# Intellectual Property Protection For New Plant Varieties

Michael R. Ward, Ph.D., J.D. Morrison & Foerster LLP June 22, 2006 Pullman, Washington

© 2005 Morrison & Foerster LLP All Rights Reserved

# Michael R. Ward, Ph.D., J.D.

- M.S., Agronomy, UC Davis
- Ph.D., Plant Physiology, UC Davis
- Post Doc, Plant Molecular Biology, Harvard Medical School
- J.D. Golden Gate University
- Partner, San Francisco Office of Morrison & Foerster
- Head of the firm's Plant IP Group

# **Plant IP: Industry Trends**

- Companies and Universities are becoming more aggressive in protecting, defending and enforcing plant IP both in the U.S. and abroad.
- Germplasm is key.
- The world is smaller: no one just focuses on the US any longer for plant IP



# How are companies protecting their new plant varieties?

Breeding programs often produce a series of lines that all have similar, novel characteristics

- A heat tolerant broccoli or lettuce plant.
- A salt tolerant plum tree.
- An apple scab resistant apple tree.
- A powdery mildew resistant strawberry plant.

# How can you Protect a Heat Tolerant Broccoli Plant?

• Plant Variety Certificate?

• Utility Patent?

• Plant Patent?

#### Three Forms of Intellectual Property Protection Available for Plants in the U.S.

- 7 U.S.C. 2327
  - Plant Variety Protection
  - Dept. of Agriculture / AMS
- 35 U.S.C. 101
  - Utility patent
  - Dept. of Commerce/ US PTO
- 35 U.S.C. 161
  - Plant patent
  - Dept. of Commerce/ US PTO

MORRISON

FOERSTER

#### How Can You Protect a Heat Tolerant Broccoli Plant?

- U.S. Plant Variety Protection Provides Protection for:
  - Sexually (seed) reproduced plants
  - Tuber Propagated Plants
  - F1 Hybrids
- Asexually reproducing plants (buds and cuttings) are the subject of plant patents under 35 U.S.C. 161.
- Sexually reproducing plants (flowers and seeds) and genetically engineered plants are the subject of utility patents under 35 U.S.C. 101.

#### **PVP Applications and Patents**

Why are there 2 forms of IP protection (utility patents and PVP certificates) for sexually reproducing plants in the US?



# Decided by the Supreme Court in **Pioneer v. J.E. M**.

- Pioneer obtained utility patents on new corn varieties.
- Pioneer sued J.E.M. for infringement of the patents.
- J.E.M. asserted that the Pioneer patents were invalid arguing that new plant varieties should be exclusively protectable under the P.V.P.

#### **The Supreme Court Rules for Pioneer**

- Sexually reproducing plants are patentable as utility patents and protectable under the PVP
- No Congressional intent to exclude patentability of new plant varieties
- No irreconcilable conflicts between PVP and utility patents.

#### How Does Patent Protection Differ from PVP Protection?

- No research exception for patented varieties: patent holder can prevent other breeders from using a patented variety in breeding
- PVP protection covers a single variety and essentially derived varieties.
- Utility patent protection can be broader: trait claims.



#### Claims

Claims define the "metes and bounds" of the invention.

- PVP Certificates have no claims.
- Plant Patents have only 1 claim.
- Utility patents have multiple claims.
  - Seed deposit claims
  - Trait claims
  - Breeding methods
  - Food product claims



 A new and distinct variety of peach tree, Prunus persica, designated 'Redhaven' substantially as herein shown and described.



#### **Utility Patent "Seed Deposit" Claims**

- 1. A broccoli seed designated 393-2-19 and having ATCC Accession Number 203533.14
- 2. A broccoli plant having all the phenotypic characteristics of a plant produced from the seed of claim 1.
- 3. A seed from the plant of claim 2.



A broccoli plant or parts of said plant wherein said plant comprises:

a center head having a diameter of 3 to 10 inches at maturity when said plant is exposed to a maximum daily temperature of 90 degree F to 100 degree F for 5 consecutive days during the bud development phase of said plant,

wherein said plant exhibits no heat stress symptoms including one or more of the following: non-uniform beads; brown, yellow, light-green or purple colored heads; flat heads; bracts; rapid fracturing of the head, "cateye", and hollow stems.

# Why Obtain Trait Utility Patent Claims?

- Significantly broader than seed deposit claims.
- Cover those varieties developed and disclosed in the patent application without need for seed deposit.
- Cover those varieties <u>independently</u> developed later that fall within the claim.

#### How to Obtain Trait Claims in Utility Patents

- Requires defining your invention in broader terms
  - A heat tolerant lettuce plant.
  - An apple scab resistant apple tree.
  - A powdery mildew resistant strawberry
- Requires describing a large number of varieties that exhibit similar characteristics.
- Patent application needs to be written strategically.
- Patent attorney should work closely with breeders.

#### The Utility and Plant Patent Examination Process

• Application sent to the U.S. Patent Office.

