



A Breed Apart: The Plant Breeder's Guide to Preventing Patents through Defensive Publication

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This Guide is Not Legal Advice

This guide provides general legal information for educational purposes only. It is not meant to substitute, and should not be relied upon, for legal advice. Each patent, application, and related document is unique and the information contained in this guide is specific to the time of publication. Accordingly, for legal advice, please consult an attorney licensed in your state.

Contents

I. INTRODUCTION	6
Purpose of this Guide	7
Scope of this Guide	7
How to Use this Guide	7
II. INTELLECTUAL PROPERTY & PATENTS	8
A. Patent Law Fundamentals	8
Types of Relevant Intellectual Property Protections	8
Licensing	10
Comparing Intellectual Property Protection Instruments	10
B. A Comprehensive Look at Utility Patents	11
Who Governs Patents?	11
What Are the Legal Requirements to Obtain a Utility Patent?	11
What Are the Components of a Utility Patent?	13
III. DEFENSIVE PUBLICATION	15
A. What is Defensive Publication?	15
B. Why is Defensive Publication Used?	15
C. How is Defensive Publication Related to Prior Art?	16
Printed Publications in General	16
What Qualifies as a Printed Publication?	17
Sales as a Form of Prior Art	18
Best Practice: Sales and Printed Publications	18
D. Creating Defensive Publications	19
Format	19
Scope and Depth: Enabling	21
Terminology	21
Third-party Submissions as a Form of Defensive Publication	23
IV. PRACTICAL CONSIDERATIONS	26
A. Current USPTO Search Techniques Overlook Many Defensive Publications	26
B. Practical Publishing Considerations	27
C. Issues to Consider Before Publishing Defensively	28
V. CONCLUSION	29
VI. APPENDICES	30
A. Appendix A – Relevant Sections of Patent Law	30
B. Appendix B – How to Read Legal Citations	31
C. Appendix C – Sample Utility Patent	32
D. Appendix D – Common Plant Descriptions from PLANTS Database	41
E. Appendix E – Further Resources	42
F. Appendix F – Glossary	43

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About the Center for Agriculture and Food Systems at Vermont Law School

The Center for Agriculture and Food Systems trains law and policy students to develop real-world solutions for a more sustainable and just food system.

To do this, CAFS educates students through a comprehensive array of residential, online, and experiential courses. Students can pursue a degree or certificate in food and agriculture law as a Master's, JD, or LLM student. CAFS' diverse course offerings, Food and Agriculture Clinic, and varied degree options give students the opportunity to explore food and agriculture law from a variety of perspectives and experiences.

CAFS is also a center for research and advocacy. As a clinician in the Food and Agriculture Clinic or as a Research Assistant, students can work with local, regional, national, and international partners and engage in law and policy work geared toward addressing food systems challenges related to the environment, public health, the economy, food security, and animal welfare. Working with project partners, students can develop legal tools and policy recommendations for stakeholders across the food system, including farmers, food producers, entrepreneurs, distributors, consumers, legislators, and administrators.



About the Rural Advancement Foundation, International-USA

Mission: To cultivate markets, policies, and communities that support thriving, socially just, and environmentally sound family farms.

The Rural Advancement Foundation, International (RAFI-USA) believes in order to ensure a safe, adequate supply of healthy food, we must protect farm workers and encourage environmentally sound farming. We see environmental sustainability, economic viability, biodiversity, and social justice as inextricably linked. Therefore, the best way to ensure a just, sustainable future for farming is to create a reality where farmers feel supported and protected and have the resources to thrive.

