Role of Government in IP Commercialization

Opportunities/Challenges in Commercialization of Plant Varieties
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UNITED STATES
PATENT AND TRADEMARK OFFICE
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TOPICS

- Policy Objectives
- Legal Framework
  - -IP Law
  - -Technology Transfer Law
- Government Programs
- Examples

Promoting Innovation in the U.S.

Today, over 40% of the U.S. Economy and 60% of U.S. exports are attributable to Intellectual Property.

"IP-dependent industries represent 40% of U.S. economic growth, account for more than $5 trillion of the gross domestic product, and comprise more than half of all exports. Additionally, 18 million Americans work in IP-intensive industries. These jobs often pay better and are expected to grow faster over the next decade than the national average."
http://www.thetruecosts.org/category/tags/ip-and-jobs, 03/23/11.

Policy-Promote Plant Breeding

Why New Plant Varieties?

- Food security
- Adverse environment conditions
- Quality foods
- Renewable energy-bio fuels
- Storage, transport, distribution concerns
- Consumers' needs-fruit, vegetables, ornamentals

Policy Objectives

- Incentivize investment in plant breeding and new variety development
- Encourage private sector participation and public-private cooperation
- Increase numbers of new/improved varieties
- Provide access to quality seed/planting materials to farmers
- Encourage sharing of information and genetic materials
- Promote businesses and trade

IP Law for Protection of Plant Related Inventions

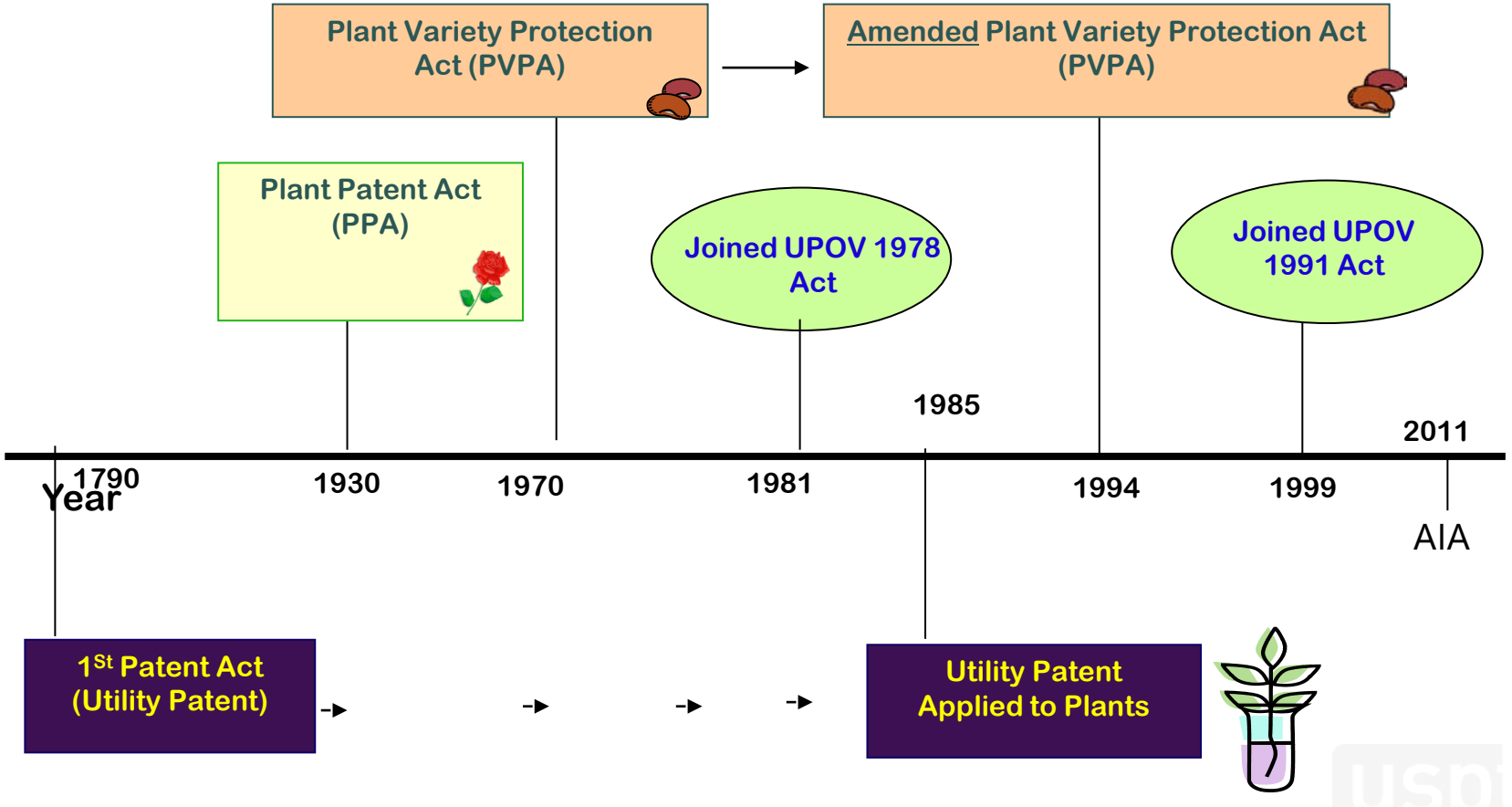
- **Utility Patent**
  - All technologies
- **Plant Patent (PPA)**
  - Asexually reproduced plants

