can be cost effective	Can be expensive and result might be undesirable (stronger or broader patent)
4. Seek nonassertion covenant	Is cheap and effective	Rarely allows for the in-licensing of valuable know-how
5. 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
<b>R&amp;D STRATEGIES</b>		
6. 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
7. Invent around	Could lead to cross-licensing position	Could lead to delays in product launch and might be costly; incurs opportunity costs
<b>BUSINESS STRATEGIES</b>		
8. Wait and see	Gives time for strategic positioning	Could lead to litigation and jeopardize investment already made
9. Abandon project	Is simple and effective	May be costly (need to write off R&D investments already made; incurs opportunity costs)
10. Merger/ Acquisition	Is highly effective	May distract from main business focus

**In Practice****A combination of several options implemented concurrently**

Source: Krattiger, 2007.<sup>3</sup> The original table in Chapter 14.1 also includes a column listing the key challenges for the public sector for each of the ten strategies.

One of the underlying “technologies” for conducting an FTO analysis is the **patent search**. Such searches are also relevant when an institution is deciding whether to file a patent on a new invention (meaning when one is searching for prior art) or when scientists want to review patent literature. Fortunately, many IP search tools are accessible online at no cost. The chapter by Thangaraj, Potter, and Krattiger<sup>5</sup> provides a “guided tour” of online patent search engines, including a description of the major ones:

- the European Patent Office (EPO’s esp@cenet)
- the U.S. Patent and Trademark Office (PTO)
- the Patent Cooperation Treaty (PCT) Web interfaces of the World Intellectual Property Organization (WIPO)

In addition, the chapter reviews subscription-based services and other paid services, such as Delphion and Derwent World Patent Index (DWPI). Although the discussion is by no means exhaustive, the chapter lists links to many useful sites.

The chapter by Fenton, Chi-Ham, and Boetiger<sup>6</sup> provides an examination of **how the private sector thinks about FTO**. Offering a comprehensive overview of the FTO process, the chapter sheds light on when to invest in FTO analysis and highlights the important role played by law firms in obtaining FTO. As mentioned earlier, for the public sector the strategic relevance of FTO is quite different from that of the private sector. Even when the public sector intends to commercialize products, its mission and goals differ from those of the private sector, and deciding when to pursue FTO becomes a very different question. Nonetheless, given the growing number of public-private partnerships, it is important for the public sector to understand how private companies approach FTO issues. This chapter discusses both private- and public-sector considerations for deciding **whether, when, and how an FTO analysis should be conducted**.

FTO analysis defines options; it provides a map of the relevant IP landscape. Hence, an FTO analysis presents the most viable options for achieving institutional goals. Fenton and colleagues conclude their discussion with a case

study of an FTO analysis initiated by the Public Intellectual Property Resource for Agriculture (PIPRA). The case study explains the process used by PIPRA, from defining the scope of the investigation, to the delivery of the findings.

In the last chapter of Section 14, Boadi<sup>7</sup> looks at the aspect of FTO that includes legal liabilities beyond intellectual property and, appropriately, considers **stewardship as the central tool to managing liabilities**. The legal framework for dealing with liability relies on the country, or legal jurisdiction, in which the intellectual property is being exploited. Even so, GMOs (and indeed non-GMOs) have the potential to cross national borders. This has led to intense debate about whether a liability regime specific to such organisms and crops should be created. Providing an overview of current common law and statutory theories of liability, the chapter considers liability issues facing public sector efforts to develop and disseminate agricultural biotechnologies.

While debate rages about liability and redress issues contained in the Cartagena Protocol on Biosafety, developing countries need to think carefully about how to manage liability today. Referencing the African Agricultural Technology Foundation (AATF), Boadi provides several liability-management practices that can be of great value, including:

- ensuring compliance with intellectual property, license, and regulatory requirements
- including indemnification provisions in technology transfer agreements
- using warranty disclaimers
- obtaining letters of nonassertion
- adhering to appropriate technology stewardship best practices

Already, innovative developing countries (or IDCs), including India, Korea, China, Brazil, South Africa, and others are embracing novel opportunities provided by the new global IP regime. Having established technology transfer offices (TTOs) for organizations in both the public and private sectors, these countries have overseen the controlled, streamlined transfer of crucial technologies, often with clear public benefits. Such efforts, of course, require investments

in both infrastructure and personnel to in-license, out-license, and ensure that investments in product development are accelerated through appropriate FTO considerations during the R&D process and beyond. ■

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All chapters refer to: *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*. 2007. A Krattiger, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez, and SP Kowalski (eds.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at [www.ipHandbook.org](http://www.ipHandbook.org). The online version contains for each chapter a detailed Editor's Summary, Implications, and Best Practices.

