

Freedom-to-Operate Tutorial on IP Searches

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PLS28809 **TRANSGENIC PLANT AND *IN VITRO* PLANT-BASED EXORESSION SYSTEMS**

Faculty: Karen McDonald & Abhaya Dandekar

Guest Lecture: May 14, 2009

Presentation Outline

- ❖ **Background on IP & Freedom to Operate (FTO)**
- ❖ **Overview of FTO Search Process**
- ❖ **FTO Search Samples/Database Exercises**

Freedom to Operate



Freedom to Operate

...is an ongoing legal assessment of the intellectual property rights covering a particular technology space.

...performed to ensure that a new innovation does not infringe other's intellectual property.

IP in Ag Biotechnology

Traits

Disease/Stress resistance
Nutritional enhancement
Stress (salt/drought) tolerance

Enabling Technologies

Vectors
Promoters
Selectable markers
Transformation Methods

Germplasm

Cultivars



Forms of IP in Biotechnology

❖ No IP Protection, Public Domain

❖ Inventions and Know-how

- Patents and patent applications (*territory and for specified period*)
- Trade Secrets

❖ Copyright

❖ Corporate Identity

- Domain names
- Trademark

i.e. Trademarks in Agriculture

❖ Plant Breeders rights (*Plant patents, PVP*)

❖ Tangible property (*MTA*)

- Germplasm
- Cell lines
- Transgenic mice
- Plasmids



Plant Patent

- ❖ **US Only** (countries may use plant breeder's rights; PVP)
- ❖ **Asexually reproduced plants**
- ❖ **New and distinct**
- ❖ **Can use PVP and patent**

Plant Patents most common IP protection.

**Total CA
strawberry
industry US\$1.3
billion**



UC DAVIS STRAWBERRY LICENSING PROGRAM

- **75% MARKETSHARE OF CALIFORNIA PRODUCTION**
- **#1 IN MARKETSHARE OF WORLDWIDE COMMERCIAL PRODUCTION**

FACULTY: DR. DOUGLAS SHAW AND DR. KIRK LARSON

ient knowledge technology innovation intellect discovery

UC Annual Licensing Revenue \$4.5 million dollars

Bennett AB and M Carriere. 2007. The University of California's Strawberry Licensing Program. In Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

Han American Seed, a division of Ball Horticultural Company

Whereas, THERE HAS BEEN PRESENTED TO THE

Secretary of Agriculture

AN APPLICATION REQUESTING A CERTIFICATE OF PROTECTION FOR AN ALLEGED DISTINCT VARIETY OF SEXUALLY REPRODUCED, OR TUBER PROPAGATED PLANT, THE NAME AND DESCRIPTION OF WHICH ARE CONTAINED IN THE APPLICATION AND EXHIBITS A COPY OF WHICH IS HEREUNTO ANNEXED AND MADE A PART HEREOF, AND THE VARIOUS REQUIREMENTS OF LAW IN SUCH CASES MADE AND PROVIDED HAVE BEEN COMPLIED WITH, AND THE TITLE THERETO IS FROM THE RECORDS OF THE PLANT VARIETY PROTECTION OFFICE, IN THE APPLICATIONS INDICATED IN THIS SAID COPY, AND WHEREAS, UPON DUE EXAMINATION MADE, THE SAID APPLICANT(S) IS (ARE) ADJUDGED TO BE ENTITLED TO A CERTIFICATE OF PLANT VARIETY PROTECTION UNDER THE LAW.

NOW, THEREFORE, THIS CERTIFICATE OF PLANT VARIETY PROTECTION IS TO GRANT UNTO THE SAID APPLICANT(S) AND THE SUCCESSORS, HEIRS OR ASSIGNS OF THE SAID APPLICANT(S) FOR THE TERM OF TWENTY YEARS FROM THE DATE OF THIS GRANT, SUBJECT TO THE PAYMENT OF THE REQUIRED FEES AND PERIODIC DEPOSITMENT OF VIABLE BASIC SEED OF THE VARIETY IN A PUBLIC REPOSITORY AS PROVIDED BY LAW, THE RIGHT TO EXCLUDE OTHERS FROM SELLING THE VARIETY, OR OFFERING IT FOR SALE, OR REPRODUCING IT, OR EXPORTING IT, OR IMPORTING IT, OR CONDITIONING IT FOR PROPAGATION, OR STOCKING IT FOR ANY OF THE FOREGOING PURPOSES, OR USING IT IN PRODUCING A HYBRID OR DIFFERENT VARIETY THEREFROM, TO THE EXTENT PROVIDED BY THE PLANT VARIETY PROTECTION ACT. (84 STAT. 1542, AS AMENDED, 7 U.S.C. 2521 ET SEQ.)

VINCA

'Lavender Blue 99-665'

In Testimony Whereof, I have herewith set my hand and caused the seal of the Plant Variety Protection Office to be affixed at the City of Washington, D.C. this twenty-fifth day of January, in the year two thousand and seven.

Attest:

[Signature]

Commissioner
Plant Variety Protection Office
Agricultural Marketing Service

[Signature]

Secretary

- ❖ IP rights granted to breeders of sexually propagated (seeds) or tuber-propagated plants
- ❖ UPOV International Union for Protection of New Varieties of Plants
- ❖ Ratified in 1968 with conventions in 1972, 1978, & 1991.
- ❖ Protection timeframe:
 - 20 yrs herbaceous
 - 25 trees
- ❖ Country specific
- ❖ Requirements:
 - Distinct
 - Uniform
 - Stable

Forms of IP: Cambia Vector MTA

The *gus* gene in this material is protected and assigned to Cambia Biosystems LLC. Patent No. 6,391,547 and is patent pending elsewhere. Hygromycin resistance gene and its use is subject to the usage restrictions being the components of these vectors may be protected for ensuring that all relevant licenses are obtained.

USAGE RESTRICTIONS

These vectors are provided on to you on the conditions of this notice by returning this notice to Cambia Biosystems LLC, Academic and Non-Profit Laboratories unless the recipient receives a copy of a Commercial Use License. A license is required of academic or non-profit status and is obtained from CAMBIA, GPO Box 320, 4002 Basel, Switzerland Fax +41 (0) 79 31 00 20.

General: Users will cite the provision of this material as "pCambia....." as part of the pCambia designation, as these designers are responsible for ensuring that all relevant licenses are obtained. Until a journal article describing the construction of this material is published, the CAMBIA AF234316.

The *gusA^{gsp}* gene is currently unpublished. Patent No. 6,391,547 and WO 99/130,130.

WARRANTY

This material is provided without warranty of any kind, and without any representation, copyright, trademark or other right transferred to you under this notice. You assume all damage or liability, of whatsoever kind.

pCAMBIA2201

pCAMBIA2201
11785 bp

Material Transfer Agreements may protect IP and biological materials for a period of time even longer than patents.

IP Used by UC Students? PCR

Taq DNA Polymerase
with Standard Taq Buffer



1-800-832-7789
info@bio.com
www.bio.com

M0273L



2,000 units 5,000 U/ml[†] Lot: 7

RECOMBINANT Store at -20°C

Description: *Taq* DNA Polymerase is a thermostable DNA polymerase that possesses a 5' → 3' polymerase activity and a double-strand specific 5' → 3' exonuclease activity.

It is supplied with 10X Standard Taq Reaction Buffer, which is detergent-free and designed to be compatible with existing assay systems.

Source: An *E. coli* strain that carries the *Taq* DNA Polymerase gene from *Thermus aquaticus* YT-1.