U.S. Patent and Trademark Office (USPTO)

- **Plant Variety Protection Certificate (PVPA)**
  - Seed reproduced varieties
  - Edible tubers

USDA-Plant Variety Protection Office (PVPO)

Development of of Plant Variety Protection Laws



IP Protection for Plants in U.S.

U.S. Patent and Trademark Office (USPTO)

- **Plant Patent (PPA)**
  - ➢ Asexually reproduced plants

Plant Variety Protection Office (PVPO)

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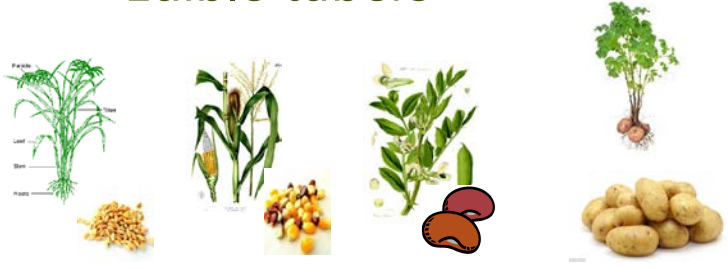

UPOV Member

Plant Patent

Basic Requirements:

- Plant is new and distinct from other known varieties
- Plant has been asexually propagated
- If "discovered," plant was found in a cultivated area
- Description must be as full and complete as possible
- Non obviousness
- Useful

Plant Patent

- 20 year term from date of filing
- Right to exclude others from making, using, selling, offering for sale and importing the plant, or any of its parts
- Protects a single plant and asexual progeny

Plant Variety Protection (PVP)

Main Requirements

- New, distinct, uniform, stable
- Plants must be sexually reproducible
- Denomination
- Deposit of propagation material
  - Stored at the USDA National Center for Genetic Resources Preservation (NCGP)

PVP Rights Granted

- Term: 20 years (25 years for trees or vines) from issuance of the certificate
- Rights to exclude others from
  - Selling or marketing
  - Conditioning or stocking
  - Offering for sale or reproducing
  - Importing or exporting
  - Using the variety to produce (as distinguished from develop) a hybrid or different variety


THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

Turf Merchants, Inc.

Secretary of Agriculture

BLUEGRASS, KENTUCKY

Technology Transfer Laws

- Bayh-Dole Act of 1980
- Stevenson-Wydler Technology Innovation Act of 1980
- Federal Technology Transfer Act of 1986 (FTTA)
- Executive Order 12591 “Facilitating Access to Science and Technology” April 10,1987
- The National Competitiveness Technology Transfer Act of 1989

Highlights of Bayh-Dole Act

- Universities may elect to retain title to invention; must file for patents on inventions they elect
- Encourage collaboration with industry
- Preference for small businesses
- Exclusive or partially exclusive licensing allowed
- Retain March-in rights (require or grant license to a third party)
- Identify Government interest in patent text

