

Unintentional Overprotection of GM Plant Intellectual Property

How Normal Use of Patented Articles Becomes Patent Infringement

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Plant Reproduction Schemes

In order to understand how plant intellectual property is affected by self reproduction of genetically modified plants, it is first necessary to remember the methods by which plants reproduce:

Sexual Reproduction

- ▶ Pollen from a first plant encounters flower from a second plant, triggering fruit & seed formation.
- ▶ Key element = **Gene transfer**

Asexual Reproduction

- ▶ A physical part (root, branch) is removed from a first plant and **grafted** onto a second plant to keep the removed portion alive and to *use* the grafted part.
- ▶ Key element = **Physical division**, *not* **gene transfer**.

A Patent Infringement Story

Traditional Farmer v. Modified Farmer

- ▶ **Traditional farmer** raises heirloom corn for sale to a French company to make corn chips in Europe.
- ▶ **Modern farmer** raises GM corn to take advantage of a new herbicide and boost harvest.
- ▶ Traditional tries to prevent GM contamination (buffer zone).
- ▶ Traditional's fields are contaminated by pollen or spilled seed and her heirloom corn crop contains seed with patented genes.
- ▶ Traditional cannot sell her corn to the European Union and loses money on her crop this year.

Introduction

Just How Far do Patent Rights Reach?

- ▶ Patents protect inventions from *intentional* and *unintentional* infringement.
 1. What if the *inventor sells* the invention to another person?
 2. What if a *third party sells* the invention instead?
 3. What if *nobody sells* the invention?
- ▶ What legitimate control can a patent holder exercise to prevent people from making or using a patented invention?
- ▶ When does making or using an invention *not* infringe a patent?

Infringement when Nobody Sells the Patented Invention

Major Position Points:

- ▶ IP statutes must be *narrowly tailored* to avoid overprotection.
- ▶ Genetically modified organisms (GMOs) are unique subject matter, and *require a unique interpretation* of what it means to infringe, because:
- ▶ GMO intellectual property can easily spread *beyond user's control*. Innocent (i.e., non-infringing) parties may be liable for infringement that occurs *outside their knowledge* and *despite their efforts* to avoid infringement.
- ▶ A *statutory remedy* is the best solution to this problem, given the difficulty of achieving a judicial remedy.

Legal Protection

Four Forms of Plant IP Protection

- ▶ Utility Patents – 35 U.S.C. §§101 *et seq.*
- ▶ Plant Patents – 35 U.S.C. §§161–164
- ▶ Plant Variety Certification – 7 U.S.C. §2402
- ▶ Contractual Protections (e.g., seed purchase licensing agreements)

Protection, Infringement, & Safe Harbors – Patents

Utility Patents

What IP is Protected?

- ▶ Any machine, manufacture, process, composition of matter. 35 U.S.C. §101.

What Infringes that IP?

- ▶ Any unauthorized making, use, offers to sell, actual sale, or importation into the U.S. of the patented article. 35 U.S.C. §271(a).

Protection, Infringement, & Safe Harbors – Patents

Plant Patents

What IP is Protected?

- ▶ A single asexually-propagated plant. 35 U.S.C. §161.
- ▶ Asexually-reproduced progeny of the parent plant. *Imazio Nursery v. Dania Greenhouses*, 69 F.3d 1560 (1995) (considered the same plant because all progeny contain *all* of the claimed traits of the original patented plant).

What Infringes that IP?

- ▶ Any unauthorized making, use, offers to sell, actual sale, or importation into the U.S. of the patented article. 35 U.S.C. §271(a). **Exactly the same as for utility patents.**

Protection, Infringement, & Safe Harbors – Patents

Safe Harbors: Patent Law

Utility Patents & Plant Patents

- ▶ There are **no** safe harbors available: **any** unauthorized making, use, sale, etc of patented inventions infringes on the relevant patent.

Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.
35 U.S.C. §271.

- ▶ All unauthorized making and use is **strictly barred**.

Protection, Infringement, & Safe Harbors – Plant Varieties

Plant Variety Certification

What IP is Protected?

- ▶ Plant breeders may register *any* sexually-reproduced plant variety that is new, distinct, uniform, and stable. 7 U.S.C. §2402.

What Infringes that IP?

- ▶ Any unauthorized sale, offers to sell, delivery or transfer of title, possession, solicitation to buy, or propagation to produce a hybrid for farming purposes.
- ▶ But there *are* safe harbors!

Protection, Infringement, & Safe Harbors – Plant Varieties

Safe Harbors: Plant Variety Certification

1. Farmers may raise and retain seed for *their own farming uses* **indefinitely**, but:
 - ▶ They may *not* sell retained seed to *other* farmers for farming purposes.
2. Researchers may use and reproduce a registered plant variety for *bona fide* research purposes.
3. *Substantially similar* plant varieties developed within one year of registration of the protected variety are "grandfathered" and not barred from separate registration.

Summary: IP Protection and Safe Harbors

Are there implicit safe harbors for unintentional / accidental infringers?