Supplied with Standard Taq Reaction Buffer

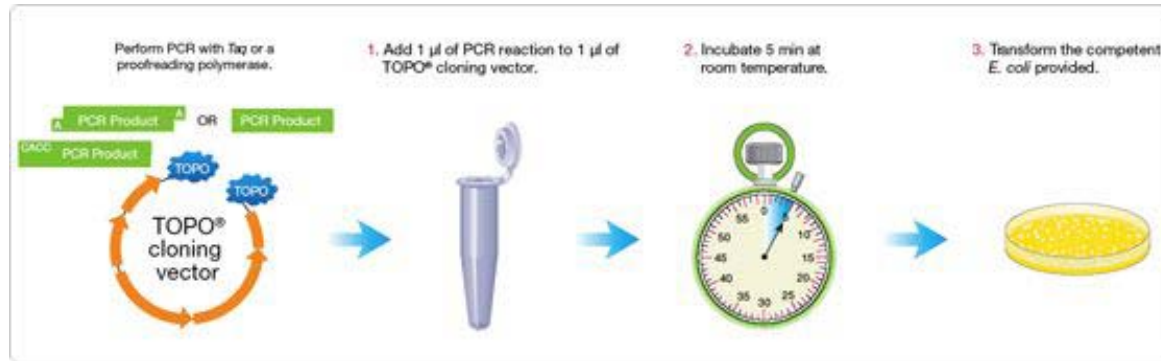
Exonuclease Activity: Incubation of 20 units of *Taq* DNA Polymerase with 1 µg φX174 RF I DNA for 4 hours at 75°C in a 50 µl reaction resulted in < 10% conversion to RF II as determined by agarose gel electrophoresis.

Patents/Disclaimer: Some applications in which this product can be used may be covered by patents issued and applicable in the United States and certain other countries. Because purchase of this product does not include a license to perform any patented application, users of this product may be required to obtain a patent license depending upon the particular application in which the product is used. The PCR process is the subject of European Patent Nos. 201,184 and 200,262 owned by Hoffman-LaRoche. These patents will expire on March 29, 2006. The corresponding PCR process patents in the United States expired on March 29, 2005.

(see other side)

CERTIFICATE OF ANALYSIS

IP in DNA TA Cloning



Invitrogen website: www.invitrogen.com

Limited Use Label License No. 116: Adenoviral Technology

This product is covered by United States Patent No. 6,136,594, under which Invitrogen has been granted a limited right to provide products for research purposes. Your use of this product constitutes your agreement to use this product for internal research purposes only and not for any clinical, therapeutic, prophylactic, diagnostic or production use. If you do not agree to be bound by these terms, return the unopened container(s) to Invitrogen for a full refund.

Limited Use Label License No. 117: Thermostable DNA Polymerase Blend

This product is the subject of U.S. Patent No. 5,436,149 and corresponding foreign patents licensed by Takara Corporation to Invitrogen. This product may be used only for research purposes and may not be resold or used for therapeutic purposes.

Limited Use Label License No. 118: TOPO® Cloning Products

The TOPO® Cloning Technology products and their use are the subject of one or more of U.S. Patent Nos. 5,766,891, 6,548,277 and/or other pending U.S. and foreign patent applications licensed to Invitrogen Corporation. The purchase of this product conveys to the buyer the non-transferable right to use the purchased amount of the product and components of the product in research conducted by the buyer (whether the buyer is an academic or for-profit entity). The buyer cannot sell or otherwise transfer (a) this product (b) its components or (c) materials made using this product or its components to a third party or otherwise use this product or its components or materials made using this product or its components for Commercial Purposes. The buyer may transfer information or materials made through the use of this product to a scientific collaborator, provided that such transfer is not for any Commercial Purpose, and that such collaborator agrees in writing (a) not to transfer such materials to any third party, and (b) to use such transferred materials and/or information solely for research and not for Commercial Purposes. Commercial Purposes means any activity by a party for consideration and may include, but is not limited to: (1) use of the product or its components in manufacturing; (2) use of the product or its components to provide a service, information, or data; (3) use of the product or its components for therapeutic, diagnostic or prophylactic purposes; or (4) resale of the product or its components, whether or not such product or its components are resold for use in research. Invitrogen Corporation will not assert a claim against the buyer of infringement of the above patents based upon the manufacture, use or sale of a therapeutic, clinical diagnostic, vaccine or prophylactic product developed in research by the buyer in which this product or its components was employed, provided that neither this product nor any of its components was used in the manufacture of such product. If the purchaser is not willing to accept the limitations of this limited use statement, Invitrogen is willing to accept return of the product with a full refund. For information on purchasing a license to this product for purposes other than research, contact Licensing Department, Invitrogen Corporation, 1600 Faraday Avenue, Carlsbad, California 92008. Phone (760) 603-7200. Fax (760) 602-65

IP in DNA TA Cloning

What Is A Patent?

- ❖ A contract with the government
 - You disclose an invention
 - You receive a 20 year (from filing) **MONOPOLY**
- ❖ Right to EXCLUDE others from practicing an invention
- ❖ Awarded to inventor (Title/Ownership)
- ❖ Geographical Limitation

Anatomy of Patent



US006174724B1

(12) **United States Patent**
Rogers et al.

(10) **Patent No.:** **US 6,174,724 B1**
(45) **Date of Patent:** ***Jan. 16, 2001**

(54) **CHIMERIC GENES SUITABLE FOR
EXPRESSION IN PLANT CELLS**

(75) Inventors: **Stephen G. Rogers**, Webster Groves;
Robert T. Fraley, Glendale, both of
MO (US)

(73) Assignee: **Monsanto Company**, St. Louis, MO
(US)

Leemans et al. 1982. pp. 537–545 in: *Mol. Biol. Plant
Tumors*, Kahl et al., eds., Academic Press: New York.*

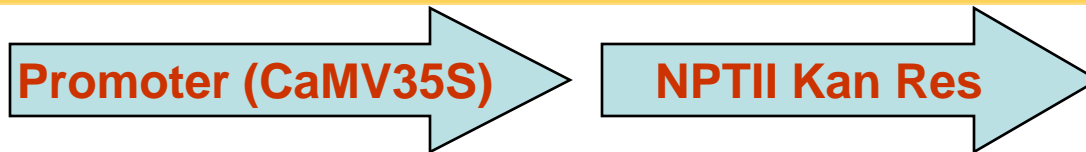
Goodman et al. 1987. *Science* 236:48–54.*

Lippincott et al. 1978. *Science* 199:1075–1078.*

Bevan et al. (1983), “A chimaeric antibiotic resistance gene
as a selectable marker for plant cell transformation,” *Nature*
304:184–187.

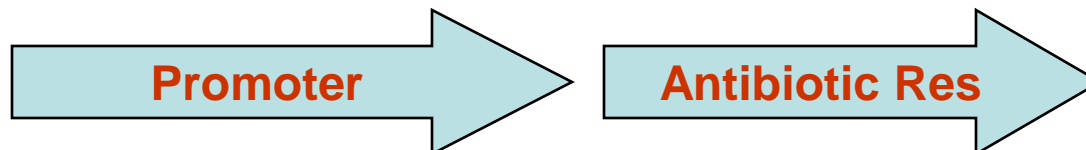
Reck et al. (1982) “Nucleotide sequence and exact localiza-

Patent Claims



A chimeric plant-expressible gene, said gene comprising in the 5' to 3' direction:

- (a) **a promoter** region derived from a gene that is naturally expressed in a plant cell and that is capable of effecting mRNA transcription in the selected plant cell to be transcribed, operably linked to
- (b) a structural **DNA sequence** encoding a polypeptide that **permits the selection of transformed plant cells** containing said chimeric gene by rendering said transformed plant cells resistant to an amount of **an antibiotic** that would be toxic to non-transformed plant cells, operably linked to
- (c) a non-translated region of a gene naturally expressed in plant cells, said region encoding a signal sequence for **polyadenylation** of mRNA.