• Patent Office sends an Office Action rejecting claims.

• Applicant responds with a claim amendments and arguments refuting the rejection.

#### The Utility and Plant Patent Examination Process (continued)

• Patent Office agrees/disagrees.

• Interview with Examiner: get breeder involved.

• Allowance or Appeal.

• Grant of Patent



#### **Protection outside the U.S.**

- Plants are patentable in Japan and Australia
- Plants are protectable as Plant Breeder's Rights or Plant Variety Certificates in most key agricultural countries.
- Comparative testing is often required as part of the PBR process.
  - Make certain that you control the plant material
  - Everyone who handles the material should be bound by contract

# **Utility Patent Infringement**

 A patent holder may prevent others from making, using, selling, offering for sale or importing the claimed invention

 Varieties can and should be marked "patent pending" once patent application has been filed and "Patented" and the US Patent Number once granted.

 Patent rights can be enforced only when a patent after a patent issues.

## **Plant Patent Infringement**

 Plant patent holder has the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, <u>or any of its</u> <u>parts</u>, throughout the United States, or from importing the plant so reproduced, or <u>any parts thereof</u>, into the United States.

# **PVP Marking**

• Once a PVP application is filed, variety label may indicate "Unauthorized Propagation Prohibited."

 After Certificate Issues, one can add words such as "U.S. Protected Variety."

# **PVP Infringement**

- PVP holder can sue for PVP infringement once the variety is distributed with Notice of PVP pending or after the Certificate Issues.
- No damages collected unless variety marked properly or the infringer has actual knowledge that the variety is protected.
- Damages for infringement prior to issuance of the Certificate are discretionary if the court finds that the infringer had innocent intentions.

# **PVP Infringement**

Can exclude others from:

- Selling or marketing the variety
- Conditioning or stocking the variety
- Offering the variety for sale or reproducing it
- Importing or exporting the variety
- Using the variety to produce (as distinguished from develop) a hybrid or different variety
- Certificate holder has these rights for 20 years (25 years for trees or vines) from issuance of the certificate



# **PVP Rights Granted**

Rights extend to:

- ✓ Essentially derived varieties\*
- ✓ Indistinct varieties
- ✓ Harvested materials
- ✓ Varieties which require repeated use of the protected variety

# **PVP Exemptions**

- Farmers Exemption: Save for use on farm but NO transfer to others for reproductive purposes
- Research Exemption: Others can use the variety in plant breeding or other research



#### **Restricted Use Licenses**

- Examples of restrictions:
  - Use for planting a commercial crop for a single season
  - To not supply any of the seed to any other person or entity
  - To not save any crop produced for replanting or supply saved seed for replanting
  - To not use the seed for breeding, research or seed production.
- Can apply to patented, PVP-protected and non-patented or non-PVP-protected seeds.



# Restricted Use Licenses for non-patented or non-PVP-protected seeds

- Generally OK if reasonable
- Possible business issues if terms are unreasonable and if other seed sources available.
- Be certain to inform customer: place restrictions on the purchase order in addition to on the seed container.
- Be careful to not mislead customers that the seeds are patented or PVP protected if they are not.

#### **Restricted Use Licenses for Patented Seeds**

- Enforceable as determined in McFarling V. Monsanto
- McFarling signed a Technology Agreement with Monsanto for Round Up Ready seeds agreeing to:
  - Use for planting a commercial crop for a single season
  - Not supply any of the seed to any other person or entity
  - Not save any crop produced for replanting or supply saved seed for replanting
  - Not use the seed for breeding, research or seed production

#### **Restricted Use Licenses for Patented Seeds**

- McFarling argued that Monsanto had committed patent misuse because Monsanto had impermissibly tied an unpatented product to a patented product.
- Policy of the patent misuse doctrine is to prevent a patent holder from using the patent to obtain market benefit beyond the statutory patent right.
- If patent misuse is found, the patent would be unenforceable.



#### **Restricted Use Licenses for Patented Seeds**

- Did Monsanto impermissibly broaden the scope of its patent by precluding McFarling <u>from</u> using seed produced from the patented seed?
- The patent covers the sold seed <u>and</u> the seed produced from the sold seed.
- The Court held that the license did <u>not</u> extend Monsanto's rights beyond the patent.
- No patent misuse.



#### **Restricted Use Licenses for PVP Seeds**

- Does the patent misuse defense apply to PVP protected seeds?
- Contract extends the scope of protection of the PVPprotected seed to obtain market benefit beyond the statutory PVP right.
  - Research Examption
  - Farmer's exemption
- Valid for trade secret (no protection) and therefore should be valid for PVP-protected seed.

#### **Maximizing Protection Of Your New Varieties**

- Seek "trait-type" utility patent claims.
- Seek patent claims covering the varieties that you intend to sell.
- Seek PVP protection on the varieties that you intend to sell.
- Use restricted licenses on your seed bags.
- Seek International protection in key markets.

