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Freedom-to-Operate in the Crop Sciences: Principles
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Abstract
Research and development in the crop sciences is increasingly impacted by the risk of infringing the intellectual property rights (IPRs; e.g., patents) and tangible property rights (TPRs; e.g., material transfer agreements) of others. Since crop science products now entail such a high degree of technical complexity, and the processes and components to make such products are so ubiquitously available, the potential for such infringement is simply omnipresent. A freedom to operate (FTO) analysis is a tool that provides the requisite information so as to systematically, and prophylactically, assess such legal risks, which can then be managed and significantly diminished. FTO, therefore, 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, i.e., whether a product can be made, used, sold, offered for sale, or exported, with a minimal risk of infringing the unlicensed IPRs or TPRs of another.

INTRODUCTION
Increasingly, proprietary issues are impinging on the research, development, sale and distribution of crop science products. There is a complex web, interconnecting the essential components and processes embedded in these products with property rights potentially held by other parties.

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 crop science 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 others.[1–4] Conversely, the absence of FTO would be where the unlicensed IPRs/TPRs of others effectively impede the research, development and/or commercialization of a new crop science product.[4]

In order to explain FTO in the crop sciences, a basic understanding of key concepts is essential. Accordingly, this paper addresses:

1. Principles of FTO. What is FTO and what does it seek to accomplish?
2. Property Particulars. What are the three types of property rights generally present in crop science products?

PRINCIPLES OF FTO
FTO analysis (the assessment of potential IPRs and TPRs appurtenant to a crop science product) is about risk management. It is about providing the maximum amount of sound information and proficient analysis such that informed decisions can be made, and a reasonable course of action taken.[2,5] So, the term ‘freedom’ in FTO does not imply an absolute freedom or guarantee, but instead indicates a carefully executed analysis leading to a reasoned opinion that one can legally proceed with research, development or sale, in a given jurisdiction at a given point in time. Typically, FTO analyses are focused on one specific form of IPR, namely patents. However, in the crop sciences, due to the complexity of transgenic plants, an FTO analysis is an intricate three-dimensional task. To conduct an FTO analysis, one must simultaneously analyze IPRs, TPRs, and germplasm rights.[6]

PROPERTY PARTICULARS
Proprietary rights can be broadly categorized as either IPRs or TPRs. IPRs deal with products of the intellect (property having no physical existence) and include trademarks, copyrights, trade secrets and patents. TPRs, on the other hand, deal with corporeal property, that is, what can be seen, weighed, measured or touched.[7]

To conduct an FTO analysis, the technical sub-pieces of the crop science product that delineate the array of FTO analytical questions must be reviewed for applicable
proprietary rights. In the crop sciences, proprietary rights fall into three categories:

1. Utility patents (IPRs)
2. Material transfer agreements (bailments), bag-tags (TPRs)
3. Germplasm rights (IPRs), including applicable treaties

Utility Patents

Utility patents are the best known, and arguably the most ubiquitous, IPRs that will be encountered in a complex crop science product. For example, in the FTO analysis of Golden Rice, up to 70 patents and patent applications were preliminarily identified as relevant. A patent can be viewed as a sort of contract between the inventor and the government, wherein the inventor agrees to fully disclose his invention in the patent specification, in exchange for the right to exclude others from making, using or selling his claimed invention, for a limited term (20 years from the filing of the patent application). To be patented, an invention must be useful, novel, and not obvious to one skilled in that field of technology. In the biological and crop sciences, utility patents may be granted claiming products, processes or plants (see below).

Material Transfer Agreements/Bag-Tags

A material transfer agreement (MTA) is a binding contract for the transfer of biological materials that are unavailable in the public domain. Although the precise legal definition of an MTA apparently still remains to be sorted out, MTAs resemble bailments more than they do either licenses or leases. While there is a change in the actual physical possession of the property, there is no transfer of ownership. So, title remains with the owner/transferor, even though possession has shifted to the recipient. Although sometimes used to transfer patented materials, MTAs are most commonly used when transferring nonpatented proprietary materials and information, such as trade secrets, and are governed according to relevant state law. Examples of biological materials covered by MTAs are plasmid constructs, cell lines, transformation vectors and plant genetic resources. Contractually, MTAs define and limit how the recipient scientist or institution can use the transferred biological materials (tangible property), and may also specify reach-through rights granted back to the transferor. Therefore, one must exercise caution when executing an MTA because the downstream ramifications may become onerous.