- 1 Chapter 14.1 by A Krattiger titled Freedom to Operate, Public Sector Research and Product-Development Partnerships: Strategies and Risk-Management Options, p. 1317.
- 2 Chapter 14.2 by SP Kowalski titled Freedom to Operate: The Preparations, p. 1329.
- 3 See *supra* note 1.
- 4 See Case Study 3 by A Krattiger and I Potrykus titled Intellectual Property Management and Freedom to Operate for Golden Rice in the insert of this *Executive Guide*, p. 11-14.
- 5 Chapter 14.3 by H Thangaraj, RH Potter, and A Krattiger titled How and Where to Search for IP Information on the World Wide Web: The "Tricks of the Trade" and an Annotated Listing of Web Resources, p. 1345.
- 6 Chapter 14.4 by GM Fenton, CA Chi-Ham and S Boetiger titled Freedom to Operate: The Law Firm's Approach and Role, p. 1363.
- 7 Chapter 14.5 by RY Boadi titled Managing Liability Associated with Genetically Modified Crops, p. 1385.



## FOR GOVERNMENT POLICYMAKERS

- ✓ As intellectual property becomes more prevalent in health and agricultural research, public and not-for-profit institutions may increasingly need to consider the intellectual property of **third parties**. This may allow for efficient in-licensing of intellectual property and accelerate the development of products. For such purposes, a good knowledge of “who owns what” is needed. That is what a freedom to operate (FTO) analysis provides.
- ✓ Translating an FTO analysis into an effective strategy requires some **shifts in culture and thinking** by those public sector institutions that are engaged in the development of products. Although a legal opinion by an attorney may be based on a solid FTO analysis, the use of such an analysis is strategic. National governments have a great responsibility to encourage the establishment of best practices in IP management, through sound national policies and funding allocations.
- ✓ Taking FTO into consideration as one element of any product development strategy allows for a more judicious use of resources that can often lead to stronger and more effective partnerships, can increase **opportunities for international collaboration**, and may underpin effective public-private partnerships.
- ✓ Governmental policies and programs that support capacity building in IP management should include the **training of senior management** in FTO strategies, including institutional boards. A dialogue between boards, which are responsible for policy, and senior managers that are more concerned with implementation is essential since an FTO analysis is a **risk-management tool**. This approach increases efficiency in the handling of products for further development and/or commercialization, even if the goal is to address the needs of the poor.
- ✓ **High speed Internet** access and patent databases are valuable tools that can assist research-based institutions in the undertaking of meaningful patent and information searches that are necessary to conduct FTO analyses.

*Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.*



## FOR SENIOR MANAGEMENT

(UNIVERSITY PRESIDENT, R&D MANAGER, ETC.)

- ✓ As public sector and nonprofit institutions increasingly move in the direction of **product development**, whether they do so independently or in partnership with other organizations, freedom to operate (FTO) will contribute increasingly to sound IP management strategy. As such, an FTO analysis is a management tool for assessing and managing certain types of risks.
- ✓ Some public sector institutions need not be concerned with FTO. For example, a typical university that mainly licenses patents or occasionally forms a spinout company can **leave FTO concerns to others**.
- ✓ Public sector research institutions should not necessarily assume that they are exempt from IP infringement liability due to their nonprofit (or governmental or parastatal) status. Although government institutions per se may be shielded from liabilities, FTO rarely ends with these institutions. Eventually other institutions taking on the products may need to be able to deal with FTO (such as commodity exporters). Hence **FTO analysis is just one tool** for making the technology transfer process more effective, and FTO is particularly warranted as an institution expands its mission into product development and distribution.
- ✓ FTO opinions do not eliminate risks related to third-party intellectual property. Instead, they allow for the development of sound **risk-management strategies** (which may be of a legal/licensing nature, involve business approaches, or be research based). Implementing the strategy requires clear pathways of communication and dialogue between science managers, product development, licensing personnel, and senior management.
- ✓ Obtaining FTO includes the review of the patent landscape (FTO analysis) and may include a formal legal FTO opinion. But, in essence, obtaining FTO is a process to be “managed” as an **interdisciplinary endeavor** and considered within the context of the institution’s overall mission (as such it involves senior management), business development, research and technology transfer, and tolerance for risk.
- ✓ Institutional policies that support capacity building in IP management should include the training of senior management in FTO strategies, including institutional boards. A **dialogue** between boards (responsible for policy) and senior management (more concerned with implementation) is essential, since FTO analysis is a risk-management tool.
- ✓ Commitment to the principles of FTO will demonstrate that a given institution is committed to respecting, and of **building upon, the intellectual property of others**.
- ✓ The more downstream a research-based institution operates, the more important FTO considerations become. A system should be in place to help decide **whether, when, and how** a public sector institution should conduct an in-house FTO analysis or commission a legal FTO opinion.

