



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, 1930**
 - 35 U.S.C. §§ 161-164
- **Plant Variety Protection Act, 1970, 1994**
 - 7 U.S.C. §§ 2321 et seq.
- **Utility Patent to a Plant, 1980**
 - 35 U.S.C. §§ 111 (101, 102, 103, 112)



Legal History

- Plant Patent Act of 1930
 - Held asexually propagated plants excluding tubers, patentable
- Plant Variety Protection, 1970
 - In the U.S., protection afforded to sexually propagated plants, including tubers
- 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



What Protection is the Best?

- **Depends on the business model**
 - May have one or all three
 - May have trade secrets
 - May lease plants/seeds
- **Depends on what type of plant**
 - Sexually propagated, asexually propagated, depositable, tuber
- **Depends on how much protection one desires**
 - Broader vs. narrower protection
 - Plant, plant parts, methods of breeding, etc
- **Depends on how much money one has**
 - Cost of filing
 - Burden of proving distinctiveness
 - Maintenance fees



Comparisons

	Plant Patents	Plant Variety Protection	Plant Utility Patents
Protection	The plant and its clones	The plant and its clones, or plant and its homozygous seed	The plant, methods of making, methods of using, methods of breeding, etc
Type of plant	Asexually reproduced plants, excluding edible tubers	Sexually reproduced plants, edible tubers	Any kind of plant that can be deposited
Cost	Starting at ~\$1900 for small corporations, fees a la carte, no maintenance fees	\$5,150, burden on applicant to show distinctiveness, no maintenance fees	Starting at ~\$1300 for small corporations, fees a la carte, up to \$7560 maintenance fees, possible deposit fees
Advantages	Least expensive	“Softer” system, giving back to the community, no maintenance fees	Broad coverage possible, burden on office to show not in conformance with the statutes



Utility v. 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 v. 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



Plant Patent Act

- First protection of its kind worldwide - 1930
- Relaxed 35 USC § 112, first requirement
- 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 19,712 plant patents



Art Unit 1661- Plant Patents (PLTs)

