

UNIVERSITY of NEW HAMPSHIRE

SCHOOL of LAW

THE  
FRANKLIN  
PIERCE *Center for*  
INTELLECTUAL  
PROPERTY



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FREEDOM TO OPERATE,  
PRODUCT  
DECONSTRUCTION, AND  
PATENT MINING:  
PRINCIPLES AND  
PRACTICE

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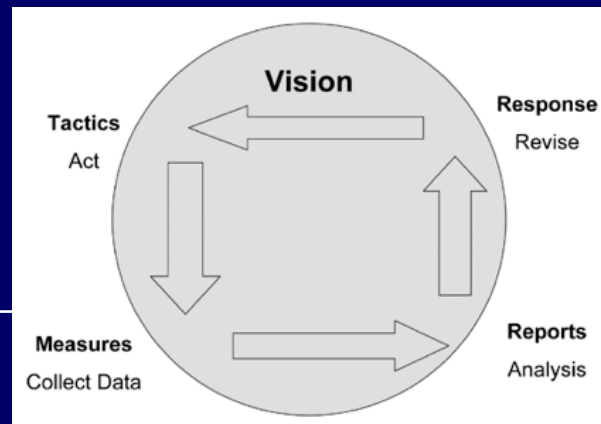
## PATENT SEARCHES

A **patent search** identifies relevant categories of patents, pending patent applications, and can be extended into a search of international patents and also non-patent literature (NPL). A patent search helps to develop options as to where to file a patent application, enforce or defend rights, optimize research efforts, launch a new product in the market, or establish freedom to operate. Patent searches can answer specific questions and are thus categorized accordingly.

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## PATENT SEARCHES

- Patent searching involves more than just searching patents
  - Patent searching also involves searching NPL
- Patent searching is an iterative process
  - Involves continual modification applying new information obtained in prior searches to new searches



# PATENT SEARCHING PROCESS

1. Understand the technology
  - From conception to commercialization
2. Determine scope of search
  - Patent issuing authorities, time, non-patent literature, etc.
3. Formulate search approach
  - Keywords, assignees, inventors, classifications, claims, titles, etc.

## PATENT SEARCHING PROCESS

4. Develop a list of search terms
  - Breakdown the invention's essential elements, process, function, and problem solved
5. Choose search database/service
  - Content, cost, value added options, etc.
6. Formulate searches
  - Keyword, classification, and hybrid search

## PATENT SEARCHING CONSIDERATIONS

- Patent protection is geographically and time limited
  - Patents are granted by countries and regional offices
  - No world patents, the PCT issues applications
  - Patents are enforceable for a limited time, U.S. 20 years from applications
- Technology does not have a uniform terminology
  - Patent applicants are their own lexicographer
  - New technologies may not have an accepted vocabulary  
Example: Kevlar's patent title was "Optically anisotropic aromatic polyamide dopes"

## TYPES OF PATENT SEARCHES

- Keyword
  - Uncontrolled search
- Classification
  - Controlled search
  - Subject to the classification designation of the issuing office and patentee
- Hybrid
  - Best of both worlds

## RECALL & PRECISION

- **Recall:** search for *all* potentially relevant items
  - Often provides more references with some that lack applicability
- **Precision:** search for *only* potentially relevant items
  - Often provides more applicable references but tends to miss other potentially relevant references



## TYPES OF PATENT DATABASES

- Bibliographic
  - No full text
  - Provides citation, dates, classes, and abstract
- Full Text
  - Basic or enhanced record
- Hybrid
  - Full text plus abstract

# NO INTERNATIONAL PATENT DATABASE

## Comprehensive Databases:

- INPADOC (EPO) – 80 countries
- World Patent Index (Derwent) – 41 patent issuing authorities
- PCT (Patent Cooperation Treaty) – PCT patent applications covering 142 contracting states

## PATENT DATABASES

### Free

- WIPO
- EPO (esp@cenet)
- National Offices
  - USPTO
  - JPO
  - KIPO
  - SIPO
- Google Patent
- Pat2PDF

### Commercial

- Thompson Innovation
- LEXISNEXIS TotalPatent
- Westlaw
- DialogPRO
- Delphion
- Micropatent

# CHOOSING A PATENT DATABASE

- Cost and pricing structure
- Familiarity
- Purpose and type of searches being conducted
- Value added features
- Database customer service
- Sophistication

