

Patentability of Agricultural Research Outputs

February 27, 2014



Constitutional Basis of Patenting

Article XIV, Section 13 of the 1987 Philippine Constitution:

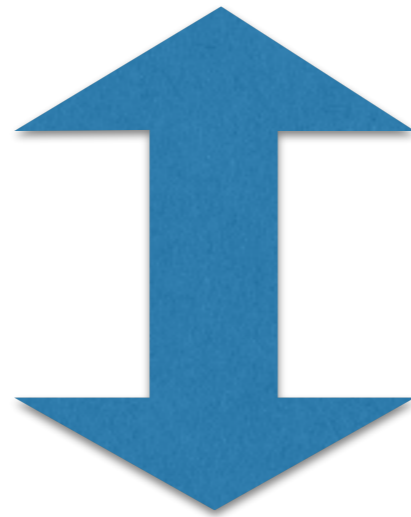
“ The State shall protect and secure the exclusive rights of scientists, inventors, artists, and other gifted citizens to their intellectual property and creations, particularly when beneficial to people, for such period as may be provided by law.”

Why do we patent?

- Protect intellectual property
- Right to exclude others (from making, using, selling, importing the claimed invention)
- Economic incentive (monopoly) to promote R&D

Quid pro quo of the patent system

Full disclosure of invention



Monopoly for 20 years from date of filing

Patents promote R&D

- Full disclosure provides information to other researchers
- Market monopoly provides opportunity to generate revenues

Example of value of patents:

Drug discovery

- Patents are country specific - right to exclude is geographically restricted
- Patent laws differ from one country to the next, but generally exclude from patentability natural phenomena, abstract ideas, laws of nature

Example: Philippines and U.S.

- Philippines: **NOT patentable:**
programs for computer, therapeutic and diagnostic methods on animals, plant varieties, animal breeds and their biological production, aesthetic creations
- US: **Patentable**

Plant Variety Protection Act (PVPA)

- mechanism in the Philippines to protect intellectual property in new varieties developed
- confers patent-like rights and longer term than patents (20-25 years from issuance of certificate)
- different requirements (new, distinct, stable, uniform) than patents (new, inventive step, industrial applicability)
- exempts certain activities from coverage, e.g., acts done for the purpose of breeding other varieties; acts for non-commercial purposes (cf. same for patents so long as no economic prejudice to patentee)

US has both PVPA and patent mechanisms for plants.

J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l Inc.,
534 U.S. 124 (2001):

“[N]either [the Plant Patent Act of 1930 nor the Plant Variety Protection Act] forecloses utility patent coverage for plants.”

Various mechanisms operate in the United States to protect intellectual property developed from plant research.

- Plant Patent Act of 1930 — conferred patent protection to asexually reproduced plants.
- Plant Variety Protection Act — conferred limited patent-like protection for certain sexually reproduced plant varieties that are new, distinct, uniform and stable.
- General Utility Patent Statutes (United States Code Title 35) — conferred patent protection for inventions that are useful, novel, and non-obvious.

Differences among Plant Variety Protection Acts across ASEAN nations

For example, term of protection:

Philippines: 25 years for trees and vines; 20 years for others

Singapore: 25 years

Malaysia: 25 years for trees and vines; 20 years for others that are new, distinct, uniform, stable; 15 years for varieties that are new, distinct, identifiable (developed/discovered by farmer, local community, indigenous people) (measured from filing date)

Thailand: 12 years (bears fruits within 2 years); 17 years (bears fruits after 2 years); 27 years (trees)

Indonesia: 25 years (perennial crops); 20 years (seasonal plants)

Singapore allows for patenting of higher life forms.

- Singapore laws only preclude inventions that are “expected to encourage offensive, immoral or anti-social behavior” from patentability
- “Animal breeds” and “plant varieties” are explicitly stated as unpatentable in the Philippines and Malaysia (“plant or animal varieties”).
- Indonesia’s exclusion of life forms is broader, precluding “all living creatures, except micro-organism.”
- Thailand’s exclusion sounds even broader than Indonesia’s, precluding “animals, plants or extracts from animals or plants.”