1661

1 Expert examiner

3 Primary examiners

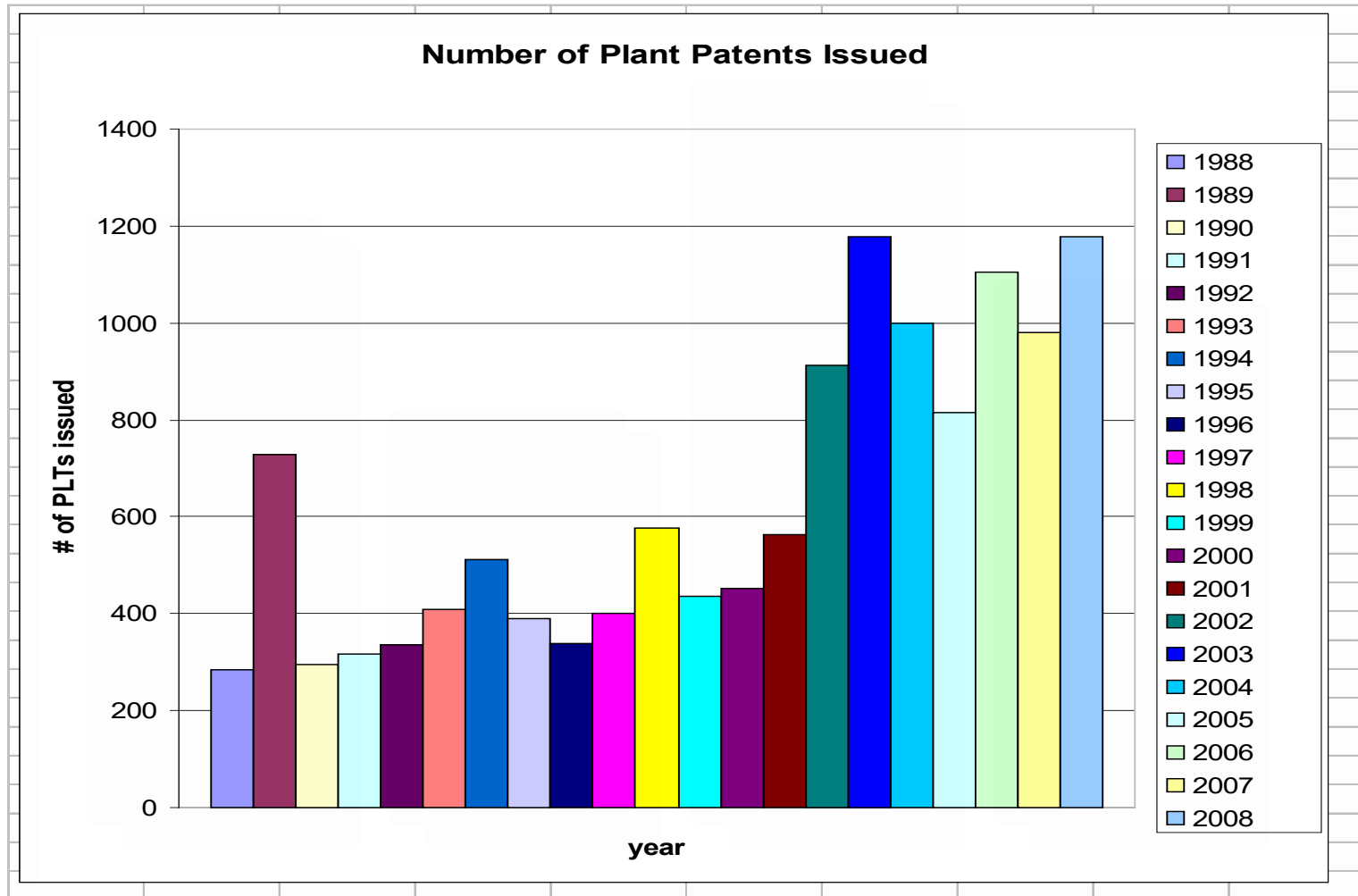
2 Assistant examiners

1 hybrid classifier/examiner

Total = 7 examiners



Plant Patent Trends





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).



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...”



Plant Patent Representative Claim

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



Quick Examination Overview

- PALM inventor search, terminal disclaimer
- Oath/declaration indicates asexually reproduced and if found, found in a cultivated area (37 CFR 1.162)
- Color chart/dictionary
- Comparison to parents, other known variety
- Description as complete as is reasonably possible
- A single claim in a particular format, must say “as described and illustrated”, must be drawn to entire plant
- Title drawn to plant
- Denomination
- Color drawings
- No unwarranted advertising, laudatory expressions



Quick Examination Overview continued

- **Novelty**
 - **In re Elsner**

- **Obviousness**
 - **Radiation**
 - **Colchicine**
 - **Known plant with a known transgene**



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 (35 U.S.C. 112, relaxed enablement requirement)**
- **Plant has been asexually propagated**
- **If “discovered,” plant was not found in an uncultivated state**
- **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 03-1569 (Fed. Cir. Aug 16, 2004))
- Obviousness in view of the prior art
- Edible tuber propagated plant
- Description not as complete as is reasonably possible



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 edible 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

10 Primary examiners

5 Assistant examiners

Total = 17 examiners



Utility Patent

- **Technology neutral**
 - **Traditional breeding, transgenics**
- **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 a class of varieties with a specific trait, plant parts and methods of producing or using plant varieties**



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
- Altered morphological phenotype
- Male sterility
- Phytoremediation and heavy metal tolerance
- 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



Growth of Genetically Modified Plants (GMP)

- 1996 - 17,000 km²
- 2004 – 809,000 km²
 - Soybean (63%)
 - Maize (19%)
 - Cotton (13%)
 - Canola (5%)
- 2008
 - 114 m hectares across 23 countries
 - <http://www.guardian.co.uk/environment/2008/feb/13/gmcrops.food>
- 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 - Products

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

- **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.**



Restriction Practice

- **Claim 1.** A soybean plant 37691, representative seed of said soybean cultivar having been deposited under ATCC Accession Number _____.
- **Claim 2.** A method for producing a soybean seed comprising crossing soybean plants and harvesting the resultant soybean seed, wherein at least one soybean plant is the soybean plant of claim 1.
- **Claim 3.** Oil derived from the seed of claim 1.
- **Claim 4.** A composition comprising soybean meal of the plant of claim 1.