Form of Protection	What's Covered?	Safe Harbors?	Subj. Matter has Built-in Safe Harbor?
Contract	The IP described in the contract.	No	No
Plant Variety Certification	"Purebred" sexually reproduced plants.	Yes	Yes
Plant Patent	Single asexually-reproduced plant (described in patent claim).	No	Yes
Traditional Utility Patent	The invention (device, method, system, composition of matter) described in the patent claim(s).	No	Yes
GMO Utility Patent	Gene, gene sequences, and plant parts containing the protected gene <i>wherever they are found</i> .	No!	No!

Asking an *Additional* Question

First Objective: *Establishing* protection for an invention or creative work.

Can this invention be patented?

Second Objective: *Protecting* the invention or creative work.

Did the defendant actually infringe the IP?

But we *rarely* consider a third, and perhaps more important question:

Should infringement liability exist at all?

Do We Need a New Safe Harbor?

Identity-based Subject Matter Classification

Patent law recognizes two broad categories of *patentable subject matter*.

- ▶ 35 U.S.C. §161 - Plants
- ▶ 35 U.S.C. §101 - Machines, Manufactures, Processes, and *Compositions of Matter*

Compositions of Matter come into play when the invention deals with:

- ▶ Chemistry & Materials Science (alloys, medicines)
- ▶ Biology (*Chakrabarty* - GM organisms)

This is simplistic!

The law only considers *identity* (or nature), of the subject matter, not it's *functionality* (or behavior).

New Classification Scheme: Nature + Function

Nature – Is the invention *Living* or *Non-Living*?

Function – Can the invention *Self-Reproduce*?

	Non-Living Invention	Living Invention
<i>Does not Self-Reproduce</i>	Type 1 - Classical inventions	Type 2 - Plant patents
<i>Can Self-Reproduce</i>	Type 3 - Software, Nanotechnology	Type 4 - GM Organisms Problem Area!

The self-reproducing status is arguably more important than the living/non-living nature of the invention.

Creation, Infringement, and Human Intervention

Non-Self-Reproducing Inventions

- ▶ Human intervention is **required** for creation and infringement of non-self-reproducing inventions.
 - ▶ Examples: Mechanical devices, artificial chemicals.

Self-Reproducing Inventions

- ▶ *Initial* creative act **requires** human activity.
- ▶ *Subsequent* creative acts **do not require** human intervention.
- ▶ *Infringement: Making or Using* an invention **does not require** human intervention.

Distinguishing Between *Making* and *Using*

Traditional Definitions:

- ▶ **Make:** To create by an affirmative act.
- ▶ **Use:** To employ for a particular purpose.

When can you distinguish between *making* and *using*?

Legal Basis	Subject Matter	Make v. Use	Examples
Plant Patent	Asexual Reproduction	Always	Honeycrisp apple
PVPA	Sexual Reproduction	Always	Heirloom corn
Utility Patent	Non-plant	Always	Mechanical device
Utility Patent	Asexual GM Plant	<i>Sometimes</i>	Seedless Grapes
Utility Patent	Sexual GM Plant	<i>Never?</i>	Herbicide-resistant corn

Limitations on IP Protection

Type 1 Classical Inventions & Utility Patents

- ▶ **Patent Exhaustion** restricts the power of a patent holder to control the ultimate uses to which a purchaser of a patented article can put the purchased invention. *Quanta Computer*, 577 U.S. 617 (2008).

Type 2 Inventions & Plant Patents

- ▶ Control over the IP *ends* when the asexually-propagated plant reproduces sexually. Sexual offspring (different traits, outside scope of the plant patent claim) are not protected by plant patent.

Type 4 Inventions (GM Organisms) & Utility Patents

- ▶ **No limits?** (*see Patent Exhaustion*). **Bowman v. Monsanto**.
- ▶ Gene escape scenarios can create *unwitting, unwilling innocent infringers*.

Four Infringement Scenarios

1. **Intentional Seed Saving** in violation of the *IP Owner's* purchase / license agreement (i.e., farmer keeps seed to plant an unlicensed second crop). [LINK: *Monsanto v. Swann*, 308 F.SUPP.2D 937 (E.D. Mo. 2003).]
2. **Intentional Seed Purchase:** GM seed is purchased from *commodity* seed supplier and replanted. No license agreement signed, seeds on "open market." [*Bowman v. Monsanto.*]
3. **Accidental Seed Intrusion** by GM seed spilled by trucks or carried by humans or animals.
[LINK: *Monsanto Canada Inc. v. Schmeiser* [2004] 1 S.C.R. 902, 2004 SCC 34.]
4. **Accidental Pollen Intrusion** from adjoining fields containing GM crops, transforming the *nature* of the crop that the farmer *intended* to grow. **No litigation on point.**