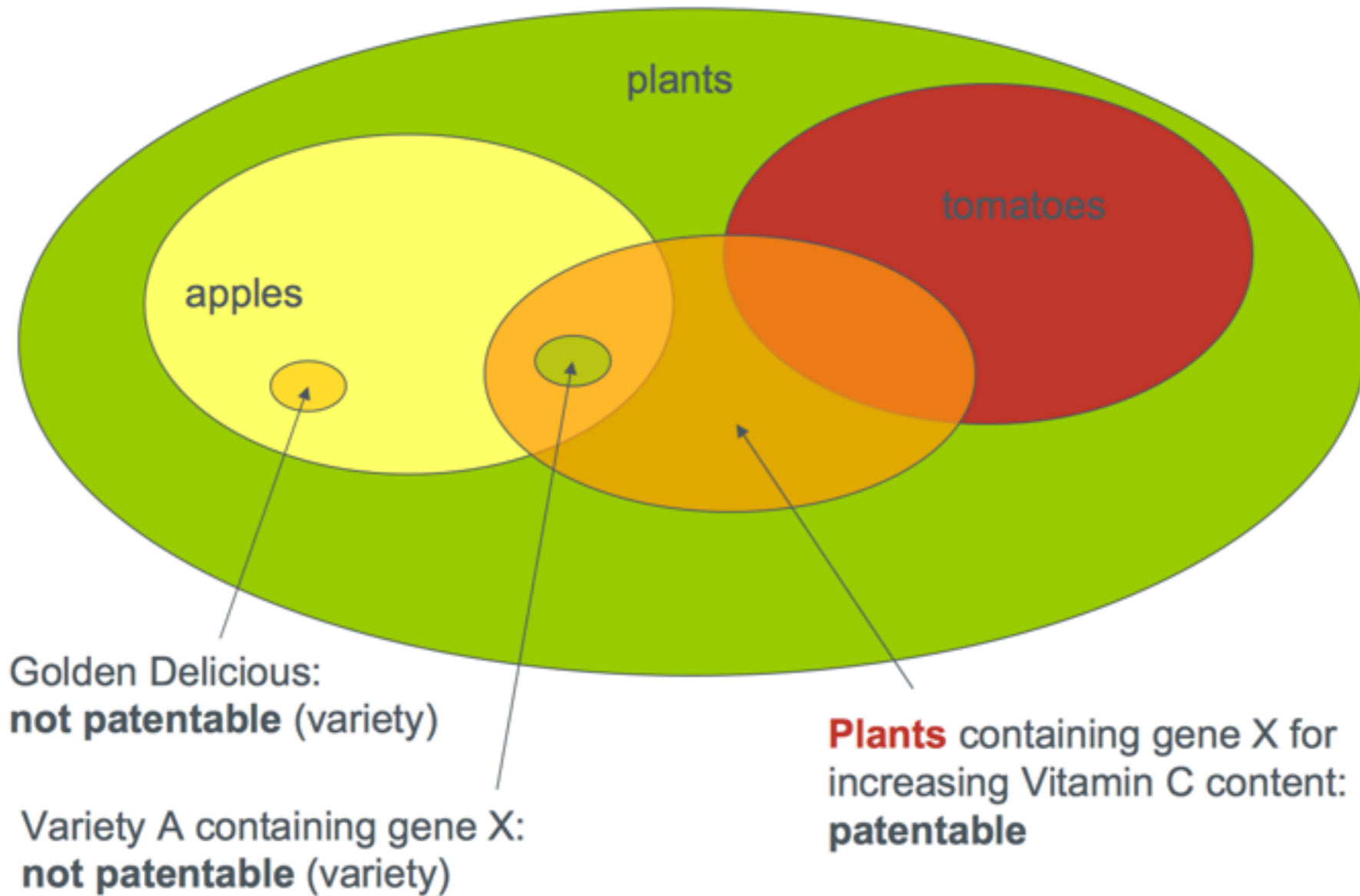
The Philippines does not specifically exclude from patentability extracts prepared from plants and animals.

- Thailand specifically excludes “extracts from animals or plants”
- Malaysia and Indonesia do not exclude plant/animal extracts from patentability

Exclusion of “animal breeds” and “plant varieties” tracks language of the European Patent Convention, Article 53(b), which precludes from patentability “plant or animal varieties.”

Europe however grants patents to plants characterized by specific genes, but not if characterized by variety

Plants versus varieties



http://ec.europa.eu/food/plant/propertyrights/docs/conf_11102011_11_00_epo_en.pdf

How to patent inventions relating to plant varieties? [For example, corn variety with increased disease resistance]

