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Intellectual Property and Freedom to Operate

2013 Cotton Biotechnology Workshop

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Intellectual Property

* **Patents**
* **Trademarks**
* **Trade Secrets**
* **Copyrights**

Rights of a Patent Owner

* **An issued patent grants the right to its owner to prevent (exclude) others from making, using, selling, offering for sale or importing the patented invention into the United States without authorization of the owner for a period of 20 years from the date of filing.**

Common Misconceptions

* **If I am the owner of a patent, it gives me the right to practice (make, use, sell, offer for sale and import) the invention.**
  * **No, as the owner, you can exclude others from practicing the invention, but you can still be sued by other patent holders if you violate their patents in the course of practicing your invention.**
* **As an academic or public researcher, I can use someone else's patented invention if I use it solely for teaching and/or research purposes, including proof of concept.**
  * **No, there is no research exemption under the U.S. Patent Statutes. Anyone who wishes to make, use, sell, offer for sale and/or import the patented invention must have a license from the patent owner.**

How do I determine if someone else has a patent that creates issues for my Research & Development?

Conduct a Freedom to Operate (FTO) assessment.

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What is Freedom to Operate?

* ***Freedom to Operate (FTO)*** **is the ability to proceed with research, development and commercialization of a 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 imported, with a minimal risk of infringing the intellectual property rights others.**

FTO Principles

* **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 and/or sale, in a given jurisdiction (country) at a given point in time.**

FTO Principles

* ***FTO analysis*** **(the assessment of potential IP associated with a product) is about risk management: providing the maximum amount of sound information and proficient analysis, such that informed decisions are made, and a reasonable course of action taken.**

FTO Analysis

* **An FTO analysis is a focused and intense investigation, performed by meticulously dissecting a biotechnological product or process into its fundamental components and then scrutinizing each for any associated intellectual property of third parties. Importantly, don't overlook methods, e.g. *Agrobacterium* transformation methods, that may be patented to produce a product.**

FTO Opinion

* **Based on the results of the FTO analysis, your patent attorney will draft an FTO opinion that indicates the likelihood that the biotechnological product or process infringes the IP rights or tangible property rights of others. Such infringement likelihood might be either low or high, depending on the results of the FTO analysis. Drafting an FTO opinion, helps protect you from the possibility of treble damages in a patent infringement suit!**

