Intellectual Property Protection for Plants in the United States

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Art Units 1661 and 1638

Three Types of Protection

- Plant Patent Act
  - 35 U.S.C. §§ 161-164
- Plant Variety Protection Act
  - 7 U.S.C. §§ 2321 et seq.
- Utility Patent to a Plant
  - 35 U.S.C. §§ 111 (101, 102, 103, 112)

Art Unit 1661- Plant Patents (PLTs)

1661

- 1 Senior examiner
- 2 Primary examiners
- 3 Assistant examiners
- 2 hybrid/dual examiners

Total = 8 examiners

Plant Patent Act

- First protection of its kind worldwide - 1930
- Relaxed enablement requirement, new matter
- Applies to asexually reproduced plants (not including edible tuber propagated plants)
- 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
- Total 18,488 plant patents

Plant Patent Act

- 35 U.S.C. 161 states:

  "Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor…"

Requirements for Patentability

- Plant is new and distinct from other known varieties (35 U.S.C. 102, 103)
- Plant description as complete as is reasonably possible (112, relaxed enablement requirement)
- Plant has been asexually propagated
- If “discovered,” plant was found in a cultivated area
- Plants discovered in the wild are excluded

Patentability May be Negated by:

- Lack of novelty
- Sale or public use of the plant in the U.S. more than 1 year prior to filing for U.S. patent
- Description of the plant in a printed publication, combined with public availability (anywhere) more than 1 year prior to filing for U.S. patent (In re Elsner, 381 F.3d 1125, 72 USPQ2d 1038 (Fed. Cir. 2004)
- Obviousness in view of the prior art
- Edible tuber propagated plant
- Description not as complete as is reasonably possible

Plant Patent Representative Claim

A Petunia plant substantially as described and illustrated in the specification herein.

Plant Variety Protection Act (PVPA)

- Administered by U.S. Department of Agriculture (USDA)
- Enacted in 1970, Amended in 1994
- Plant must be New, Distinct, Uniform and Stable
- In U.S. applies only to sexually reproduced plants and tuber propagated plants
- 20-25 year protection from date of grant
- Exclude others from selling, offering for sale, multiplying, conditioning, importing, exporting and stocking the variety
- Breeder's exemption, farmer's exemption

Requirement for PVP

- New
  - has not been sold or otherwise disposed of for purposes of exploitation for more than one year in the United States, or more than four years in any foreign jurisdiction (six years for trees and vines).
- Distinct
  - clearly distinguishable from any other publicly known variety. Distinctness may be based on morphological, physiological, or other characteristics, including commercially valuable characteristics.

Requirement for PVP

- Uniform
  - any variations are describable, predictable, and commercially acceptable.
- Stable
  - the variety, when reproduced, will remain unchanged with regard to its essential and distinctive characteristics within a reasonable degree of commercial reliability.

Art Unit 1638- Plant Utility Patents

1638

- 2 Senior examiners
- 8 Primary examiners
- 7 Assistant examiners

Total = 17 examiners

Utility Patent

- Technology neutral
- 20 year protection from date of filing
- Right to exclude others from making, using, selling, offering for sale, and importing the patented plant in the granting territory
- Possible to protect varieties having specific traits, plant parts and methods of producing or using plant varieties

Utility Patents: History

- Diamond v. Chakrabarty, 447 U.S. 303 (1980)
  - Held living things were indeed patentable
- Ex Parte Hibberd, 227 USPQ 443 (PTO Bd. Pat. App. & Int. 1985)
  - Ruled that seeds, plant tissue cultures, and the plant itself are patentable subject matter under the utility patent statute
- J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124, 60 USPQ2d 1865 (2001)
  - Held newly developed plant breeds fall within the scope of §101, and neither the PPA or PVPA limits this coverage

Agronomic Objectives of Plant Utility Patents

- Disease and insect resistance
- Drought and salt tolerance
- Herbicide resistance
- Improvement of fruit and flower quality
- Modification of fatty acid and oil composition
- Increases in amino acids and nutrition
- Improvement of sugars and carbohydrates
- Increases in secondary plant products
- Male sterility
- Production of mammalian peptides and vaccines

