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# Freedom-to-Operate in the Crop Sciences: Procedure

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## Abstract

Freedom to operate (FTO) is the ability to proceed with research, development and commercialization of a crop science product, while fully accounting for any potential risks of infringing activity, that is, whether a product can be made, used, sold, offered for sale, or exported, with a minimal risk of infringing the unlicensed intellectual property rights (IPRs) or tangible property rights (TPRs) of another. An FTO analysis begins with the 'FTO team' systematically dissecting the crop science product into the components, combination of components, processes and germplasm that went into its research and development. This is followed by generating a series of FTO analytical questions, whereby each piece of the product is carefully scrutinized for the presence of potential IPRs, TPRs and germplasm property rights held by other parties. Finally, patent counsel may render an FTO opinion, indicating the likelihood of the risk of infringing the unlicensed IPRs or TPRs of another should research, development or commercialization proceed. FTO is not absolute. The proprietary landscape is in a continual state of flux, both in time and in space, as in the case where patents issue/expire in countries around the world. Therefore, an FTO analysis is a risk-management tool which is only applicable for a given product, at a given time, in a given jurisdiction, and, as such, must to periodically updated.

## INTRODUCTION

A freedom to operate (FTO) analysis is a coherent and methodical procedure for dealing with, sorting out, understanding and organizing the complex technical/legal challenges associated with assessing whether or not a crop science product possesses FTO. The results of the FTO analysis provide a crucial informational tool for assessing the overall likelihood of infringement risk. The general procedure of FTO analysis is sequential: from product deconstruction, to the formulation of a series of FTO analytical questions, to patent and scientific database research, and then (if necessary) ultimately to an FTO opinion rendered by the patent counsel. Accordingly, in order to explain the procedure of FTO analysis in the crop sciences, this paper will systematically present:

1. Product Deconstruction. What are the steps needed to dissect and identify the essential components and processes used to generate a new crop sciences product?
2. Procedure of FTO. What are the three tiers in an FTO analysis?
3. Perspective. What does the FTO analysis mean? What follows? When should it be performed and how often should it be updated?

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*Keywords:* Bag-tag; Due diligence; Infringement; Intellectual property; Intellectual property management; Licensing; Material transfer agreement; Patent counsel; Plant patent; Plant variety protection; Product clearance; Tangible property; Utility patent.

## PRODUCT DECONSTRUCTION

Product deconstruction, a thorough technical description of the product to be cleared, is the preliminary step to an FTO analysis.<sup>[1]</sup> This entails the meticulous, time-consuming dissection of a crop science product into the individual pieces (components, processes, and germplasm) used in its research and development, or in the case of a product that is still in the conceptualization phase, the components, processes and germplasm that are under consideration.<sup>[2]</sup> Each dissected piece of the product, or proposed product, will then generate an FTO analytical question. That is, the piece is sufficiently technically discerned to permit a comprehensive analysis of embedded intellectual property rights (IPRs), tangible property rights (TPRs) or germplasm rights.<sup>[1]</sup> Additionally, the combinations of the components should also be carefully analyzed, since only certain combinations might be patented. To illustrate this important point, a promoter/structural gene construct serves as an example: a construct having a promoter linked to gene-A is patented, but a construct with the same promoter linked to gene-B is not patented.

### Deconstruction of Golden Rice

Crop science products with greater technical complexity will pose a greater array of FTO analytical questions. Transgenic crops are categorically such products. For example, genetically engineered pro-vitamin A rice, 'Golden Rice,' was dissected into four broad technical pieces (germplasm, gene constructs, plant transformation,

DNA amplification), and each of these was further dissected into sub-pieces apt for FTO analytical question formulation. For example one of the Golden Rice plant transformation vectors (pBin19hpc) was ultimately dissected into: a plant gene promoter, an endosperm specific gene promoter, a selectable marker, a transit peptide, a selectable marker, a carotenoid biosynthetic gene, and transformation and co-transformation technologies.<sup>[2]</sup> Each of these sub-pieces defined an FTO analytical question, which was subsequently subjected to FTO analysis.