Identify Potential Road Blocks

Antibiotic selection of transgenic plants: GEOGRAPHICAL

Monsanto's Antibiotic Patent
PIPIRA: Draft Patent Family Tree

US PATENT
App #: US1983000458414
Abandoned?
Priority Date 01/17/1983

WIPO APPLICATION
WO8402913
WO1984US0000048
Filing Date: 01/16/1984
Pub Date 08/02/1984

Australian
AUSTRIAN PATENT
406
A4000900782
1/16/1984
3/115/1991

German
GERMAN PATENT
DE3484215
#: EP1984000900782
le Date: 01/16/1984
b Date: 04/11/1991

Chinese
SE APPLICATION
30500796T2
P1984000500625
ate: 05/30/1985

Where will the research be done? What Countries will the products and its derivatives be marketed?

US APPLICATION
App #: US1985000793488
Priority Date: 10/13/1985

US PATENT
US5034322
App #: US1989000333802
File Date: 04/05/1989
Pub Date: 07/23/1991

US

BRAZIL PATENT
BR1101069
App #: BR1997001101089
03/21/2000

JAPANESE APPLICATION
JP76315381A2
App #: JP1994000057652
Priority Date: 11/15/1994

JAPANESE APPLICATION
JP72645217B2
App #: JP1994000057652
Pub Date: 08/25/1997

US APPLICATION
App #: US1986000931492
Priority Date: 11/17/1986

US APPLICATION
App #: US1990000825637
Priority Date: 12/07/1990

US APPLICATION
App #: US1993000146621
Priority Date: 10/28/1993

US APPLICATION
App #: US1994000300029
Priority Date: 09/02/1994

US APPLICATION
App #: US199600069672
Priority Date: 06/24/1996

US APPLICATION
App #: US1999000228638
Priority Date: 01/11/1999

EUROPEAN APPLICATION
App #: EP1984000900782
01/23/1985

EUROPEAN PATENT
EP131623B1
App #: EP1984000900782
Pub Date: 03/06/1991

EUROPEAN PATENT
EP13162
App #: EP1984/07/28/15

European

US APPLICATION
App #: US1991000732974
Priority Date: 07/19/1991

US APPLICATION
App #: US1993000127100
Priority Date: 09/24/1993

US APPLICATION
App #: US1993000127100
Priority Date: 09/24/1993

US APPLICATION
App #: US1995000435951
Priority Date: 05/04/1995

US PATENT
US6174724
App #: US1995000435951
File Date: 15/04/1995
Pub Date: 01/16/2001

US

US PATENT
US5530196
App #: US1994000300029
File Date: 09/02/1994
Pub Date: 06/25/1996
Expires 06/25/2013

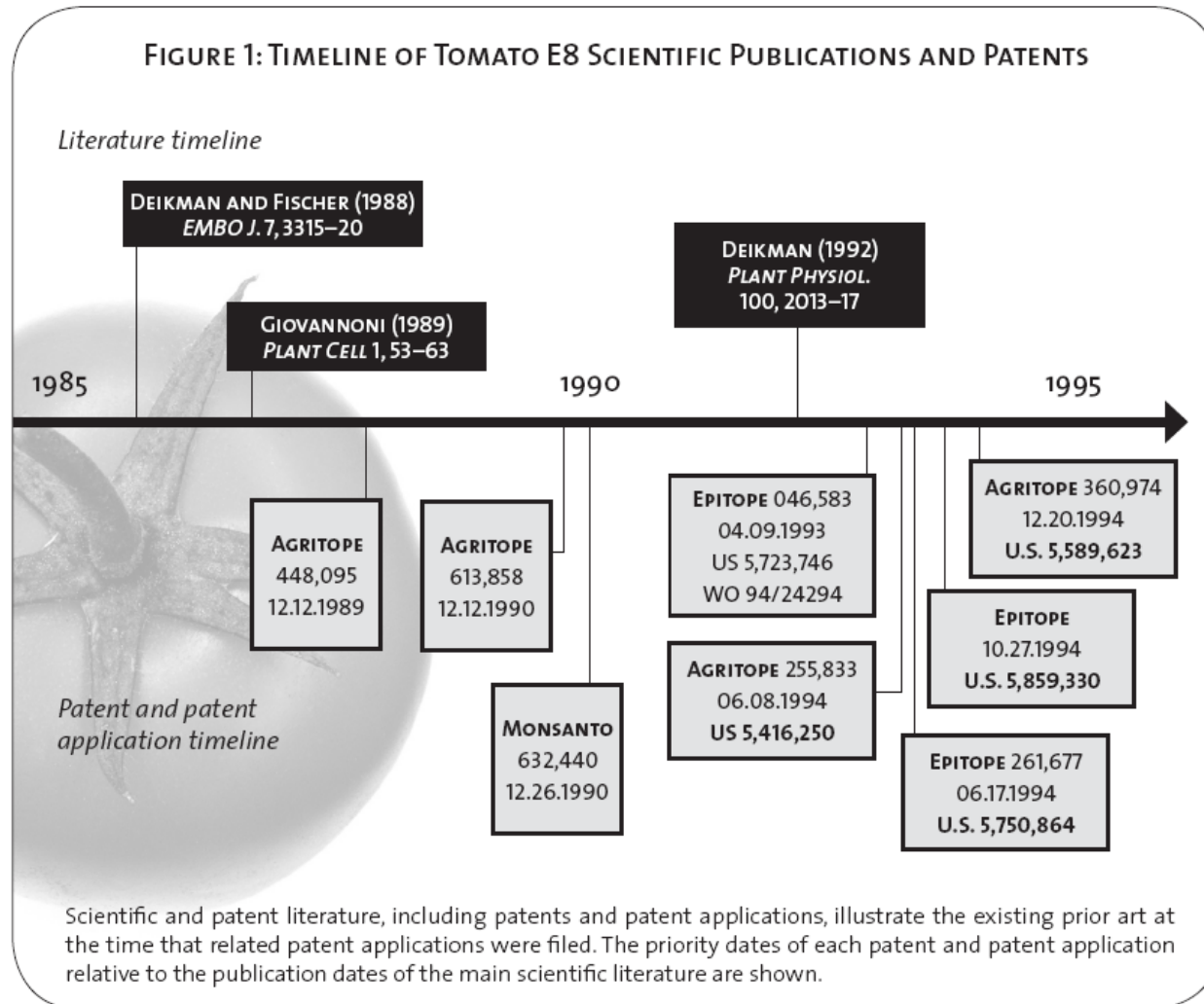
US

US PATENT
US6255560
App #: US1999000228638
File Date: 01/11/1999
Pub Date: 07/3/2001

US PATENT
US5352605
App #: US1993000146621
File Date: 10/28/1993
Pub Date 10/04/1994

US PATENT
US5858742
App #: US199600069672
File Date: 06/24/1996
Pub Date: 01/12/1999

IV. FTO Investigation (Legal Counsel)



**Agronomic Characteristics
(nutrition/processing)**

Nutrition

US6608246 Chalcone
Isomerase
(modify flavonoids)

Fruit Ripening

US5512466 1-aminocyclo propane-1-
carboxylic acid deaminase

US6031154 Frk1 polypeptide

US5723746 and US5859330
S-adenosylmethionine hydrolase

US6156956 ACC Synthase

US5328999 and US5585545
Antisense endo-1, 4-b-glucanase

Sugar/solid content

US5914446 and US6124528
sucrose phosphate synthase

US5234834 and US5739409
Monellin or thaumatin

US6011199
alcohol dehydrogenase II
(improved flavor)