Commercial Agricultural Products Overview

PRODUCT	GENETIC MODIFICATION	PURPOSE
tomatoes, peas, peppers, tropical fruit, broccoli, raspberries, melons	controlled ripening	Allow shipping of vine-ripened tomatoes; improve shelf life, quality.
tomatoes, potatoes, corn, lettuce, coffee, cabbage family, apples	insect resistance	Reduce insecticide use.
peppers, tomatoes, cucumbers	fungal resistance	Reduce fungicide use.
potatoes, tomatoes, cantaloupe, squash, cucumbers, corn, oilseed rape (canola), soybeans, grapes	viral resistance	Reduce diseases caused by plant viruses and — since insects carry viruses — reduce insecticide use.
soybeans, tomatoes, corn, oilseed rape (canola), wheat	herbicide tolerance	Improve weed control.
corn, sunflowers, soybeans, and other plants	improved nutrition	Increase the amount of essential amino acids, vitamins or other nutrients in the host plant.
oilseed rape (canola), peanuts	heat stability	Improve processing quality; permit new food uses for healthier oils.

Sources: The Hale Group/Decision Resources, Inc., *Food Processing* and *BIO/technology* magazines

http://www.fmi.org/consumer/biotech/biotechnology.pdf

Growth of Genetically Modified Plants (GMP)

- 1996 - 17,000 km^2
- 2004 – 809,000 km^2
  - Soybean (63%)
  - Maize (19%)
  - Cotton (13%)
  - Canola (5%)
- 4 countries grow 99% of the GMP
  - United States (68%)
  - Argentina (22%)
  - Canada (6%)
  - China (3%)

http://en.wikipedia.org/wiki/Genetically_modified_food

Plant Utility Patent Claims

- Plants
- Plant organs or tissue
- Pollen
- Ovules
- Tissue or cell culture
- Seeds

Plant Utility Patent Claims

- Isolated plant polynucleotides and polypeptides
- Isolated plant regulatory elements (e.g. promoter, transcriptional elements)
- Expression cassettes or vectors
- Transgenic plants having a novel phenotype
- Products produced from transgenic plants

Plant Utility Patent Claims

- Methods of breeding novel/nonobvious plants using traditional methods
- Methods of molecular plant breeding
- Methods of producing a transgenic plant having a novel phenotype
- Novel plant transformation methods
- Methods of plant cell and tissue culture

Plant Utility Patent Representative Claims

Claim 1. Seed of plant variety NN deposited as ATCC Accession No. _____.

Claim 2. A plant grown from the seed of Claim 1.

Claim 3. An isolated DNA encoding protein X.

Claim 4. A method of making a transgenic plant having phenotype Y comprising transforming a plant with said DNA of Claim 3.

Claim 5. A transgenic plant produced by the method of Claim 4.

Basic Patentability Standards

- 35 USC § 101, Utility
- 35 USC § 102, Anticipation (Novelty)
- 35 USC § 103, Obviousness
- 35 USC § 112, 1st Paragraph, Written Description
- 35 USC § 112, 1st Paragraph, Enablement

Utility: 35 U.S.C. § 101

- A patent application must set forth a utility that is:
  - Specific
    - Utility specific to the subject matter claimed as opposed to a general utility to a broad class of inventions
  - Substantial
    - Utility that defines a “real world” use
  - Credible
    - Reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility

Anticipation/Novelty

- 35 U.S.C. § 102

  Generally, a person shall be entitled to a patent unless the invention was:

  - patented
  - described in a printed publication in U.S. or a foreign country
  - in public use or on sale in the U.S. more than one year prior to the date of the application

Anticipation: 35 USC § 102

- Does the prior art teach a plant variety with the same characteristics?
- Does the prior art teach an isolated DNA as claimed?
- Does the prior art teach a method of making a transgenic plant comprising the isolated DNA as claimed?
- Largely dependent on the breadth of the claims

Non-Obviousness 35 U.S.C. § 103

- Are the characteristics of the claimed plant variety obvious over a prior art variety when grown under different conditions?
- Are the characteristics obvious morphological variants?
- Is the claimed DNA suggested by the prior art?
- If so, is there a reason to produce a transgenic plant comprising the DNA?
- Is there an expectation of success in obtaining a transgenic plant with phenotype Y?