35 USC §101

- **Non-Statutory**
 - The “use” of
- **Product of nature**
 - Isolated, operably linked, heterologous
- **Specific, Substantial, Credible utility**
 - MAS (marker assisted selection)



Examples of 35 USC §101 issues

- **Claim 1. A method of breeding wheat plants by evaluating SSR markers selected from table 1 and associating the correlation between yield and a marker defined by the polymorphic loci of table 1 in a breeding population.**
 - Non-statutory; not tied to a particular machine or apparatus, and does not transform a particular article to a different state or thing
- **Claim 2. A method of breeding wheat plants as described in claim 1 wherein a wheat plant determined to have a change in a biochemical pathway is crossed with another wheat plant having a change and selecting progeny having said change.**
 - Lacks specific, substantial, and credible utility
 - Followed by 35 USC §112, first
- **Claim 3. A plant transformed with gene X or progeny of said plant.**
 - Product of nature



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



Examples of 35 USC §102 issues

- **Claim 1. A striped tomato comprising:**
 - a fruit having a red background color; and
 - at least one dark stripe associated with the fruit.
- **Claim 101. An F2 hybrid derived from the plant of claim 1.**
- **Claim 1. An isolated promoter comprising:**
 - (a) a nucleotide sequence having SEQ ID No. 1
 - (b) a nucleotide sequence having a deletion, substitution or addition of one or more nucleotides from SEQ ID No. 1, or
 - (c) a nucleotide sequence hybridizing under stringent conditions with SEQ ID No. 1.



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 motivation to produce a transgenic plant comprising the DNA?
- Is there an expectation of success in obtaining a transgenic plant with phenotype Y?



Examples of 35 USC §103 issues

- **Claim 1. Seed of soybean variety X, representative seed having been deposited under ATCC Accession No. ____.**
 - Note that variety x appears to be identical to variety W with the exception of resistance to a herbicide for which there are known resistance transgenes.
 - This information may be in a Requirement for Information under 37 CFR 105.
- **Claim 1. A genetically modified plant cell having increased activity A that has been transformed with the nucleotide sequence having Seq ID No. 1.**
 - Note that the nucleotide sequence, although novel, codes for a known protein having the same function
 - Or the nucleotide sequence may differ from a known sequence but it was isolated from the same organism





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?**
- **No new matter may be added to the specification or claims**
- **The written description requirement is separate and distinct from the enablement requirement.**



Written Description

35 USC § 112, 1st Paragraph

- How many DNAs (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?
- Should generally include structural as well as functional claim language.
- Is the phenotype of the transgenic plant described?
- Is the genus of genes, recited or implied, responsible for conferring the claimed phenotype adequately described?



Examples of written description issues

- **Claim 1. A pepper plant having fruits that are purple in coloration.**
- **Claim 1. A transgenic plant having a polynucleotide sequence that is 90% identical to SEQ ID No. 1.**



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 specific guidance for isolation of other functionally related DNAs, including structurally unrelated DNAs?
- Should generally include structural 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?



Examples of Enablement Issues

- **Claim 1. A transgenic plant having a polynucleotide sequence that is 85% identical to SEQ ID No. 1 wherein the plant exhibits a particular phenotype associated with the sequence.**
- **Claim 1. A method of making any mutant in any species by suppressing the expression of an xyz homologous gene in a plant.**
- **Claim 1. A method to confer disease resistance to a plant, comprising transforming the plant with an insecticidal gene.**



Definiteness

35 USC § 112, 2nd Paragraph

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.



Definiteness

35 USC § 112, 2nd Paragraph

- **Lack of antecedent basis**
- **Metes and bounds not defined**
- **Lack of clarity**
- **Terminology contrary to art-recognized definitions**
- **Lacking an essential step**



Examples of Indefiniteness

- **Claim 1. A method of making a transformed plant comprising: transforming a plant cell with gene x.**
 - Lacks essential step
- **Claim 1. A plant comprising gene X.**
- **Claim 2. The tomato plant of claim1, wherein gene X is suppressed**
 - Lacks antecedent basis for tomato plant
- **Claim 1. A method of transforming a tree, comprising: transforming a corn cell with gene X, and regenerating a whole corn plant from the transformed cell.**
 - Contrary to art-recognized definitions as corn is not a tree.
- **Claim 1. A method of transforming a plant cell by culturing said plant cell with Agrobacterium for 1 minute to 7 days, preferably 30 minutes to 3 days, more preferably 4 hours to one day, for example 8 hours and 7 minutes.**
 - Metes and bounds not clearly set forth



Utility v. 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 v. 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
New matter	No	New information may be added as long as it is drawn to the same plant as claimed
Invention must be novel, non-obvious	Yes	Yes



Utility v. 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	Yes, if not enabled by other means	No
Variety name required	No	Yes



Thanks

■ 1638

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- Beth McElwain
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- Cathy Worley
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■ 1661

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