Control Gene Expression

US6392121 Gemini virus vectors
for gene expression in plants

US6118049 Synthetic E8/E4 Hybrid
Promoter

E8 Promoter

– Public Domain –

Bio-pharmaceutical

US6551820 plant expressed anti-hepatitis
vaccines

**Excluding specific
promoter constructs
and gene combination,
the promoter itself is in
the public domain**

Overview FTO Process

- I. Define Subject Matter**
- II. Formulate FTO Team**
- III. Define Questions and IP Search Strategy**
- IV. FTO Investigation**
 - Scope of typical FTO search
 - Levels of FTO investigations
- V. Product of the FTO Search**
- VI. Strategies to Manage FTO Risks**

I. Subject Matter of the FTO

❖ Define subject mater

- Describe technology
- Anticipated field of use

❖ Dissect the technology

- Identify technologies used to make the product including:
 - Trait genes, germplasm, selectable markers, transformation technologies, methodologies, etc.
 - Material transfer agreements and property trail
- Distinguish 'core' and 'substitutable' technologies

❖ Geographies

- Countries in which the product will be developed, manufactured, approved by regulatory agencies, and marketed/sold

❖ Time-frames

- Awareness of 18 month period of periods of silence of US patent applications
- Patent Maintenance or Life-time (US 17 or 20 years)

II. Formulate FTO Team

- ❖ Develop a team capable of analyzing all aspects of the product development
- ❖ Build multidisciplinary team
 - Technical: scientific, biotech, pharma
 - IP/technology transfer, patent agents, internal or external legal counsel
 - Legal counsel/ patent attorneys may be sought only if warranted (later stages, significant legal questions)
 - Consider pro-bono legal counsel (i.e. Public Interest Intellectual Property Advisors); IP service groups (MIHR, PIPRA, university)
 - Regulatory & business development experts

Workshop on Optimization of Plant Transformation Vectors Danforth Center St. Louis, MO October 27, 2004

SCIENTISTS

Stanton Gelvin, Purdue University
Kan Wang, Iowa State University
Pal Maliga, Rutgers University
David Ow, USDA-ARS, UC Berkeley
Brian Miki, Agriculture and Agri-Food Canada
Vibha Srivastava, University of Arkansas
Chris Taylor, Donald Danforth Plant Science Center

David Tricoli, University of California Davis
Francois Torney, Iowa State University
Robert Houtz, University of Kentucky

Attorneys

Michael Lang, Harness, Dickey & Pierce, P.L.C.
Michael Ward, Morrison & Foerster LLP
Clinton Neagley, University of California, Davis
Charles McManis, Washington University Law School
James Surber, Patent Attorney, Bryan Cave Chuck LLP
Chuck McManis, Washington University School of Law

Ag-Biotech Companies

Robert Horsch, Monsanto
Qi Wang, Monsanto

Regulatory Experts

Keith Redenbaugh, Seminis Vegetable Seeds
[Name obscured], Biotech Business Development, J.R. Simplot Company

PIPRA

Alan Bennett, PIPRA, University of California Davis
Karel Schubert, Donald Danforth Plant Science Center
Sara Boettiger, PIPRA, University of California Berkeley
Cecilia Chi-Ham, PIPRA, University of California Davis

III. Define Questions

❖ Interview and laboratory history

- Interview scientific, technical, and technology transfer/IP staff
- Technical description of the technology
 - Review published literature, presentations, research proposals, etc.
- Deconstruction of the technology components, methods, protocols, germplasm etc.
- Acquisition trail: MTA—who got what from whom?
- Source of research funds, confidentiality agreements, employment agreements
 - IP restrictions imposed by funding sources, collaborators, universities, etc.

❖ Meticulously develop series of questions congruent with the projects immediate and future goals.

IV. Scope of FTO Investigation

❖ Scientific and Patent Databases

- Integral to the FTO analysis
- Reinforce each other throughout the FTO process
- Search Strategies: Cross-check with keywords, DNA/protein sequences, lead authors, cited references
- Considerations in choosing databases:
 - limitations of databases (geographical and temporal coverage)
 - Output of data – excel/access databases
 - Analytical tools
 - Consider free and fee-based databases

❖ Press releases, news report, Meeting/symposium presentations and abstracts.

❖ IP Search Strategy

- Broad Search
- Limitations (geographical/temporal—scientific)
- Record rationale for IP search strategy; how data is gathered and analyzed; keep ALL data—even data deemed not relevant.

❖ Freely Available

- Local Libraries
- Agricola <http://agricola.nal.usda.gov/>
- Google <http://scholar.google.com>
- PubMed Central <http://www.pubmedcentral.nih.gov/>
- NCBI:PubMed www.pubmed.gov

❖ Subscription/fee based

- BIOSIS www.biosis.org
- AgBiotech www.agbiotechnet.com
- ISI Web of Knowledge <http://portal.isiknowledge.com/portal.cgi>

❖ Free

- USPTO (Free and \$ portals)
 - Patent Application Information Retrieval (PAIR): <http://portal.uspto.gov/external/portal/pair>
 - Patents/applications <http://www.uspto.gov/patft/index.html>
 - Patent assignment <http://assignments.uspto.gov/assignments/?db=pat>
- European Patent Office esp@cenet.com
- Google Patent <http://www.google.com/ptshp?tab=wt>
- PIPRA www.pipra.org
- CAMBIA Patent Lens <http://www.patentlens.net/daisy/patentlens/patentlens.html>
- NCBI:PubMed www.pubmed.gov

❖ Subscription/fee based

- GenomeQuest www.genomequest.com
- Delphion www.delphion.com
- MCAM www.m-cam.com
- Others: Westlaw, Lexis, STN, etc.

IV. Level ONE of FTO Search

Are there blocking patents that could preclude pursuing a new goal?
Based on Public information

❖ Review Patent Search Results

- Identify Patents (*present risks*)
- Identify Patent Applications (*potential future risks*)

❖ Determine IP Ownership and Status

- Maintenance Status-- *anticipated expiration date, abandoned, etc.*
- Check Assignment Records
- Availability/Licensing information
 - Usually not public information
 - PIPRA's facilitates access to licensing information for its ag-portfolio

Level TWO of FTO Search

Patent Landscape | Based on Public information

❖ Construct IP Priority Timeline and “Landscape”

- Group Patent Risks by Subject Matter
- Determine relative Patent Dominance
 - priority date
 - broader vs. narrower patents-- Broader patents may have leverage to seek higher fees/control entry into the market
- Timeline of public information ‘prior art’ with patent history
- Construct Vertical / International Families
- Claim analysis by legal counsel
- Obtain & Evaluate Patent File Histories

❖ Check Patent Litigation Records

- Held Invalid? Unenforceable?
- Interferences?

cont... Level TWO of FTO Search

❖ Check Business and News Records

- Patentee's Website / Annual Report
- SEC Filings by Patentee – “Risks”
- Press Releases by Patentee
- Industry-Specific and General News Reports

❖ Is the Patentee likely to Enforce IP rights?