I. Introduction

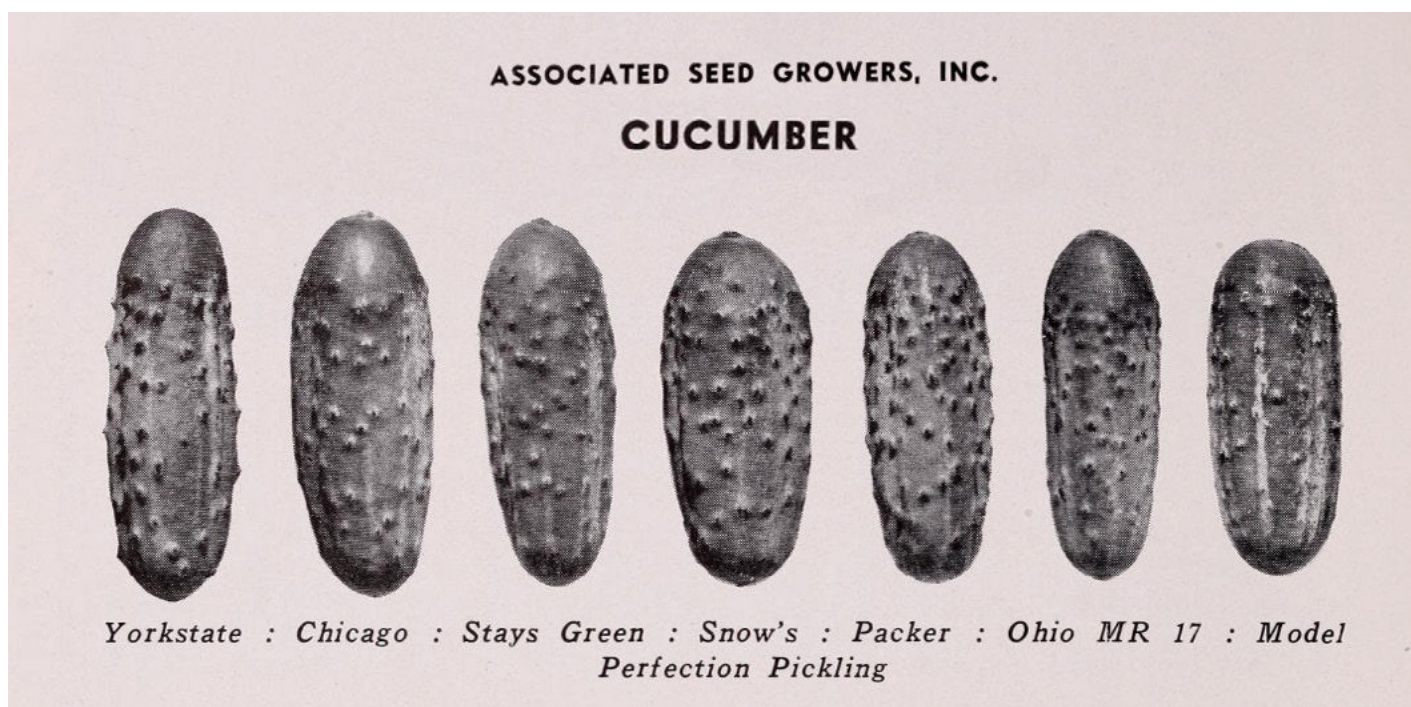
Genetic diversity in crop species provides a reservoir of traits from which farmers can find, and plant breeders can develop, plant varieties best suited to local production conditions. Accessing this reservoir of crop genetic diversity will be especially important as climate change alters growing conditions for many farmers—making some areas hotter, or drier, or shifting growing seasons or the ranges of crop pests. **Yet agricultural biodiversity throughout the world experienced a sharp decline over the past century, with around 75 percent of crop genetic diversity lost.¹**

This steep decline in agricultural biodiversity occurred hand in hand with the drastic consolidation of seed companies. Over 60 percent of proprietary seed sales worldwide now come from just four firms, where there had once been thousands of independent seed companies. The remaining seed firms are agrochemical companies² whose business model typically includes developing plant varieties that produce well when grown in combination with other inputs the company sells, such as herbicide-resistant crops that can withstand spraying by the company's proprietary

weedkiller. Companies patent the crops they develop so that no one else may sell or use them without permission.

Declining crop genetic diversity, combined with increasing patent protection over what genetic diversity remains, constrains farmers and plant breeders alike. Farmers have fewer options for planting, and plant breeders may lose access to the genetic diversity they need to create new varieties when much of that diversity is owned by agribusiness as intellectual property. Additionally, both farmers and plant breeders may fear legal action by patent holders if they inadvertently use plant varieties that are too similar to patented varieties.