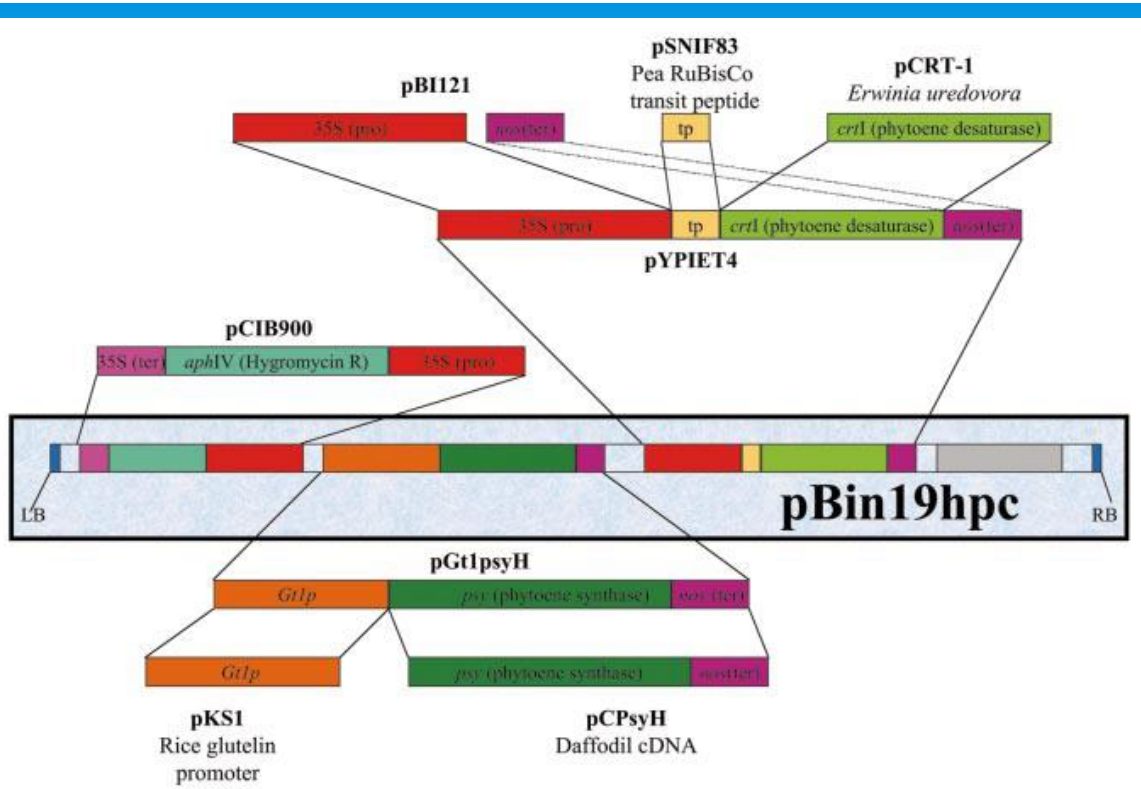
FTO Status

* **The FTO opinion will inform, with respect to the overall status of the FTO for a given product – depending on the time and place – the level of potential risk associated with contemplated R&D and/or commercialization activities. Such risks vary; hence, FTO status is relative.**

FTO Analysis:
Golden Rice

Plant J. 2002, 31(4)

407-421



Component	Reference	No. of Patents	No. of Assignees
Phytoene desturase - *crtI*	Fraser *et al.*, 1992 Misawa *et al.*, 1993	1 US 2 PCT	2
Phytoene synthase - *Psy*	Schledz *et al.*, 1996 Burkhardt *et al.*, 1997	3 US, 1 EP 1 JP, 3 PCT	6
Hygromycin phosphotransferase - *aphIV*	Waldron *et al.*, 1985 Wünn *et al.*, 1996	1 US	1
CaMV 35S Promoter - 35S(pro)		3 US 1 PCT	2
CaMV35S Terminator 35S(ter)		None found	None found
Nopaline synthase terminator - *nos*(ter)		None found	None found
Rice glutelin promoter - *Gt1p*	Okita *et al.*, 1989	1 JP 1 PCT	2
Pea RuBisCo transit peptide - tp	Schreier *et al.*, 1985	3 US	2

Obtaining FTO

* **Licensing options**
* **Invalidate patents**
* **Modify product**
* **Abandon project**
* **Invent around**
* **Non-assert**
* **Wait (and see)**

Big 6 Ag Biotech Players

* **The Big 6 (Monsanto, Bayer CropScience, BASF, Pioneer/DuPont, Syngenta, and Dow AgroSciences) own the IP on the vast majority of enabling technologies, e.g. promoters (35S), selectable markers (PAT/bar gene), etc.**

Big 6 Ag Biotech Players (Cont.)

* **Several of the Big 6 have provided some of their technologies at no cost.**
    - **Monsanto Company recently announced that it will provide a royalty-free research license to the academic community and other non-profit research institutions to a newly issued US Patent (US Patent number 8273954) related to the *Agrobacterium* transformation method.**

http://monsantoblog.com/2012/09/25/helping-academic-research/

Big 6 Ag Biotech Players (Cont.)

* **"Syngenta e-licensing heralds new era for sharing of plant science innovation" PR Newswire Jan. 17, 2013**

  - Easy, internet-based access to key patented technologies

  - Fair, reasonable and transparent terms for all

  - Free use for academic and non-profits for R&D purposes and distribution of resulting products in developing countries.

  - www.traitability.com

Generic Event Marketability and Access Agreement (GEMAA)

* **Prompted by first ever generic trait entering commercial market when all patents on RoundupReady® soybeans expire.**
* **All Big 6 players have signed, except Syngenta.**
* **Requires signatories to disclose date of last to expire patent on commercial events with some caveats.**
* **http://www.agaccord.org/?p=notices**

Generic Event Marketability and Access Agreement (GEMAA)

* **Monsanto has provided notice that all the patents on the MON810 event (YieldGard® corn) will expire no later than Nov. 2014**
* **Go into regulatory filings to see construct for MON810: http://www.aphis.usda.gov/brs/aphisdocs/95_09301p.pdf (pg. 45). http://www.aphis.usda.gov/brs/aphisdocs2/96_01701p_com.pdf**
* **You will then know that you have FTO with respect to the components of the MON810 event, e.g. promoter and selectable marker, and may use them in your research.**

Patents on Germplasm

* The FTO assessment on germplasm is much easier because only one patent usually exists on a given inbred or cultivar.
* Always need to consider that a Plant Variety Protection Certificate ("PVP") may exist in addition to a patent. http://www.ars-grin.gov/cgi-bin/npgs/html/pvplist.pl
* For a small fee, patented seed can be obtained from the patent depository (usually ATCC). http://www.atcc.org/en/Support/How_to_Order.aspx
* Even if the germplasm patent has expired, it may contain a biotech trait on which the patent has not expired and you need to breed away from the biotech trait.

Thank You

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