Claim categories

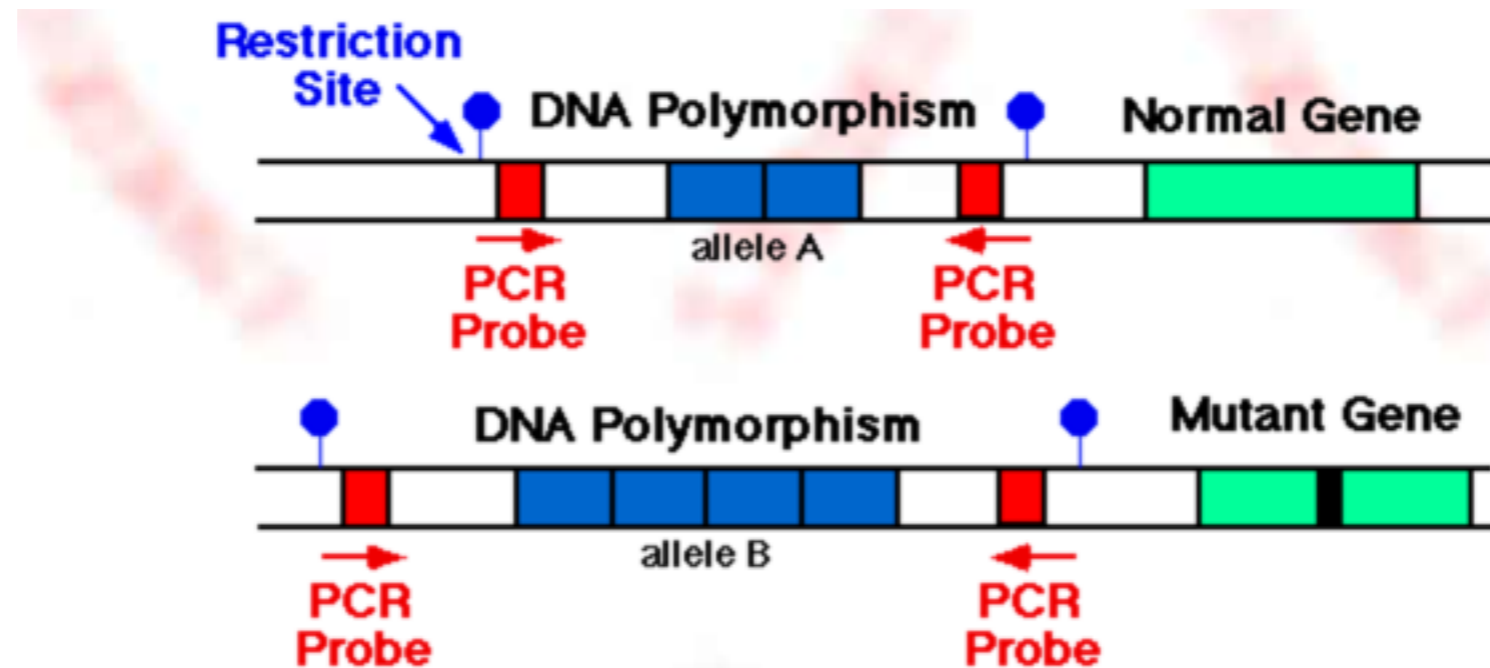
- Apparatus (e.g., machine or device)
- Method or process or use
- Product or composition

How to patent inventions relating to plant varieties? [For example, corn variety with increased disease resistance]

- Plant claim. Do not claim in terms of variety but in terms of specific gene content.
 - “A plant containing gene X (or marker A tightly linked to gene X) for disease resistance.”

- Method or use claim. Can claim method of using variety A for producing corn or use of variety A for producing corn.
- Composition/product claim. Can claim plant parts (e.g., corn kernels) or products further downstream (e.g., corn meal prepared using variety A corn)