Another form of a TPR in the crop sciences is the bag-tag license, a contract restricting the licensee (grower) in the use and reuse of seed, which otherwise would be permissible. The bag-tag license is analogous to shrink-wrap, box-top, and tear-me-open software license transactions, such that an implicit contract is formed upon breaking the seal, obligating the grower to the terms of the license. The key provisions of bag-tag licenses are likely enforceable.

Germplasm IPR Protection

In the United States, there are three principal types of statutory germplasm IPR protection: Plant Patents, Plant Variety Protection, and Utility Patents. Since this discussion deals primarily with United States law, the reader is referred elsewhere for an excellent overview of international IPR protection for plants.

Plant Patents

The Plant Patent Act (PPA), passed by congress in 1930, provides IPR protection for asexually (vegetative) propagated plants, such as plants that are propagated by cuttings, budding, or grafting. However, tuber propagated plants (potato varieties) are excluded. The PPA is a section of the general federal patent statute (35 U.S. Code). The term of a plant patent is 20 years from the date of first filing.

Plant Variety Protection

The Plant Variety Protection Act (PVPA), passed by congress in 1970, provides IPR protection for sexually propagated plant varieties, F1 hybrids, and also tuber-propagated plants (potato varieties). In order to obtain protection, the plant variety must be new, distinct, uniform and genetically stable. Unlike the PPA, the PVPA is not a section of the general federal patent statute, but rather is found in 7 U.S. Code. Consequently, plant variety certificates are issued by the U.S. Department of Agriculture and not the U.S. Patent and Trademark Office. The term for a PVP is 20 years, except for trees and vines where the term is for 25 years.

Utility Patents for Plants

Compared with plant patents and plant variety protection, utility patent protection for plants requires greater expense and effort by the applicant. However, the level of IPR protection is much broader than that afforded by either the PPA or the PVPA. Whereas the PPA and PVPA only provide IPR protection for certain plant varieties, utility patents for plants can claim plants, plant varieties, plant parts, seeds, and tissue cultures.

Trade Secrets

Under certain circumstances, plants can be protected as trade secrets. For example, the ‘genetic messages’ that are...
contained within and integral to inbred maize parental seeds are confidential information that can be protected under state trade secret laws. So, intense scouting for an errant inbred parental in a vast field of hybrid maize might constitute misappropriation of another’s trade secret.\[17\]

**Germplasm IPR Treaties**

Two treaties that address germplasm IPR protection are the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA),\[18\] and the Convention of the International Union for the Protection of New Plant Varieties (UPOV).\[19\]

**UPOV**

UPOV, of which approximately 50 nations are signatories, seeks to harmonize international IPR protection for plant varieties by providing a *sui generis* system of protection. Member nation plant breeders are guaranteed a right of priority and national treatment in all other UPOV Member nation plant breeders are guaranteed a right of priority and national treatment in all other UPOV signatory states.\[8,19\] In 1981, UPOV became law in the United States.\[8\] Accordingly, the PVPA has been amended to conform to UPOV.\[8\] As with the PVPA, the fundamental criteria for IPR protection under UPOV are distinctiveness, uniformity and stability.\[19\]

**PGRFA**

After having been ratified by the requisite number of countries (including the United States in November 2002), PGRFA went into effect in 2004. Under the auspices of the FAO, the PGRFA places restrictions on germplasm received from the ‘Multilateral System’, which includes national germplasm repositories, and, significantly, the vast CGIAR collections. Important provisions include an agreement not to claim IPRs for any of the germplasm resources ‘in the form received’ from the Multilateral System, and also a benefit-sharing scheme triggered by the commercialization of new plant varieties.\[18,20\] Adherence to these provisions will be articulated in an MTA accompanying germplasm transfer.\[18\]

**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. The critical prerequisites to an FTO analysis are a solid understanding of the principles of FTO and an awareness of the various IPRs and TPRs potentially associated with a new crop science product.

**ARTICLES OF FURTHER INTEREST**

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

**REFERENCES**