Four Harm Scenarios

1. **Intentional Seed Saving:** The **IP Owner is harmed** by the licensee-farmer's contract violation.
2. **Intentional Seed Repurchase:** The **IP Owner is harmed** by lost sale of GM seed to the infringing farmer.
3. **Accidental Seed Intrusion:** The **farmer is harmed** by the seed intrusion. *GM Contamination* (lower crop prices, potential market exclusion), *Potential Infringement Liability* (retroactive licensing fees, penalties)
4. **Accidental Pollen Intrusion:** The **farmer is harmed** by the pollen intrusion. *GM Contamination* (lower crop prices, potential market exclusion) *Potential Infringement Liability* (retroactive licensing fees, penalties) *Organic farmers:* Certification Costs to return to “organic” status

Four Remedy Scenarios

1. **Intentional Seed Saving:** The *IP Owner* can *sue* the infringing farmer for
 - ▶ breach of contract / licensing agreement, or
 - ▶ patent infringement.
2. **Intentional Seed Purchase:** The *IP Owner* can sue the allegedly infringing farmer for *patent infringement*. (e.g., *Bowman v. Monsanto*).
3. **Accidental Seed Intrusion:** The farmer has *no practical legal recourse*.
[LINK: LEGAL SCHOLARSHIP PAGE]
4. **Accidental Pollen Intrusion:** The farmer has *no practical legal recourse*. [LINK: LEGAL SCHOLARSHIP PAGE]

Remedy Scenarios - Judicial Solution

A judicial remedy is unlikely, given:

- ▶ Courts' reliance on *stare decisis*
- ▶ Difficulty of finding a properly situated plaintiff
- ▶ Cannot establish *standing* under Declaratory Injunction Act:
 - ▶ Organic Seed Growers Trade Ass'n case was dismissed in 2012 for lack of standing. [LINK: ORGANIC SEED GROWERS' TRADE ASSOCIATION V. MONSANTO]

Remedy Scenarios - Statutory Solution

A statutory solution is more likely:

- ▶ Existing *current* exception to patent infringement for recombinant genetics involved in information disclosures for medical and veterinary products. 35 U.S.C. §271(e)(1).
- ▶ Parallel legislation for design patents: Promoting Automotive Repair, Trade and Sales (PARTS) Act, H.R. 3889, 112th Cong. (2012)

Remedy Scenarios - Statutory Solution

A statutory solution should include:

- ▶ Absolute patent rights, as now, for a shorter patent term,

or

- ▶ A **statutory exception** to infringement or **affirmative defense**.
- ▶ The exception/affirmative defense should include some a **business practice verification**, similar to the *National Organic Program* organic certification program.
- ▶ Exception/affirmative defense would **shift burden of proof** (and litigation costs?) from the alleged infringer to the patent holder.

Conclusion

- ▶ Current interpretations of patent infringement caselaw do not reflect the reality of a *new type* of patentable subject matter: living, self-reproducing inventions.
- ▶ Overprotection of GM plants by utility patents is an *actual* but underappreciated form of liability for farmers that choose to grow non-GM plants.
- ▶ A **statutory change** is the best means of protecting farmers from being liable for innocent, unintentional infringement of GM plant patents.

Some Important Peripheral GMO Issues

Development of herbicide-resistant weeds.

- ▶ Who should bear elevated costs of eradicating herbicide-resistant weeds in areas that have had prolonged GMO crop usage? [LINK: *Nature* PIGWEED ARTICLE.] What if these weeds spread across country borders? Is there international liability?

New technology evades USDA regulation of GMOs

- ▶ USDA regulations over GM crops are based on *how* they are made, **not** the *nature* of the plant (i.e., transgenic). Some new methods of making GM plants fall outside USDA regulatory authority. [LINK: *Nature* GRASS ARTICLE.]

Animal GMOs can also escape

- ▶ FDA approval of GM salmon for human consumption. [ARTICLE LINK]
- ▶ “Mostly” sterile fish not a risk to wild populations. [LINK: ABC NEWS]

For Further Reading I



[In A Grain Of Golden Rice, A World Of Controversy Over GMO Foods](#)
Dan Charles, NPR News, March 07, 2013 2:59 AM.

[\[LINK: NPR STORY\]](#)



[Center for Food Safety Report - *Seed Giants vs. U.S. Farmers*](#)
Report discusses issues of sustainable agriculture and food crop biodiversity in light of widespread adoption of patent-protected GM food crops.

[\[LINK: DOWNLOAD REPORT\]](#)

Select Legal Scholarship on GM Organisms

Liability Theory and Agricultural Impacts

1. IN PARI DELICTO AND CROP GENE PATENTS: AN EQUITABLE DEFENSE FOR INNOCENTLY INFRINGING FARMERS, 3 Ky. J. Equine, Agric. & Nat. Resources L. 179 (2010)
2. LEGAL LIABILITY, INTELLECTUAL PROPERTY AND GENETICALLY MODIFIED CROPS: THEIR IMPACT ON WORLD AGRICULTURE, 19 Pac. Rim L. & Pol'y J. 459 (2010).
3. Stuart J. Smyth & Drew L. Kershen, AGRICULTURAL BIOTECHNOLOGY: LEGAL LIABILITY REGIMES FROM COMPARATIVE AND INTERNATIONAL PERSPECTIVES, 6 Global Jurist Advances 6-2 article 3 (2006).