Level Three FTO Search

Patent Landscape | Requires Confidential Information and Cooperation from Patentee, Contracts and Grants and Tech Transfer Offices

❖ Unpublished Patent Applications

- U.S. Provisional Applications
- U.S. Utility Applications < 18 months
- File Histories of Pending Applications

❖ Unpublished research data, manuscripts

❖ Business Goals / Project Status

❖ Threatened Litigation

cont... Level Three of FTO Search

❖ Contracts affecting Ownership

- Assignments, Licenses
- Funding/research agreements
- Availability/Licensing information
 - Usually not public information
 - PIPRA's may provide licensing information for its ag-IP portfolio includes

V. Product of the FTO Search

❖ Attorney-Client Privilege

- According to US law product of FTO search is considered attorney-client privilege information
- Information remains confidential if the client chooses to do so
- Not all legal counsel are attorneys
 - ...thus Degree of protection may vary
 - Such terms should be discussed in advance

❖ Oral Advice of Counsel

❖ Written Report

- Scope of Search, Search Strategies
- Listing of Identified Risks
- Analysis of Identified Risks

❖ Formal Written Opinion

- Noninfringement or Invalidity

❖ Patent Landscape Changes over Time

- FTO product is a “Living Document” and requires constant updates

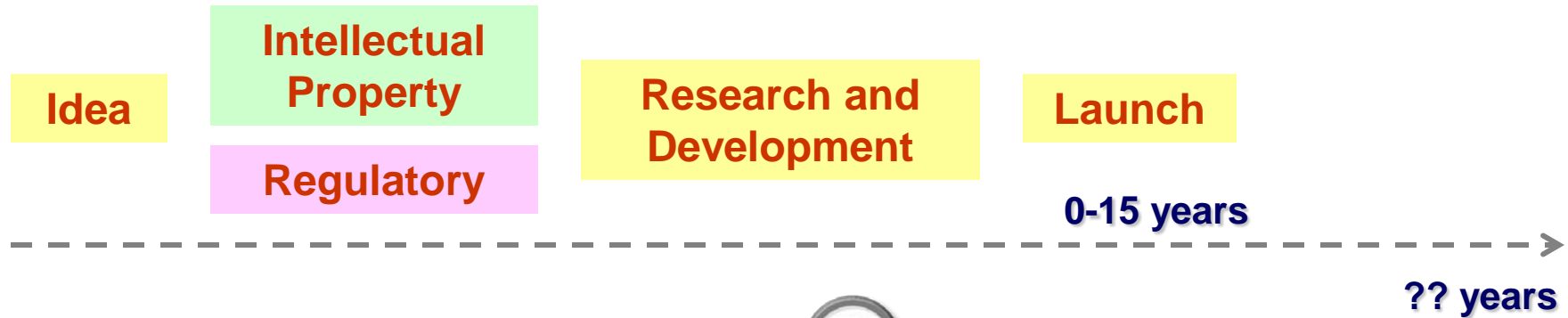
VI. Strategies to Manage FTO Risks

- ❖ **Abandon or modify business/research goals** (*field of use, geographies*)
- ❖ **Assume current path despite FTO risk evaluation** (*can one tolerate risk of infringement litigation?*)
- ❖ **Replace with substitute technologies with greater FTO**
- ❖ **Purchase the Patent(s) or In-License rights**
- ❖ **Cross-License**
- ❖ **Invent around the blocking patent**
- ❖ **Develop a patent pool or a clearinghouse**

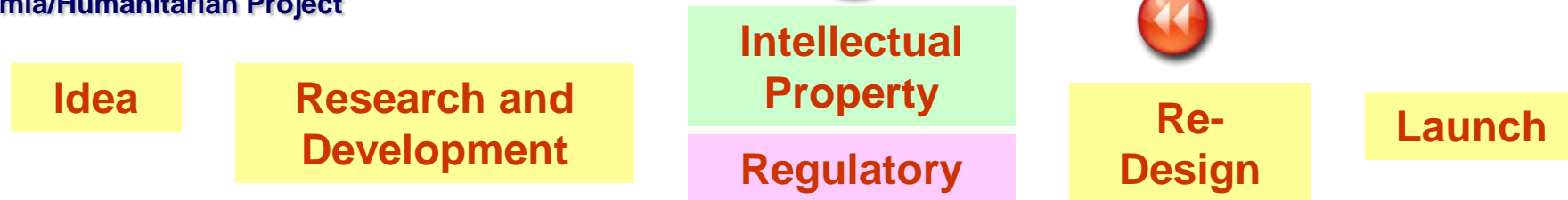
IP Analysis in Industry vs Academia

- ❖ FTO Search is a dynamic on-going analysis
- ❖ Should be conducted as EARLY as possible in the research planning stages

Ag-biotech
Industry



Academia/Humanitarian Project



Research Exemption?

Research exemption should be justified because... the experimental use is for basic science advancement and **NOT** for commercial use



Education is a business objective

Fundamental research gives prestige to the institutions and attracts substantial research grants that support students, faculty and research institutions

**In US Bottom Line: there is effectively
NO experimental use exception**

Tutorial on Using Selected Patent Databases

Cecilia Chi-Ham

**Director Biotechnology Resources
University of California, Davis, CA**

Tel: 530 754 6717 | clchiam@ucdavis.edu



**The Management of Technological Innovations in Public Institutions:
Workshop on Intellectual Property Rights, Technology Transfer, and Research Tools**

Santiago, Chile, August 20-21, 2007

Choosing an IP Database

❖ Database content

- Patent Collections
- Geographical Coverage
- Coverage (time-frame)
- How frequently is the data uploaded

❖ Search parameters

- Keyword, citation, DNA sequence
- DNA or Protein sequences
- Size of the target technology—short peptides, PCR primers?
- Drug targets
- Methodologies or protocols

❖ Output of data

- Does the program allow you to export data?
 - Important when one needs to manipulate data
 - Format to export -- excel/access databases
- Can you save, share the data?

❖ Analytical tools

Patent Database

❖ Free

- USPTO (Free and \$ portals)
 - Patent Application Information Retrieval (PAIR): <http://portal.uspto.gov/external/portal/pair>
 - Patents/applications <http://www.uspto.gov/patft/index.html>
 - Patent assignment <http://assignments.uspto.gov/assignments/?db=pat>
- European Patent Office esp@cenet.com
- Google Patent <http://www.google.com/ptshp?tab=wt>
- PIPRA Ag-IP www.pipra.org/
- CAMBIA Patent Lens <http://www.patentlens.net/daisy/patentlens/patentlens.html>
- NCBI:PubMed www.pubmed.gov

❖ Subscription/fee based

- GenomeQuest www.genomequest.com
- Delphion www.delphion.com
- MCAM www.m-cam.com
- Others: Westlaw, Lexis, STN, etc.