In an effort to combat the trends of declining diversity and intellectual property restrictions on plants, some plant breeders are seeking options to prevent plant genetic resources from ending up in agribusiness patents. One of these is **defensive publication—the act of publishing details about an invention or discovery to preclude others from patenting it.**



Purpose of this Guide

This publication has four primary purposes:

1

Provide all readers with an understanding and familiarity with the U.S. patent process generally, and how defensive publications fit into that process

2

Assist plant breeders in drafting their own defensive publications

3

Provide plant breeders a realistic perspective on practical challenges in defensive publication

4

Provide plant breeders resources for further exploration of defensive publications and patents

Ultimately, this guide is a tool to help users of all skill levels draft, publish, and use their own defensive publications in the plant-breeding industry.

COMMON ACRONYMS USED THROUGHOUT THIS GUIDE:

AMS: Agricultural Marketing Service

IP: Intellectual property

MPEP: Manual of Patent Examining Procedure

NPL: Nonpatent literature

PPA: Plant Protection Act

PTAB: Patent Trials and Appeals Board

PVPA: Plant Variety Protection Act

USDA: United States Department of Agriculture

USPTO: United States Patent & Trademark Office

Scope of this Guide

Defensive publications and utility patents are the primary focus of this guide. However, this guide will also explain and reference other forms of intellectual property protections arising under the Plant Patent Act, the Plant Variety Protection Act, and utility patents for non-plant inventions. This guide is not an exhaustive explanation of all patent law and intellectual property, nor is it a scientific publishing guide. Rather, this guide will present a foundational view of current patent laws as they relate to defensive publications in the plant-breeding context.

How to Use this Guide

This guide is intended to aid plant breeders who want to preserve plant genetic resources outside of the patent system. Its intended readers include those who are unfamiliar with the U.S. patent system as well as those well versed in defensive publication and intellectual property. For this reason, this guide starts with the very basics of intellectual property and gradually shifts into a more advanced analysis of patent law. This guide is written so that understanding each section does not necessarily depend on reading the previous section. For example, practitioners who are familiar with patent law may choose to skip the first section of this guide.

II. Intellectual Property & Patents

Intellectual Property (IP) is a field of property rights which comprises all valuable products created through human invention and intellect. These valuable products include things like mechanical inventions, logos, works of art, songs, recipes, and algorithms. The purpose of providing legal IP protections is to encourage people to continue inventing, creating, discovering, and sharing new and useful things.

This is accomplished in two ways. **First, IP law allows inventors and creators to gain the exclusive benefit of their inventions for a limited time.** If other people want to use their invention, they need to receive permission from the inventor. In exchange, the inventor may require payment and royalties from anyone seeking to use their invention. Furthermore, they may restrict how

and when others can use their invention. Having exclusive control over the use of their invention is intended to entice people to continue inventing without fear of having their work stolen or used unfairly.

Second, patent law encourages scientific advancement by ensuring that information is shared. The inventor, through the patent, is required to disclose to the public the method used to create their invention. This disclosure must be thorough enough that once the patent expires, practitioners can use the information to continue advancing the state of the art. But the price of securing IP protection, or the fear of accidental IP infringement, is often a severe deterrent to independent inventors.

A. Patent Law Fundamentals

United States law most commonly provides IP protections in three different ways: **through patents, copyrights, and trademarks.** Generally speaking, patents protect inventions, copyrights protect works of art like songs and literature, and trademarks protect “designations” like logos and brand names. **This guide focuses on patents**—specifically utility patents—because plants, seeds, genes, and breeding methods all qualify as inventions, rather than works of art or designations.

Types of Relevant Intellectual Property Protections

There is more than one way to acquire IP protection for plants and seeds. The Plant Patent Act (PPA), Plant Variety Protection Act (PVPA), and utility patents each protect some plants and seeds, but do so in different ways. This section briefly explains these laws, which plants they protect, the scope of their protection, and how these laws work together.

PLANT PATENT ACT (35 U.S.C. § 161. PATENTS FOR PLANTS)

The Plant Patent Act (PPA) grants protection to anyone who “invents or discovers” and asexually reproduces a new and distinct variety of plant (excluding tuber propagated plants and plants “found in an uncultivated state”).³ The PPA gives the breeder the exclusive right to use the new variety, which prohibits anyone else from asexually reproducing, using, selling, or importing the plant without the breeder’s permission.