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## FOR SCIENTISTS

- ✓ Collaboration among scientists and the professionals who conduct freedom to operate (FTO) analyses is essential. **The scientist is the most important person** to explain the science behind technology, to help others understand the materials and the scientific approach, and sometimes to explain what specific patent claims mean. A scientist is the expert in his or her area of research and can provide important leads to other scientific groups, publications, and terms of art.
- ✓ Teams conducting FTO analyses will also need to understand precisely **what the product is, how it was developed, what materials were used**, and what reports were prepared. The purpose is not to check on the work, but to ascertain that all relevant information has been considered in the FTO analysis. It is important also to know what tangible property from a third party contributed to a product. A scientific member of an FTO team will need to provide this type of basic information for the FTO analysis. One of the best ways to manage that information is through careful record keeping, including rigorously kept laboratory notebooks.
- ✓ The results of an FTO analysis may **allow you to make better use of technologies in the public domain** and inform your choice of research tools or vector constructs. The analysis also may alert you to scientific discoveries and inventions related to your work.
- ✓ An FTO analysis is a foundation of IP management, but it is also something more. It is a way to demonstrate to your colleagues that you respect their property rights and understand that, when properly managed, intellectual property leads to the greater sharing of technology and related information. In a very real sense, it is a way of **building relationships** based on trust.
- ✓ Both patent search engines and scientific search engines are available at no cost on the Internet (such as the U.S. Patent and Trademark Web site and Google® Scholar).
- ✓ Knowledge of how to access, manipulate, and mine these tools for valuable information will serve you and your program well. Hence, you should encourage your staff to become **well versed in Internet database search skills**, and do not hesitate to ask your technology transfer office to organize short patent search workshops.

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## FOR TECHNOLOGY TRANSFER OFFICERS

- ✓ The management of patent infringement risks requires a good knowledge of the strategic options available. These options include **legal/licensing, business strategies, and R&D strategies**.
- ✓ Unlike at a private company, where business/legal/financial conditions often determine R&D strategies, licensing officers in public sector institutions rarely influence research projects and institutional policy. **The role of the technology transfer officer as communicator** in the public sector is therefore much more important for bringing about an IP management “culture” throughout the organization.
- ✓ A freedom to operate (FTO) analysis is an interdisciplinary endeavor best executed through FTO teams. These teams, made up of legal, business, and scientific professionals, are in themselves useful for **strengthening intra-institutional dialogue** and communications.
- ✓ The role of the technology transfer officer, and that of attorneys who may produce legal FTO opinions, is generally **to advise senior management**. It is a manager’s purview, based on your input, to decide how to deal with the risks identified in your FTO analysis.
- ✓ Much work leading to a legal FTO opinion can be done in-house, working with scientists, technology transfer professionals, business people, and others. **The role of patent counsel** is important for formal legal FTO opinions, but this expense may not often be required or justified in public research settings.
- ✓ Evaluate the pros and cons of free versus subscription-based **patent search sites**. Quite often, free services are limited in content and scope and do not allow for myriad search capabilities of paid services. But many free sites, such as WIPO’s PatentScope, are increasingly adding extremely valuable features.
- ✓ For an academic or public institution, **legal FTO opinions are unlikely to be needed** for the majority of technology transfer functions. They might be applicable if the institution is engaged in downstream product development and commercialization.
- ✓ One way to cut costs is to conduct the background research for an FTO analysis in-house. The compiled file of relevant art can then be provided to patent counsel, who can then further analyze, conduct additional searching to fill in suspected gaps, and render an FTO opinion. **Universities with law schools** might be able to give law students valuable internships in this manner.
- ✓ Through **good licensing practices** (including appropriate indemnification provisions and warranty disclaimers), much of the risk associated with IP infringement can be transferred to licensees who take over products from the public sector.

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