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# VALUE ADDED FEATURES OF COMMERCIAL PATENT DATABASES

- Textual enhancement, codifying, and uniformity
  - DWPI (Thompson Reuters)
- Ability to save search history
  - Delphion, Thompson Innovation, Micropatent, TotalPatent
- Export search history
  - Thompson Innovation
- Patent analytics
  - Delphion, Thompson Innovation, Micropatent, TotalPatent
    - Non-patent literature
      - Thompson Innovation

## MINING PATENT DATA: TYPES OF SEARCHES

- Patentability/novelty search
- Validity search
- Freedom to operate (“right to use“) search
- File wrapper search
- Assignment/inventor search
- Landscape search

## 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 exported, with a minimal risk of infringing the unlicensed intellectual property rights (IPR) or tangible property rights (TPR) of 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 or sale, in a given jurisdiction at a given point in time.
- **FTO Analysis** (the assessment of potential IPR and TPR appurtenant to 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 PRINCIPLES

- **FTO Opinion** is based on the results of the FTO analysis, patent counsel will draft an FTO opinion that indicates the likelihood that the product or process infringes the IPR or TPR of others. Such infringement likelihood might be either low or high, depending on the results of the FTO analysis.

## FTO PRINCIPLES

- FTO Analysis → Product Clearance
- Property Rights
  - Intellectual Property Rights (IPR)
  - Tangible Property Rights (TPR)
- Understanding patent information
  - File wrappers
  - Disclosures
- Remaining aware of 18 month “zone of silence”
  - From patent application to publication

## FTO PREPARATION

- Assembling the FTO Team
- Deconstructing and understanding the technology
- Understanding IP and TP rights and the patent process
- Interviewing researchers
- Locating notebooks, records, and other documents
- Finding agreements and contracts
- Formulating an FTO inquiry
- Searching NPL and patent resources
- Maintaining due diligence

## FTO PROCEDURE

- Product deconstruction
- Review and analysis
- Opinion
- Status
- Clearance strategy

# FTO PRODUCT DECONSTRUCTION

What are the steps needed to dissect and identify the essential components and processes used to generate a product?

- Analyzing, understanding, and dissecting the technology
- Formulating a series of FTO analytical questions

## FTO SEARCH

- Purpose, identify patents (IP rights) or applications that may cover a proposed product or process ....  
“Blocking patents”
- Coverage, patents (and other IP rights) still in force.  
Includes narrow and broad concepts

# FTO REVIEW AND ANALYSIS

## The FTO Analytical Funnel:

- Three tier analysis:
  - Tier 1: Collecting relevant information
  - Tier 2: Patent and NPL survey
  - Tier 3: Intensive examination of patents and NPL
- FTO review and analysis is a compounding process that is iterative...iterative...and then iterative again!

## FTO REVIEW

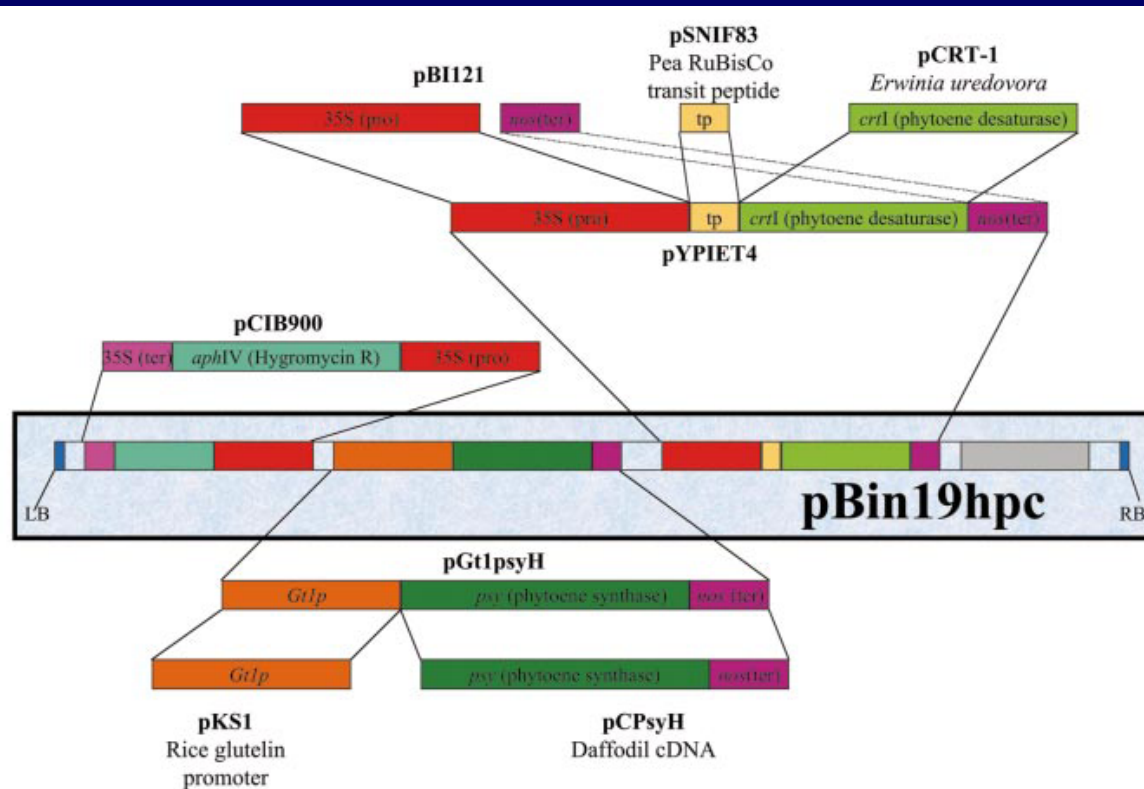
### Intellectual Property Protection Search:

- Identify patents, patent applications, and other IP rights that may cover the proposed product or method of interest
  - Blocking patents
- IP protections:
  - Time sensitive
  - Often country specific



## FTO CLEARANCE STRATEGY

- Provides a baseline for formulating a strategy for product development based upon current IP/TP rights
- Consider business and legal constraints and developing a plan that best fits the mission of the organization and its **tolerance for risk**
- Identifies potential future options, such as: licensing, attempting to invalidate blocking patents, modifying the product or process, abandoning the project, inventing around, etc.



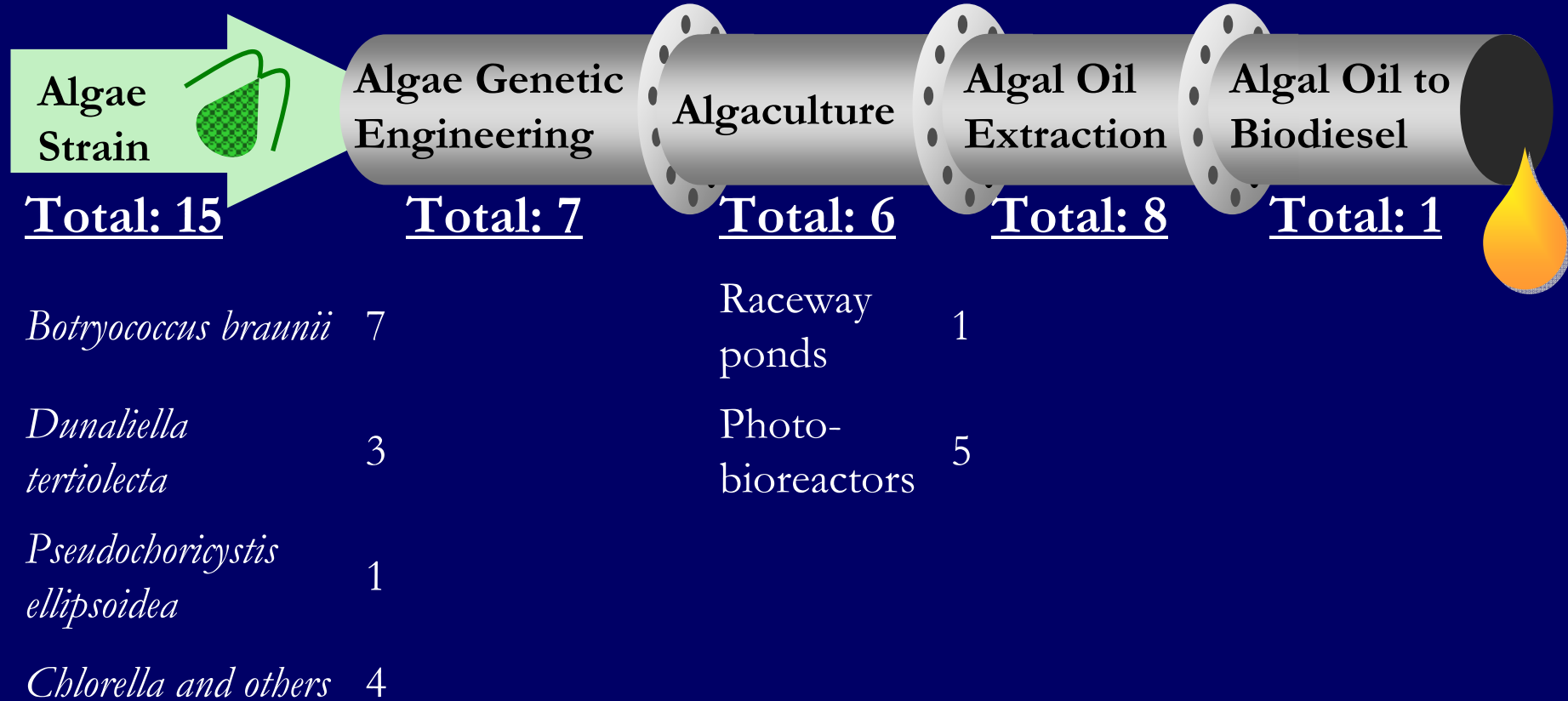
## FTO Analysis: Golden Rice

*Transgenic crops,  
biotechnology and  
ownership rights: what  
scientists need to know.*

Plant J. 2002, 31(4)  
407-421

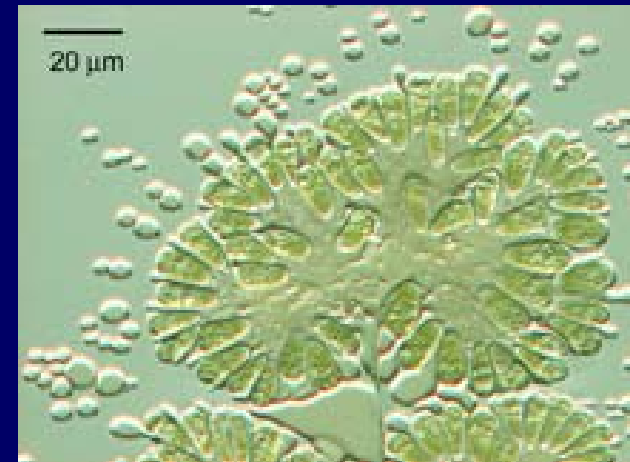
Component	Reference	No. of Patents	No. of Assignees
Phytoene desturase - <i>crtI</i>	Fraser <i>et al.</i> , 1992 Misawa <i>et al.</i> , 1993	1 US 2 PCT	2
Phytoene synthase - <i>Psy</i>	Schledz <i>et al.</i> , 1996 Burkhardt <i>et al.</i> , 1997	3 US, 1 EP 1 JP, 3 PCT	6
Hygromycin phosphotransferase -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

# ALGAL BIODIESEL PROCESS PATENTS AND APPLICATIONS



# ALGAE STRAINS FOR BIODIESEL

- *Botryococcus braunii* variety Ninsei
- Highly advantageous algae strain for biodiesel production because it secretes algal oil
- Avoids the harvest and extraction process which can be ~70-90% the production cost<sup>1</sup>
- U.S. Plant Patent No.: 21,091
- Utilization of this single strain for biodiesel can encounter many patent protections during the production process



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<sup>1</sup>Haas M et al (2006) A process model to estimate biodiesel production costs. Bioresource Technology 97:671-678; Meng X et al (2009) Biodiesel production from oleaginous microorganisms. Renewable Energy 34:1 – 5.  
Image from: <http://www.tsukuba.ac.jp/notes/index.html>

# ALGAE GENETIC ENGINEERING

- Optimizing the algal oil output of may require genetically engineering the *B. braunii* var. Ninsei
- There are a number of patents and applications related to the genetic engineering of algae for increased algal oil production/photosynthetic efficiency
- US7,745,696 – Suppression of *tlal* gene expression for improved solar conversion efficiency and photosynthetic productivity in plants and algae
- US20090280545 – Molecule production by photosynthetic organisms