PLANT VARIETY PROTECTION ACT (7 U.S.C. § 2402. PLANT VARIETY PROTECTION)

The Plant Variety Protection Act (PVPA) is not a form of patent protection, but it functions similarly. Rather than being issued by the United States Patent Office, PVPA certificates are issued by the Department of Agriculture through the Plant Variety Protection Office. PVPA certificates protect sexually and asexually reproduced plant varieties if the variety is new, distinct, uniform, and stable.⁴ Once a PVPA certificate is granted, the variety is treated as property, meaning the owner has exclusive rights to the variety and may restrict its use. However, there are two key exemptions that allow people to use protected seeds without the permission of the certificate holder: (1) buyers may save seeds for replanting; (2) plant breeders may use the variety for plant breeding or other research.

UTILITY PATENTS (35 U.S.C. § 154. CONTENTS AND TERM OF PATENT)

Utility patents are the most general patent category in U.S. law. They cover inventions from medicines to machinery. When people refer to “patents” in general terms, they are usually referring to utility patents.

Utility patents grant the most expansive protection to new plant varieties because utility patents protect “compositions of matter,” meaning they may cover seeds, plants, plant parts, seed germplasm, or genetic sequences, and other material. As long as the invention—in this case the seed, plant, or variety—is new, useful, and non-obvious, the inventor (breeder) can obtain a utility patent. Utility patents grant exclusive rights to the patent holder for twenty (20) years. Consequently, the patent holder has exclusive control over the production, use, sale, and importation of the invention within the United States for the length of the patent. Utility patents are discussed in more detail later in this guide.

Table 1: Comparison of Plant Protection Instruments

	PLANT PATENT	PLANT VARIETY PROTECTION	UTILITY PATENT
Agency	USPTO	USDA/AMS	USPTO
Requirements Under Law	<ul style="list-style-type: none">• New• Distinct• Asexually reproduced	<ul style="list-style-type: none">• New• Distinct• Uniform• Stable	<ul style="list-style-type: none">• Novel• Useful• Non-obvious
Restrictions	Asexually reproduce, use, sell, import	Sell, offer for sale, reproduce, import, export, use to produce hybrid <i>Exemptions: plant breeding and seed saving</i>	Make, use, sell, offer to sell, import
Estimated Cost (USD)	\$5,000-\$8,000	Around \$5,000	\$6,000-\$15,000

LICENSING

Licenses are not an independent form of IP protection. Instead, they are a tool patent holders frequently use to sell their inventions subject to certain limitations. Licenses act as an agreement between an inventor and someone who wants to use their invention (a licensee). Licenses are instruments for inventors to enforce limitations on the use of their invention. Bag tags are a form of licensing for seeds. Licenses specifically approve or prohibit licensees from engaging in certain acts like seed saving, experimentation, and sale. Additionally, inventors can hold license violators responsible for patent infringement because patent holders have exclusive rights to control the use of their invention.

CONCLUSION & COMPARISON

Plant patents, Plant Variety Protection Certificates, and utility patents are all methods used to protect seed breeders' intellectual property. While these protections appear similar in some respects, none of them individually affords complete control over any seed. However, if a plant or seed variety qualifies for more than one type of protection, a breeder may hold any combination of protections for the same plant.

For example, a breeder who holds both a PVPA certificate and utility patent for a seed variety could sue a seed-saving farmer for infringing the breeder's utility patent. However, the breeder could not hold the seed-saving farmer legally responsible solely under the PVPA because of the PVPA's seed-saving exemption. In other words, the breeder needs the additional protection provided by a utility patent to hold the seed-saving farmer responsible for infringement. The scope, term, and cost of protection are all deciding factors in determining which, if any, method of plant IP protection a plant breeder pursues.



B. A Comprehensive Look at Utility Patents

Most patents in the United States are utility patents, so named because they cover useful inventions in any field. This section describes the roles of various government entities with authority over utility patents and the statutory (legal) eligibility requirements for utility patents.