### The FTO Team

Before product deconstruction, an FTO team must be assembled.<sup>[1]</sup> The team should be lead by qualified patent counsel, preferably with expertise in the field of crop sciences and biotechnology. Several key scientists and technicians who worked on the research and development of the product will also be essential members of the team. They will directly cooperate with counsel to answer questions and assist in deconstructing the crop science product. Business and marketing personnel might also be members of the FTO team, depending on the marketing, advertising, distribution and sales plans for the product, for example, where and when it will be distributed. As an interdisciplinary group of professionals, the FTO team can collaboratively cooperate in assessing options available for achieving FTO, such as licensing, workaround strategies, substitute technologies, and strategic partnerships.

## PROCEDURE OF FTO

An FTO analysis is tiered, beginning broadly and then becoming increasingly refined in subsequent analyses.<sup>[1]</sup> Therefore, the FTO analytical funnel selects and then channels information that is subsequently used to address each FTO analytical question. At each tier, the FTO team must remain in close contact with any other scientists or technicians working on the research program/product, as well as with any colleagues who might be research collaborators or sources of materials. A few moments of discussion can save hours, or even days, of agony afterward. At each tier, all FTO analytical results must be systematically entered into an FTO analytical table, using a tool like Microsoft Excel.<sup>[1,3]</sup>

### Tier One Review

This is where the results of the product deconstruction, that is, the series of FTO analytical questions, are applied to a sweeping search for any potentially relevant IPRs, TPRs and germplasm rights. At this early stage of the FTO analysis, the goal is to corral any information that appears

to be potentially relevant. This is the widest part of the FTO analytical funnel.

For IPRs (patents), the FTO team must search electronic patent and scientific databases, structuring and carefully documenting their search strategies and search results. Patents are searched based on title, abstract and claims, interpreting language broadly, searching for any product or process that is even remotely relevant to an FTO analytical question. Likewise, any potentially relevant scientific literature must be documented. For processes and techniques used during research and development, the FTO team should assume that there is no experimental use exception available, even for nonprofit institutions.<sup>[4]</sup>

For TPRs (MTAs and bag-tag licenses), the FTO team must investigate every piece of tangible property that went into the product, and find any MTAs in files, in notebooks, or stuffed into drawers, as well as any bags of seed that are lying around the office, laboratory, greenhouse or fieldhouse.

For germplasm rights, the FTO team must determine the complete pedigree of the plant materials used in the crop science product, including all varieties, inbred lines, and any germplasm obtained from the 'Multilateral System' collections possibly present in the pedigree.

### Tier Two Review

For IPRs, the FTO team should cross-reference patents with the scientific literature, by authors/inventors, institutions/assignees, and results/claims. This type of survey will further map the relevant IPR landscape. Counsel can now look more closely at which patents to retain for further investigation, and which to exclude as irrelevant. At this stage, it will be necessary to examine the specifications of relevant patents in order to interpret and construe more precisely what each patent claims.

For TPRs, the FTO team must examine the terms of the MTAs and bag-tags uncovered. Also, it is very important for the FTO team to determine what other tangible property went into the crop science product's development. Specifically, at this stage of the analysis the FTO team must find any potentially misappropriated (obtained without MTA) tangible property.<sup>[2]</sup>

For germplasm rights, the FTO team might need to continue the analysis by contacting plant breeders who are familiar with the germplasm's history. This could involve correspondence and/or telephone interviews.

### Tier Three Review

For IPRs, this tier represents the narrowest phase of the FTO analysis. Here, patent counsel will carefully scrutinize the remaining relevant patents: examining and reviewing the claims and cataloging pertinent patent families. This level of analysis is needed in order to

carefully construe the scope of the patent claim language, so as to ascertain how far the patent property rights extend, and in the case of patent families, to determine in which foreign countries the relevant patents have been filed or issued.<sup>[5]</sup>

For TPRs, patent counsel must verify which MTAs and bag-tags are relevant, which are to be excluded, and whether tangible property owned by others was used without authorization.