Written Description
35 USC § 112, 1st Paragraph

The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms . . . any person skilled in the art to which it pertains . . . to make and use the same . . .

General Principles

- Basic inquiry: Can one skilled in the art reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed?

- The written description requirement is separate and distinct from the enablement requirement.

Evidence of Possession

- Reduction to Practice
  - Actual reduction to practice not always required.
  - Deposit of biological materials not a substitute for written description.
- Clear depiction of the claimed invention in detailed drawings.
- What is conventional or well known to one skilled in the art need not be described in detail.

Written Description
35 USC § 112, 1st Paragraph

- How many species of the claimed genus are described?
- Are the species that are described representative of the claimed genus?
- Does Applicant describe a structural feature(s) unique to the claimed genus?
- Applicant may need to include structural as well as functional claim language
- Is the phenotype of the transgenic plant described?

Enablement
35 USC § 112, 1st Paragraph

The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms . . . any person skilled in the art to which it pertains . . . to make and use the same . . .

Enablement
35 USC § 112, 1st Paragraph

- Basic Inquiry: Can one skilled in the art make and use the invention without undue experimentation?

Enablement
35 USC § 112, 1st Paragraph

- Has Applicant taught how to use the claimed plant variety, *i.e.* its agronomically useful phenotypic characteristics?
- Has Applicant taught how to use the claimed DNA?
- Has Applicant taught isolated DNAs?

  -- How many DNAs has Applicant isolated?

  -- Has Applicant provided <u>specific</u> guidance for isolation of other functionally related DNAs, including structurally unrelated DNAs?
- Applicant may need to include <u>structural</u> as well as functional claim language.

Enablement
35 USC § 112, 1st Paragraph

- If the DNA is not enabled throughout the scope of the claim, the method of making a transgenic plant is not enabled throughout the scope of the claim.
- Has Applicant provided guidance for making a transgenic plant having phenotype Y?
- Have related genes resulted in phenotype Y upon expression in plants?

Utility vs. Plant Patents

Requirement or Attribute	Utility Patent (35 U.S.C. 111)	Plant Patent (35 U.S.C. 161)
Generic claim or protection possible	Yes	No – patent covers a single plant and its clones
Method claims permitted	Yes	No
Number and format of claims limited	No	Yes – one claim of prescribed format

Utility vs. Plant Patents

Requirement or Attribute	Utility Patent (35 U.S.C. 111)	Plant Patent (35 U.S.C. 161)
Exclusions	Products of nature	Products of nature, edible tuber-propagated plants
Invention must be novel, nonobvious and distinct	Yes	Yes

Utility vs. Plant Patents

Requirement or Attribute	Utility Patent (35 U.S.C. 111)	Plant Patent (35 U.S.C. 161)
Invention must be “enabled”	Yes	No
Deposit of biological material required	May Be Necessary	No
Variety name required	No	Yes

Utility vs. Plant Patents

An invention may support both a utility patent and a plant patent, so long as the subject matter protected by the two patents is not identical.

Utility vs. Plant Patents

- Utility Patent- may be useful where invention is not limited to a particular variety or where method claims are desired
- Plant Patent- may be useful where it is difficult to meet the written description or enablement requirements of a utility patent

Right to Priority

- **MPEP1613 Right of Priority Based upon Application for Plant Breeder's Rights**
  - Pursuant to **35 U.S.C. 119(f)**, an application for a patent may rely upon an application for plant breeder's rights filed in a WTO member country (or in a foreign UPOV Contracting Party) for priority under **35 U.S.C. 119(a)** through (c).

Questions?

- http://www.uspto.gov/web/offices/pac/plant/index.html
- http://www.uspto.gov/web/offices/pac/utility/utility.htm
- http://www.ams.usda.gov/Science/PVPO/PVPindex.htm
- 571-272-1600 – Technology center 1600 directory
- 571-272-0975 – Anne Marie Grünberg