Explore other Databases and Resources

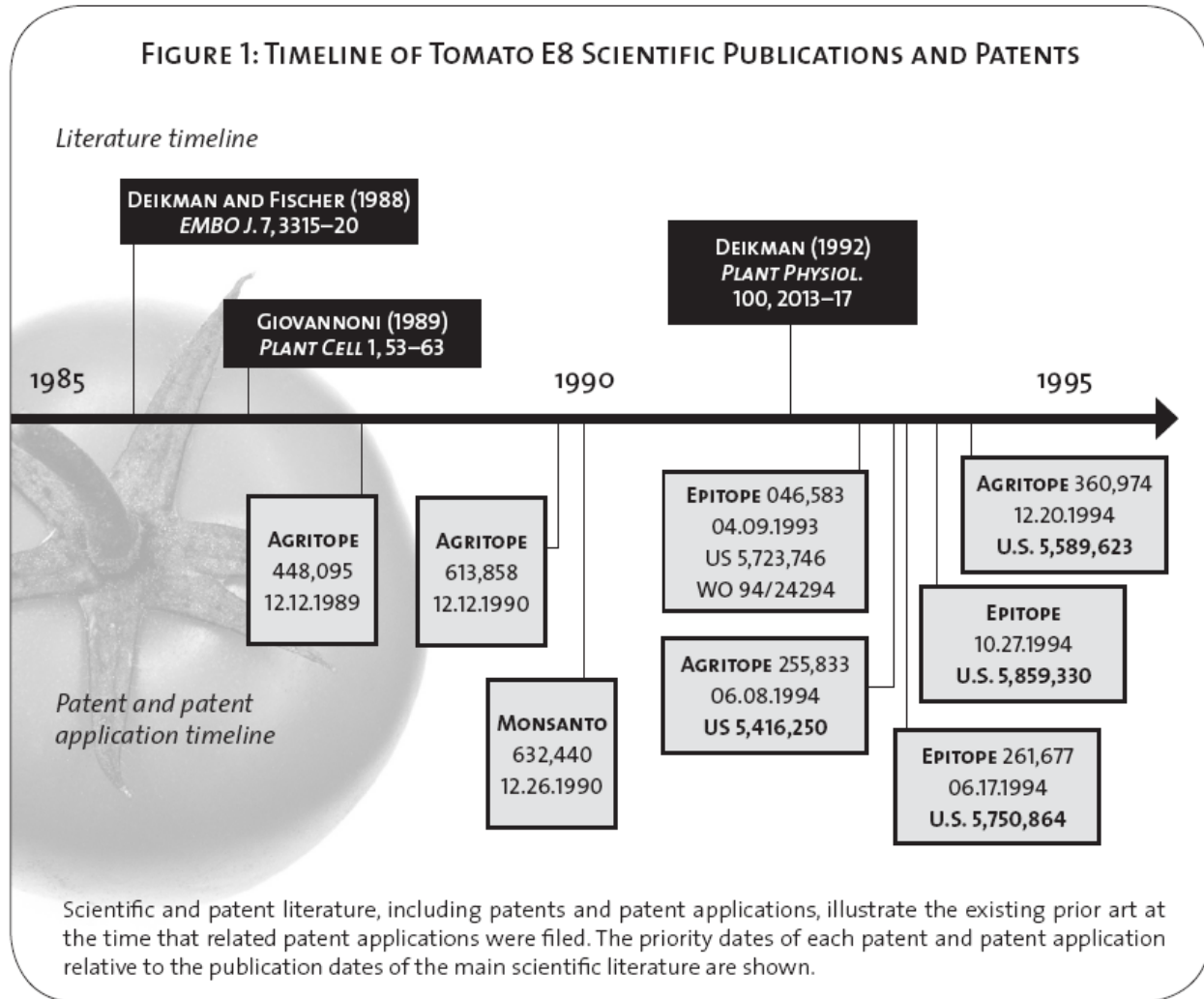
Class Demo 1: NCBI



Useful for scientific and patent landscapes

Demonstration Task: Identify patents related to Tomato E8 promoter to drive expression of a target gene (i.e. oral vaccine) in ripening fruit tissue

- 1. Identify DNA sequence for FTO Target Tomato Fruit E8 Promoter**
- 2. Conduct preliminary DNA search using NCBI's Patent Database**



NCBI: National Center for Biotechnology Information

<http://www.ncbi.nlm.nih.gov/>

Step 1. Go To: <http://www.ncbi.nlm.nih.gov/>

Step 2. Select Nucleotide

Step 3. Search for:
Tomato E8 Promoter

Identify DNA sequence for FTO Target Tomato Fruit E8 Promoter

Step 4. Select DQ317599

Nucleotide - Lycopersicon esculentum ethylene-responsive fruit ... - Windows Internet Explorer

http://www.ncbi.nlm.nih.gov/nuccore/84029145?ordinalpos=1&itool=EntrezSystem2.PEntrez.Sequence.Sequence_Resu

Convert Select

Nucleotide - Lyc... Windows Live Hot... Class_38 : Agricult...



CGCTCAGGATAGGACTTCGCGCTAGGATCGGATCCCGGCGATTATATAGCTCGATCGATC1
TTCTCTATATCCGGGATATGGGATATATACACACACATGCGGATAGCATGACTGATCTA
CCCCAGCTTCTCGCAGCTTCTCGCAGCTTCTCGCAGCTTCTCGCAGCTTCTCGCAGCTT
CACAGACTTCTCGCAGCTTCTCGCAGCTTCTCGCAGCTTCTCGCAGCTTCTCGCAGCTT

Nucleotide

My NCBI
[Sign In] [Real...

All Databases PubMed Nucleotide Protein Genome Structure PMC Taxonomy Books

Search Nucleotide for [] Go Clear

Limits Preview/Index History Clipboard Details

Format: GenBank FASTA Graphics More Formats

GenBank: DQ317599.1

Lycopersicon esculentum ethylene-responsive fruit ripening (E8) flanking region

Step 5. Select Blast Sequences

Features Sequence

LOCUS DQ317599 2175 bp DNA linear PLN 20-MAY-2008
DEFINITION Lycopersicon esculentum ethylene-responsive fruit ripening (E8) gene, promoter and 5' flanking region.
ACCESSION DQ317599
VERSION DQ317599.1 GI:84029145
KEYWORDS .
SOURCE Solanum lycopersicum (Lycopersicon esculentum)
ORGANISM [Solanum lycopersicum](#)
Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta; Spermatophyta; Magnoliophyta; eudicotyledons; core eudicotyledons; asterids; lamids; Solanales; Solanaceae; Solanoideae; Solaneae; Solanum; Lycopersicon.
REFERENCE 1 (bases 1 to 2175)
AUTHORS He,Z.M., Jiang,X.L., Qi,Y. and Luo,D.Q.
TITLE Assessment of the utility of the tomato fruit-specific E8 promoter for driving vaccine antigen expression
JOURNAL Genetica 133 (2), 207-214 (2008)
PIRMEID 17805977

BLAST Sequence

Find regions of similarity between this sequence and other sequences using BLAST.

Pick Primers

Design and test primers for this sequence using Primer-BLAST.

Recent Activity

- Lycopersicon esculentum ethylene-responsive fruit ripening (E8) gene, promoter and 5' flanking region
- Tomato ethylene-responsive fruit ripening gene E8
- tomato E8 promoter (5) Nucleotide

Nucleotide BLAST: Search nucleotide databases using a nucleotide query - Windows Internet Explorer

http://www.ncbi.nlm.nih.gov/BLAST/Blast.cgi?PAGE=Nucleotides&PROGRAM=blastn&MEGABLAST=on&BLAST_PROGRAMS=

at& Y! Search Web Yahoo! Photos Games News

Nucleotide BLAST: Search... Webpage has expired michigan.transcription.profile

BLAST Basic Local Alignment Search Tool

Home Recent Results Saved Strategies Help Register

NCBI/ BLAST/ blastn suite: BLASTN programs search nucleotide databases using

Enter Query Sequence

Enter accession number **DQ317599**

Or, upload file

Job Title

Choose Search

Database

- Genomic plus Transcript
 - Human genomic plus transcript
 - Mouse genomic plus transcript
- Other Databases
 - Nucleotide collection (nr/nt)
 - Reference mRNA sequences (refseq_rna)
 - Reference genomic sequences (refseq_genomic)
 - Expressed sequence tags (est)
 - Non-human, non-mouse ESTs (est_others)
 - Genomic survey sequences (gss)
 - High throughput genomic sequences (HTGS)
 - Patent sequences(pat)**
 - Protein Data Bank (pdb)
 - Human ALU repeat elements (alu_repeats)
 - Sequence tagged sites (dbsts)
 - Whole-genome shotgun reads (wgs)
 - Environmental samples (env_nt)

Patent sequences(pat)

transcript Others (nr etc.):

Organism Optional

Enter organism name or id--completions will be suggested

Enter organism common name, binomial, or tax id. Only 20 to

Entrez Query Optional

Enter an Entrez query to limit search

Step 6. Enter Tomato E8 promoter DNA sequence or its accession number DQ317599

Step 7. Select the Patent Sequences Databases

Consider other parameters: i.e. word size, query subrange, data output etc.