For germplasm rights, patent counsel must determine if the sources of germplasm present in the pedigree were either legitimately used or were properly obtained. To facilitate these determinations, an accurate and detailed pedigree is absolutely essential.<sup>[6]</sup>

## FTO PERSPECTIVE

### FTO Opinion

Following the three-tiered FTO analyses, counsel may draft FTO opinions for some or all of the FTO analytical questions. An FTO opinion may be rendered when an IPR, TPR or germplasm right of another cannot be readily ruled out as irrelevant for a given FTO analytical question. The FTO opinion discusses and indicates the likelihood that the crop science product, its components/subcomponents or processes infringe the proprietary rights of others.<sup>[1,3]</sup> This infringement likelihood might be either low or high, depending on the results of the FTO analysis.

### FTO Due Diligence

Broadly defined, due diligence is ‘Such a measure of prudence, activity, or assiduity, as is properly to be expected from, and ordinarily exercised by, a reasonable and prudent person under the particular circumstances; [Due diligence is] not measured by any absolute standard, but depending on the relative facts of the special case.’<sup>[7]</sup> For an FTO analysis, due diligence requires a systematic, thorough, and persistent approach, such that all possible problems are addressed and all potential risks of infringement are assessed.<sup>[8]</sup> To put it more figuratively, all stones are overturned, until one finds that the same stones are repeatedly being tipped and peeked under.

### FTO: When to Perform

If possible, an FTO analysis is best conducted before the research phase begins. This is done so that potential problems can be identified before the research team invests large amounts of time, money and effort.<sup>[1]</sup> The FTO team can then ascertain whether there are suitable alternative materials, methods and germplasm. However, it may not be economically feasible to perform an FTO analysis at such an early stage; an FTO analysis might therefore be

seriously considered only at a later stage, such as when product commercialization is under consideration. Whatever course is taken, a timely FTO analysis is prudent, because if a serious issue is only discovered when the product is on the verge of commercialization, owners of any relevant IPRs, TPRs or germplasm rights will be in a greatly superior bargaining position in the event of licensing negotiations.<sup>[6]</sup>

## FTO in Time and Space

From the perspective of time, an FTO analysis is only a snapshot, for a particular product, at a particular time, in a particular jurisdiction (country). Therefore, the utility of an FTO analysis is evanescent, being eroded by the changing legal landscape, such as in the cases when patents issue or expire, when they are assigned, when they are invalidated, when relevant patent applications may be pending,<sup>[9]</sup> when tangible property enters the public domain, and when various germplasm rights issue and expire.<sup>[2]</sup> Therefore, to keep the FTO analysis current and accurate, regular FTO analysis follow-up is necessary and prudent.<sup>[1]</sup>

From the perspective of space, when conducting an FTO analysis, it is important to remember that patents are territorial in nature,<sup>[10]</sup> and a patent right can only be enforced in the jurisdiction (country) where issued. A technology that is patented in the United States might not be patented in other countries, and similarly, some technologies may be patented in foreign jurisdictions but not in the United States. So, there is no illegality in practicing a technology in a country where it is not patented. Therefore, the FTO analysis must consider where a crop science product will be researched, developed, imported, exported, marketed and/or sold.

## FTO, A Final Note

Nothing in this paper should be interpreted as constituting either legal advice or a legal opinion. An FTO analysis must always begin by consulting qualified patent counsel. There are no exceptions to this rule. Thereafter, counsel will guide the FTO team through the complex FTO analysis procedure, and provide the advice and opinions necessary to launch a crop science product.

## CONCLUSION

It is a general maxim that it is wiser to anticipate a potential problem and remedy in advance than it is to wait until later and have to deal with, and resolve, a full-blown crisis. This is particularly true regarding the management of IPRs, TPRs and germplasm rights in the crop sciences. In the research and development of a crop science product, the possibility of infringing the proprietary rights of others

is always an issue. An FTO analysis is a systematic method designed to prophylactically preempt such infringement. Led by qualified patent counsel, the FTO team can analyze the technical components of the product, formulate the proper FTO analytical questions, conduct the FTO analysis, and counsel can then render FTO opinions as required.

### ARTICLES OF FURTHER INTEREST

Freedom-to-Operate in the Crop Sciences: Principles; Intellectual Property and Plant Science; International Treaties Relevant to the Management of Plant Genetic Resources.

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