Who Governs Patents?

Several government entities have authority over various aspects of patent law. Understanding each of their roles is important for plant breeders who want to navigate the patent legal system or advocate to change it.

CONGRESS

Congress is responsible for creating the statutes (laws) that address patents and establish the United States Patent and Trademark Office (USPTO). Congress enacted the original Patent Act in 1790 and has revised it several times. Most recently, Congress passed the [Leahy-Smith America Invents Act \(AIA\)](#), which updated the American patent system to make it more harmonious with international patent systems. Some of the relevant changes are described in the feature box on the right.

UNITED STATES PATENT AND TRADEMARK OFFICE

The United States Patent and Trademark Office (USPTO) is an agency of the Department of Commerce. Its staff of patent examiners review patent applications and determine whether to grant patents, based on the eligibility criteria discussed below. Patent examiners are guided by the USPTO [Manual of Patent Examining Procedure](#).⁵

AMERICA INVENTS ACT OF 2012:

The AIA changed the patent filing system from a first-to-invent system to a first-to-file system. Prior art can now preempt patent applications if the prior art was available prior to filing rather than prior to invention. The AIA also considers prior art from anywhere in the world, not only from the United States. Now, foreign inventions that are patented or published prior to filing in the U.S. may defeat a U.S. patent application.

COURTS

Courts interpret the laws that govern patents, and apply them to specific cases raised in lawsuits. There are two main types of legal cases involving patents: patent challenges and issues of patentability. Patent challenges are legal actions where a patent holder sues another private party. For example, a patent holder might assert that a grower used patented seeds in violation of the patent. Patent challenges can only be heard in federal court.

Issues of patentability are disputes between a patent holder or applicant and the USPTO about whether an invention is eligible for a patent. For example, an applicant might challenge a USPTO decision that a patent was invalidated by *prior art* (discussed below on page 15). Issues of patentability are decided by a court-like body called the Patent Trial and Appeal Board (PTAB). Unlike regular courts, PTAB is part of the USPTO.

What Are the Legal Requirements to Obtain a Utility Patent?

Three major patentability requirements (subject matter, novelty, and non-obviousness) determine what is eligible to receive patent protection.⁶ Generally, an inventor is entitled to patent protection for methods or tangible things that are new—or new improvements upon existing inventions—and are not obvious to practitioners in the field.

These requirements are referred to as **statutory requirements of patentability**.⁷ For the USPTO to grant a patent, the invention must meet all of the statutory requirements. The requirements are described in more detail below, and the full text of each of these sections of the law is available in Appendix A.

PATENTABLE SUBJECT MATTER (35 U.S.C § 101)

Not every invention or improvement is patentable. The law allows anyone who invents—or improves upon—“a process, machine, or composition of matter” to obtain a patent for their invention (as long as they also meet the other statutory requirements of novelty and non-obviousness).

Under the Plant Patent Act, Congress authorized the USPTO to grant patents on plants. However, plants also qualify for utility patent protection because they can also be considered “compositions of matter” under patent law.⁸ Specifically, the breeding methods used to yield the plant or seed are patentable as a method; the seed and plant parts are patentable as compositions of matter. For an example of how breeding methods and plant parts are patented within the same utility patent, see the patent sample in Appendix C.

NOVELTY (35 U.S.C. § 102)

The novelty requirement is the most relevant patent requirement for plant breeders hoping to prevent other plant breeders from patenting pre-existing plant varieties. Under the statutory novelty requirement, only new or novel inventions qualify for patent protection. *Novel* inventions are those that do not already exist within the body of knowledge in a particular field, which is known legally as *prior art*. There are several types of prior art listed within the law (and shown in Table 2, below).⁹ If an invention falls into one of those categories, it is not patentable because it is not a novel invention. The list includes items that are already “patented, described in a printed publication, or in public use, on sale, or otherwise available to the public.”¹⁰

Table 2: Forms of Prior Art

An invention cannot be patented if it falls into one or more of the categories of prior art described below.