Done Internet 100%

start Nucleotide BLA... Removable Disk... Microsoft Powe... 12:34 PM

[Distance tree of results](#) NEW

Legend for links to other resources: **U** UniGene **E** GEO **G** Gene **S** Structure **M** Map Viewer

Sequences producing significant alignments:
 (Click headers to sort columns)

Accession	Description	Max score	Total score	Query coverage	E value	Max ident
BD077997.1	Synthetic hybrid plant promoter	3967	3967	100%	0.0	99%
AR029480.1	Sequence 24 from patent US 5859330	3967	3967	100%	0.0	99%
AR007550.1	Sequence 3 from patent US 5750870	3967	3967	100%	0.0	99%
I90253.1	Sequence 12 from patent US 5723746	2037	2037	51%	0.0	99%
AR029482.1	Sequence 27 from patent US 5859330	2028	2028	51%	0.0	99%
I86984.1	Sequence 10 from patent US 5702933	2028	2028	51%	0.0	99%
I19978.1	Sequence 10 from patent US 5512466	1901	1901	48%	0.0	99%
BD077991.1	Synthetic hybrid plant promoter	1896	1896	47%	0.0	99%
I24835.1	Sequence 1 from patent US 5545815	1240	1240	31%	0.0	99%
BD077996.1	Synthetic hybrid plant promoter	1240	1240	31%	0.0	99%

Step 11. Select Patent 5859330

Alignments

Get selected sequences Select all Deselect all Distance tree of results

```
>  dbj|BD077997.1 Synthetic hybrid plant promoter
Length=2298

Score = 3967 bits (2148), Expect = 0.0
Identical = 2180/2185 (99%) Gaps = 7/2185 (0%)
```

Search Nucleotide for [] Go Clear

Limits Preview/Index History Clipboard Details

Display GenBank Show 5 Send to Hide: sequence all but gene, CDS and mRNA features

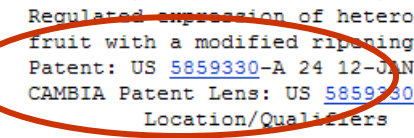
Range: from begin to end Reverse complemented strand Features: + Refresh

1: AR029480. Reports Sequence 24 from ...[gi:5941453]

Features Sequence

LOCUS AR029480 2216 bp DNA linear PAT 29-SEP-1999
DEFINITION Sequence 24 from patent US 5859330.
ACCESSION AR029480
VERSION AR029480.1 GI:5941453
KEYWORDS .
SOURCE Unknown.
ORGANISM Unknown.
Unclassified.
REFERENCE 1 (bases 1 to 2216)
AUTHORS Bestwick,R.Keith. and Ferro,A.J.
TITLE Regulated expression of heterologous genes in plants and transgenic fruit with a modified ripening phenotype
JOURNAL Patent: US 5859330-A 24 12-JUN-1999;
REMARK CAMBIA Patent Lens: US 5859330
FEATURES Location/Qualifiers
source 1..2216
/organism="unknown"
/mol_type="unassigned DNA"
ORIGIN

Step 12. Select Patent 5859330 Connects to USPTO



and a continuation-in-part of co-owned, U.S. patent application Ser. No. 08/255,833, filed 8 Jun. 1994, herein incorporated by reference, now U.S. Pat. No. 5,416,250, which is a file-wrapper continuation of co-owned, U.S. patent application Ser. No. 07/613,858, filed 12 Dec. 1990, now abandoned which is a continuation-in-part of U.S. patent application Ser. No. 448,095 filed Dec. 12, 1989, now abandoned.

Claims

It is claimed:

1. A transgenic fruit-bearing plant, comprising:

(i) a DNA sequence encoding S-adenosylmethionine hydrolase, and operably linked to said DNA sequence (ii) a promoter selected from the group consisting of: a promoter of a tomato E4 gene, wherein said E4 gene is composed of a series of nucleotides that is at least 60% identical to that presented in SEQ ID NO: 8, a promoter of a tomato E8 gene, wherein said gene is composed of a series of nucleotides that is at least 60% identical to that presented in SEQ ID NO: 27, and an avocado cellulase gene promoter,

where expression regulated by the promoter is induced during fruit ripening or by ethylene synthesis by fruit produced by said plant.

2. A transgenic plant of claim 1, wherein the promoter comprises nucleotides 1-1173 of SEQ ID NO: 10.

3. A transgenic plant of claim 1, wherein the promoter is from a tomato E4 or E8 gene.

4. A transgenic plant of claim 1, wherein the promoter is an avocado cellulase gene promoter.

5. A method for modifying ripening fruit of a fruit bearing plant, comprising:

growing the plant of claim 1, to produce a transgenic plant bearing fruit, wherein fruit produced by said plant has an initial burst of ethylene production, followed by a reduction in the level of ethylene synthesis by said fruit, resulting in a fruit having a modified ripening phenotype in which the time course of ripening is delayed relative to wild-type fruit.

Class Demo 2: PIPRA IP Database



Demonstration Task:

IP search on Tomato E8 Promoter using Keyword and filtering based on Geography and Date of Publication

- 1. Using keywords search for related patents using PIPRA's IP Database**
- 2. Filter Features**

FIGURE 1: TIMELINE OF TOMATO E8 SCIENTIFIC PUBLICATIONS AND PATENTS

Literature timeline

DEIKMAN AND FISCHER (1988)
EMBO J. 7, 3315-20

GIOVANNONI (1989)
PLANT CELL 1, 53-63

DEIKMAN (1992)
PLANT PHYSIOL.
100, 2013-17

1985

1990

1995

AGRITOPE
448,095
12.12.1989

AGRITOPE
613,858
12.12.1990

MONSANTO
632,440
12.26.1990

EPITOPE 046,583
04.09.1993
US 5,723,746
WO 94/24294

AGRITOPE 255,833
06.08.1994
US 5,416,250

EPITOPE
10.27.1994
U.S. 5,859,330

EPITOPE 261,677
06.17.1994
U.S. 5,750,864

AGRITOPE 360,974
12.20.1994
U.S. 5,589,623

Patent and patent application timeline

Scientific and patent literature, including patents and patent applications, illustrate the existing prior art at the time that related patent applications were filed. The priority dates of each patent and patent application relative to the publication dates of the main scientific literature are shown.



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- [Member IP database](#) ↗
- [Pierce's disease databases](#) ↗
- [Publications](#) ↗
- [Chile 2007 IP Workshop](#) ↗

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Geography US

Lens

Promoter

Structured Search

Exp

In Claims

» Sequence Search

Match criteria (if multiple fields are used)

E8 promoter

in claims

in title

in abstract

in inventor

in applicant/assignee

[+]

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Search Results for **((E8 AND promoter) in claims)** (in 0.007 seconds)

Showing 1-10 of 46 results

46 IP Results

Next

<input checked="" type="checkbox"/>	No	Patent No	Info	Pipra	Title
<input type="checkbox"/>	1.	US 5723746 granted patent			Reduced ethylene synthesis and delayed fruit ripening in transgenic tomatoes expressing an adenosylmethionine hydrolase
<input type="checkbox"/>	2.	US 5545815 granted patent			Control of fruit ripening in plants
<input type="checkbox"/>	3.	US 5328999 granted patent			Endo-1,4-β-glucanase genes and their use in plants
<input type="checkbox"/>	4.	US 5234834 granted patent			Constructs for expression of monellin in plant cells
<input type="checkbox"/>	5.	US 5512466 granted patent			Control of fruit ripening and senescence in plants
<input type="checkbox"/>	6.	US 6118049 granted patent			Synthetic hybrid tomato E4/E8 plant promoter
<input type="checkbox"/>	7.	US 5859330 granted patent			Regulated expression of heterologous genes in plants and transgenic fruit with a ripening phenotype
<input type="checkbox"/>	8.	US 2006/0168698 A1 patent application			Transgenic evaluation of activated mutant alleles of SOS2 reveals a critical requirement for kinase activity and C-terminal regulatory domain for salt tolerance in Arabidopsis
<input type="checkbox"/>	9.	US 7265266 granted patent			Transgenic evaluation of activated mutant alleles of SOS2 reveals a critical requirement for kinase activity and C-terminal regulatory domain for salt tolerance in Arabidopsis
<input type="checkbox"/>	10.	US 7230089 granted patent			Methods for increasing plant cell proliferation by functionally inhibiting a plant cell cycle gene