DNA markers as research outputs



Detection of DNA polymorphism via Southern Hybridization or PCR

**Detect Polymorphism
by Southern
Hybridization**



**Detect Polymorphism
by Polymrase Chain
Reaction**



from <http://www.mun.ca/biology/scarr/b4241e.html>

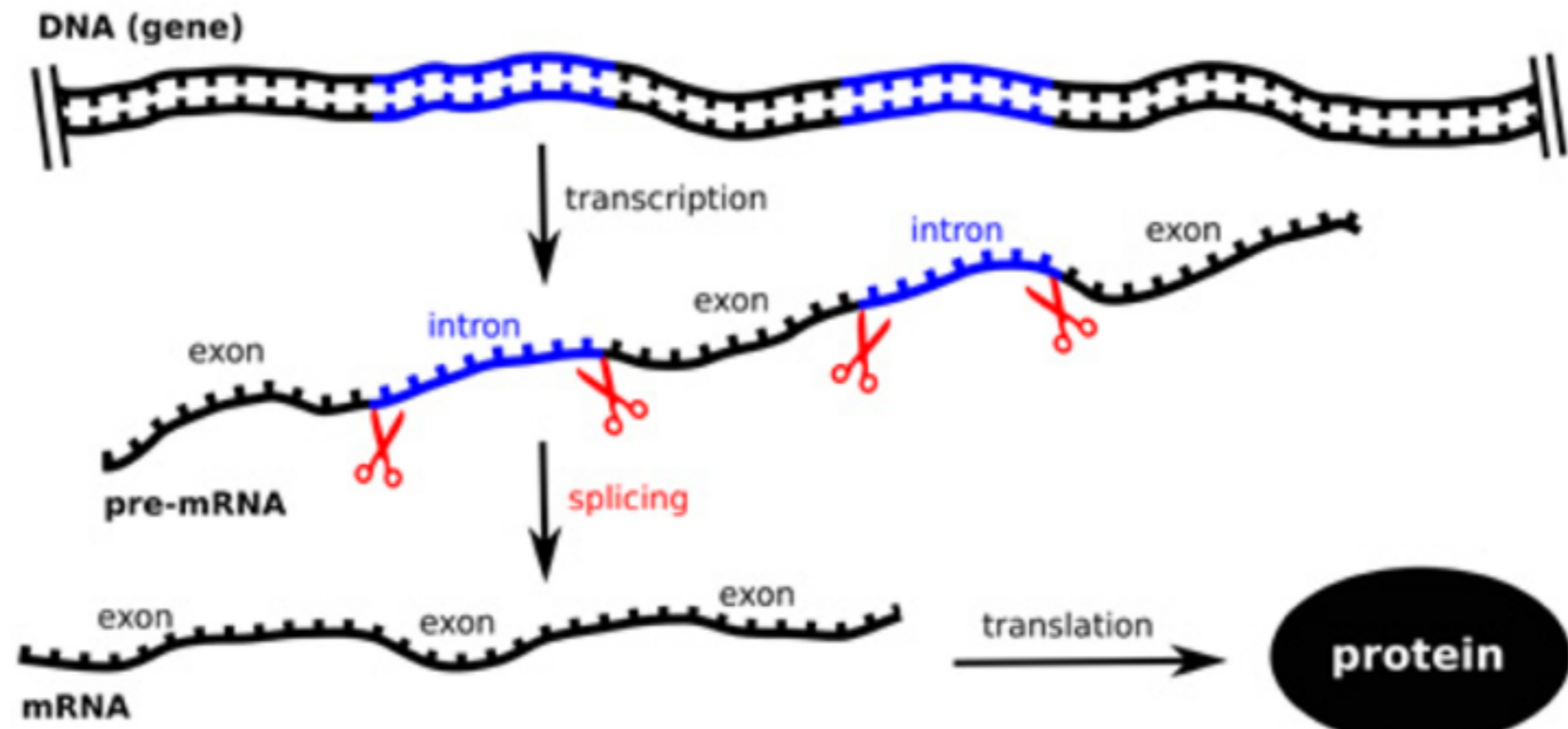
DNA markers as research outputs

DNA markers are DNA fragments amplified from genomic DNA that are found to be linked to desired traits, e.g., disease resistance, delayed ripening

Are DNA fragments patentable?

In the United States, it depends. The US Supreme Court in 2013 held that genomic DNA (even in isolated form) is not patentable while cDNAs (synthesized in the lab that contain only coding sequences and therefore exclude non-coding sequences) are patentable.

In Australia, different result.



from <http://www.sisi-chen.com/blog/>

Patentability of DNA sequences thus appears to turn on whether the claimed fragment naturally occurs in the organism, at least in the United States.

Under this standard, DNA markers likely not to be patentable. But Philippine law has not specifically excluded DNA markers.

Can otherwise claim kits and methods for analyzing/selecting plants using the DNA markers.

Requirements for patentability

- Utility / industrial applicability
- Novel / new
- Inventive step / non-obviousness
 - unexpected results based on prior art teachings
 - difficulty in making the invention
 - acclaim
 - presents a solution to a long-felt need

In re Kubin (Federal Circuit, 2009): obviousness of DNA fragments

- claim directed to polynucleotide encoding polypeptide that bind CD48, the interaction resulting in increased cell cytotoxicity and production of interferon.
- Prior art:
 - CD 48-binding protein had already been isolated, but amino acid sequence not known.
 - Monoclonal antibody specific for the CD 48-binding protein had already been disclosed.
- held the claim as obvious, given the well-known and reliable nature of the cloning and sequencing techniques in the prior art, and what was known about the CD-48 binding protein in the prior art.

Other agricultural research outputs

Apparatuses (e.g., biomass pelletizer) are patentable.

Purified enzymes with industrial application, e.g., cellulases for biofuel production: patentable

Fertilizers — compositions containing microorganisms are patentable

Animal breeds — not patentable under Philippine law, but no system analogous to the Plant Variety Protection Act to protect intellectual property

How to patent inventions relating to animal breeds?
[For example, cattle breed B that produces more milk than other breeds]

- Animal claim. Claim animal that contains specific gene or marker.
- Method or use claim. Can claim method of using breed B for producing milk or use of breed B for producing milk.
- Composition/product claim. Can claim animal products (e.g., milk) or products further downstream (e.g., ice cream prepared using breed B milk)

Patent valuation and market considerations

- evaluate importance of invention
 - one of a kind or one of many?
 - critical component?
 - easy to design around?
 - size of market?
- consider value of similar patents/
license agreements regarding similar
technology
- what the market can bear