# ALGACULTURE AND ALGAL OIL PRODUCTION

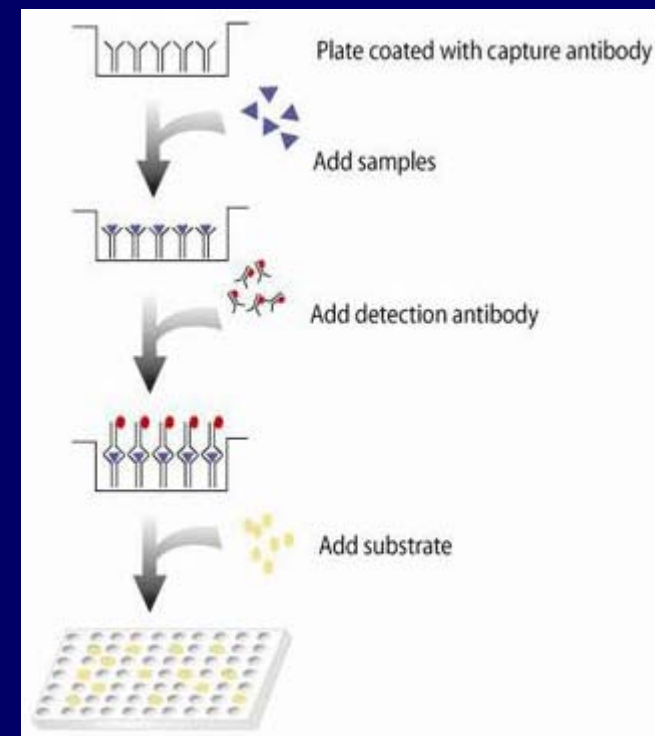
- Patent for culturing techniques and algal oil production for *B. braunii* var. *Ninsei* have also been applied for
- US20090087889 and US20060252138 – Methods and compositions for growth hydrocarbons in *Botryococcus* sp.
- These examples demonstrate how more complex technologies can encounter compounding patent protections

## DENGUE DIAGNOSTIC KIT

- ST2-Based Dengue Fever Diagnostic
- PCT Application No.: WO2009145810A2
- Claims a Kit for diagnosing Dengue by detecting a soluble interleukin (sST2) protein or nucleic acid
- Components of the Kit are:
  - ST2 antibody
  - Reagent capable of detecting sST2
  - Instruction

## DENGUE FTO

- However, ST2 antibody is patented
- Monoclonal antibody and method and kit for immunoassay of soluble human ST2
- US7,087,396
- U.S. Issue Date: September 16, 2002
- Valid until 2022





## DENGUE FTO

- Likewise, methods of detecting sST2 are patented.
- US5,639,606 (Filing Date: Jan. 28, 1994)
- US6,001,567 (Filing Date: Jul. 12, 1996)
- US6,159,750 (Filing Date: Oct. 24, 1997)

## PROSTHETIC UPPER LIMB

- Product Deconstruction:
  - Functional below elbow limb
  - Hybrid body and externally powered and controlled
  - Motorized gripper
- Advantages:
  - Reduced cost
  - Controllable gripper
  - Gripper is actuated by healthy shoulder

## KEYWORDS

### Prosthetic

- Robotic
- Artificial
- Mechanical
- Biomimetic
- Bionic
- Bioelectric
- Electronic
- Myoelectric

### Upper limb

- Arm
- Wrist
- Hand
- Elbow
- Appendage
- Upper Extremity

# INVENTORS AND ASSIGNEES

- Inventors:
  - Otto Bock
- Assignees:
  - U.S. Armed Forces
  - Motion Control Inc.
  - Touch Bionics

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The **International Technology Transfer Institute (ITTI)** is an innovation capacity building law clinic at the Franklin Pierce Center for Intellectual Property at the University of New Hampshire School of Law (UNH Law). ITTI is dedicated to promoting global innovation focusing on access to advances in health, biotechnology, and agricultural in developing countries through establishing/strengthening technology transfer offices internationally.



**Kowalski** is a Professor of Law and Director of the International Technology Transfer Institute at the University of New Hampshire School of Law. Stanley holds a PhD in plant breeding from Cornell University and a JD from the University of New Hampshire School of Law. Stanley conducted the preliminary freedom-to-operate analysis of (pro-vitamin A) Golden Rice and is an author of the *Intellectual Property Management in Health and Innovation* (<http://www.iphandbook.org/>). Stanley.Kowalski@law.unh.edu



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# THANK YOU!

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