Next

OR: Patent/Publication Number

US

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1970

1993

E8 earliest Publication 1988





Last pub on promoter 1992

17-20 year patent life term

Filtered from 48 records to 4 records BEFORE

Search Results for **((E8 AND promoter) in claims)** (in 0.153 seconds)

Showing 1-4 of 4 results

<input checked="" type="checkbox"/>	No	Patent No	Info	Pipra	Title
<input type="checkbox"/>	1.	US 5545815 granted patent		✓	Control of fruit ripening in plants
<input type="checkbox"/>	2.	US 5328999 granted patent		✓	Endo-1,4-β-glucanase genes and their use in plants
<input type="checkbox"/>	3.	US 5234834 granted patent		✓	Constructs for expression of monellin in plant cells
<input type="checkbox"/>	4.	US 5512466 granted patent			Control of fruit ripening and senescence in plants

select all

display selected patents

save selected patents

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Class Demo 3: Family Tree IP in specific geographies



Demonstration Task:

IP search relevant in geographies where research will be performed:

United Kingdom or USA (research)

G E Crop grown in Kenya

Export Markets: Japan

- 1. Search for Family Tree**
- 2. Find Status of Patents**

Identify Potential Road Blocks

Antibiotic selection of transgenic plants: GEOGRAPHICAL

Monsanto's Antibiotic Patent
PIPIRA: Draft Patent Family Tree

US PATENT
App #: US1983000458414
Abandoned?
Priority Date 01/17/1983

WIPO APPLICATION
WO8402913
WO1984US0000048
Filing Date: 01/16/1984
Pub Date 08/02/1984

Australian
AUSTRIAN PATENT
406
A4000900782
1/16/1984
3/115/1991

German
GERMAN PATENT
DE3484215
#: EP1984000900782
le Date: 01/16/1984
b Date: 04/11/1991

ese
SE APPLICATION
30500796T2
P1984000500625
ate: 05/30/1985

Where will the research be done? What Countries will the products and its derivatives be marketed?

US APPLICATION
App #: US1985000793488
Priority Date: 10/13/1985

US PATENT
US5034322
App #: US1989000333802
File Date: 04/05/1989
Pub Date: 07/23/1991

US

BRAZIL PATENT
BR1101069
App #: BR1997001101089
03/21/2000

JAPANESE APPLICATION
JP76315381A2
App #: JP1994000057652
Priority Date: 11/15/1994

JAPANESE APPLICATION
JP72645217B2
App #: JP1994000057652
Pub Date: 08/25/1997

US APPLICATION
App #: US1986000931492
Priority Date: 11/17/1986

US APPLICATION
App #: US1990000825637
Priority Date: 12/07/1990

US APPLICATION
App #: US1993000146621
Priority Date: 10/28/1993

US APPLICATION
App #: US1994000300029
Priority Date: 09/02/1994

US APPLICATION
App #: US199600069672
Priority Date: 06/24/1996

US APPLICATION
App #: US1999000228638
Priority Date: 01/11/1999

EUROPEAN APPLICATION
App #: EP1984000900782
01/23/1985

EUROPEAN PATENT
EP131623B1
App #: EP1984000900782
Pub Date: 03/06/1991

EUROPEAN PATENT
EP13162
App #: EP1984/07/28/15

European

US APPLICATION
App #: US1991000732974
Priority Date: 07/19/1991

US APPLICATION
App #: US1993000127100
Priority Date: 09/24/1993

US APPLICATION
App #: US1993000127100
Priority Date: 09/24/1993

US APPLICATION
App #: US1995000435951
Priority Date: 05/04/1995

US PATENT
US6174724
App #: US1995000435951
File Date: 15/04/1995
Pub Date: 01/16/2001

US

US PATENT
US5530196
App #: US1994000300029
File Date: 09/02/1994
Pub Date: 06/25/1996
Expires 06/25/2013

US

US PATENT
US6255560
App #: US1999000228638
File Date: 01/11/1999
Pub Date: 07/3/2001

US PATENT
US5352605
App #: US1993000146621
File Date: 10/28/1993
Pub Date 10/04/1994

US PATENT
US5858742
App #: US199600069672
File Date: 06/24/1996
Pub Date: 01/12/1999



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Patent US 6174724

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Patent/Publication Number *i*

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United Kingdom or USA (research)
G E Crop grown in Kenya
Export Markets: Japan

FAMILY MEMBERS

#	Publication date	Publication number	Country	Priority claims												
				1	2	3	4	5	6	7	8	9	10	11	12	
1	1991-03-15	AT 61406T	Austria	X	X	X	X									
2	2000-03-21	BR 1101069A	Brazil	X												
3	1991-04-11	DE 3484215D1	Germany	X	X		X									
4	1985-01-23	EP 0131623A1	Europe	X	X		X									
5	1987-09-07	EP 0131623A4	Europe	X	X		X									
6	1991-03-06	EP 0131623B1	Europe	X	X		X									
7	1999-07-28	EP 0131623B2	Europe	X	X		X									
8	1997-08-25	JP 2645217B2	Japan	X	X											
9	1994-11-15	JP 6315381A	Japan	X	X											
10	1995-02-22	JP 7014349B	Japan	X												
11	1985-05-30	JP 60500796T	Japan	X												
12	1991-07-23	US 5034322A	United States	X				X		X						
13	1994-10-04	US 5352605A	United States	X	X				X		X				X	
14	1996-06-25	US 5530196A	United States	X	X				X		X				X	X
15	1999-01-12	US 5858742A	United States	X	X				X		X				X	X
16	2001-01-16	US 6174724B1*	United States	X				X		X		X	X			
17	2001-07-03	US 6255560B1	United States	X	X				X		X				X	X
18	1984-08-02	WO 8402913A1	World	X	X											

Japan IP Expired

Reference Materials

Chapter 14: Freedom to Operate and Risk Management:

Chapter 14.3 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

Chapter 14.2 Kowalski. Freedom to Operate: The Preparation

Chapter 14.4 Fenton, Chi-Ham, and Boettiger. Freedom to Operate: The Law Firm’s Approach and Role

Krattiger, Mahoney, Nelsen, Thomson, Bennett, Satyanarayana, Graff, Fernandez, and Kowalski. 2007. Intellectual Property Management in Health and Agricultural Innovation: a Handbook of Best Practices.

www.iphandbook.org

Patent Database

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- USPTO (Free and \$ portals)
 - Patent Application Information Retrieval (PAIR): <http://portal.uspto.gov/external/portal/pair>
 - Patents/applications <http://www.uspto.gov/patft/index.html>
 - Patent assignment <http://assignments.uspto.gov/assignments/?db=pat>
- European Patent Office esp@cenet.com
- Google Patent <http://www.google.com/ptshp?tab=wt>
- PIPRA Ag-IP <http://pipra.m-cam.com/>
- CAMBIA Patent Lens <http://www.patentlens.net/daisy/patentlens/patentlens.html>
- NCBI:PubMed www.pubmed.gov

❖ Subscription/fee based

- GenomeQuest www.genomequest.com
- Delphion www.delphion.com
- MCAM www.m-cam.com
- Others: Westlaw, Lexis, STN, etc.

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Tutorial on Using Selected Patent Databases

Cecilia Chi-Ham
Director Biotechnology Resources
University of California, Davis, CA

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