University R&D	Statistics (2015)
Strong intellectual property rights help protect discoveries and ensure continued investment in research	15,953 new U.S. patent applications filed, up 14.7% over 2014 6,680 U.S. patents issued, up 4.9%
Revenues received from licensees are reinvested in additional research and development	$2.5 billion licensing income received, up 24.8% over 2014 $135.2 million licensing income attributed to equity, up 24.8%
Creating new, sustainable businesses	1,012 startups formed, up 11.3% over 2014 735 of those startups reside in institution's home state, up 4.7% 5,057 startups still operational at end of fiscal year 2015, up 7.8%
Academic research advances the economy and improves lives	3.8 million jobs have been supported through university and nonprofit patent licensing At least 153 new drugs and vaccines are on the market due to university and industry partnerships facilitated by the Bayh-Dole Act
Consumers and businesses benefit from the creation of new products	$28.7 billion net sales from new products, up 2.5% from 2014 879 new products created

http://www.autm.net/AUTMMain/media/SurveyReportsPDF/AUTM_FY2015_Highlights_US_no_appendix_FINAL.pdf

Highlights Stevenson-Wydler Act 1980

- Technology Transfer is a mission of the Federal Government
- Applicable to inventions developed by Federal laboratories
- Requires Federal laboratories to actively seek opportunities to transfer technology to industry, universities, and state and local governments

FEDERAL TECHNOLOGY TRANSFER ACT (FTTA)

Technology transfer is a priority for Government Owned Government Operated (GOGO) Laboratories employees.

Technology Transfer Activities:

◆ Technical assistance	◆ Educational partnerships
◆ Grants	◆ Cooperative agreements
◆ Patent licenses	◆ Cooperative Research and Development Agreements (CRADAs)

EXECUTIVE ORDER 12591, 1987

"Facilitating Access to Science and Technology"

- promote commercialization
- grant title to patents to contractors, in exchange for royalty-free use by or on behalf of the government
- implement royalty-sharing programs with inventors who were employees of the agency, and cash award programs

THE NATIONAL COMPETITIVENESS TECHNOLOGY TRANSFER ACT, 1989

- Made technology transfer a mission of government-owned, contractor-operated (GOCO) laboratories and their employees.

- Clarified the manner in which CRADAs are implemented.

Government Programs (Examples)

- Small Business Administration
- Federal Technology Transfer Offices

  Examples:

  - United States Department of Agriculture (USDA)

    Office of Technology Transfer-Agricultural Research Service (OTT-ARS)
  - National Institutes of Health (NIH)

    Office of Technology Transfer (OTT)
  - National Aeronautics and Space Administration (NASA)

    Goddard Space Flight Center Innovative Partnerships Program (IPP) Office

USDA-ARS-OTT

- Provide opportunities for applicants to the USDA Small Business Innovation Research (SBIR) program to partner with ARS scientists
- Provide Cooperative Research and Development Agreement (CRADA) partners opportunity to link to local Manufacturing Extension Partnership (MEP) resources to assist in commercialization efforts
- Work with regional incubators and economic development organizations to identify opportunities for ARS scientists and ARS commercial partners
- Develop Material Transfer Research Agreement (MTRA) as a new instrument to promote development and commercialization of materials from USDA
- USDA IP Management
- Commercialization of USDA owned IP

Office of Technology Transfer-ARS-USDA

Example:

'Elkton' Chipping Potato

- Resistance to Internal Heat Necrosis
- Suitable for chipping directly from field in southern locations

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- Solely owned by USDA-ARS and protected by USDA Plant Variety Protection (PVP)
- Exclusively licensed to a for profit company
- **Pathogen- free stock for a small, but very important, segment of potato farmers**

Office of Technology Transfer-ARS-USDA

Example:

'Sunpreme' Raisin Grape

- Dries on the vine naturally
- Pruning easier than typical grapes
- Raisins larger and fruitier in flavor

- Solely owned by USDA-ARS and protected by USPTO Plant Patent.
- Non-exclusively licensed to for profit companies.
- **Farmers have a new commercial production protocol for raisins.**

Mojdeh Bahar, Asst. Administrator
Office of Technology Transfer-ARS-USDA

Office of Technology Transfer-ARS-USDA

Example:

'Black Pearl' Pepper

- Unique black foliage
- Vigorous upright bushy grow habit
- Round, black fruit maturing red with very hot flavor

- Solely owned by USDA-ARS and protected by USDA Plant Variety Protection (PVP).
- Exclusively licensed to a for profit company.
- **Growers have a new type of ornamental plant market.**

Mojdeh Bahar, Asst. Administrator Office of Technology Transfer-ARS-USDA

Summary-Role of Government

- Formulate and implement policy and laws
  -IP and Technology Transfer
- Administer IP protection
- Promote Research and Development
- Promote public – private partnership
- Support SMEs and Entrepreneurship
- Engage in technology licensing and technology transfer