Patented Invention	<ul style="list-style-type: none">• Current patents, expired patents, and some published patent applications.• Unless you are the inventor and the patent application is less than one year old, published patent applications are considered prior art.
Printed Publication	<ul style="list-style-type: none">• Any publicly accessible document that has actually been disseminated to people within the art.• For a more detailed description of printed publications, see Part 2 of this guide: Defensive Publications.
Public Use	<ul style="list-style-type: none">• Inventions that are already used by the public.
Sale	<ul style="list-style-type: none">• Includes inventions that have been sold as well as inventions that are being offered for sale.• Actual purchase of the invention is not necessary if the invention is at least being offered for sale.
Otherwise Available to the Public	<ul style="list-style-type: none">• Includes third-party submissions, disclosures to the public, and any other method by which the public would know of the invention, how to use it, and how to create it.

NON-OBVIOUSNESS (35 U.S.C. § 103)

Inventions that are obvious to “a person having ordinary skill in the art” to which the invention is relevant are not eligible for patent protection. In plant breeding, the relevant standard would be an average plant breeder. An invention is obvious when, at the time the patent application is filed, the invention is something ordinary practitioners in the art would find obvious, based on existing prior art. In other words, a new plant trait would not be eligible for patent protection if other plant breeders would find the new trait obvious based on existing traits in similar plant varieties.

What Are the Components of a Utility Patent?

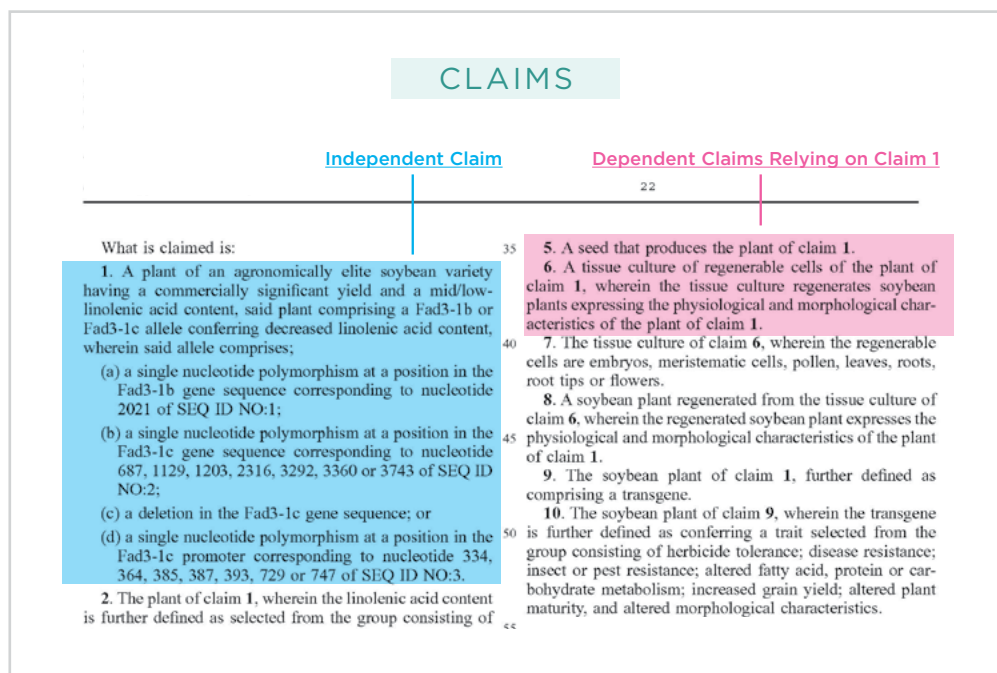
If an invention meets all the legal requirements for patentability, the inventor can apply for a utility patent. U.S. patent law mandates that a patent must include a written description.¹¹ For utility patents, the inventor must include three key written components: (1) claims; (2) specifications; and (3) references.

CLAIMS

Patent claims are one-sentence statements describing which of the invention’s attributes the inventor wants protected. One utility patent may contain many claims, which together define the entire scope over which the inventor can exercise exclusivity.¹² They typically include information about how an invention works, as well as why it is useful. For example, the sample patent in Appendix C includes a claim describing a soybean plant with specific genetic changes (how it works) that produce a low linolenic acid in the plant (why it is useful). Claims are considered the principal enforcement

mechanism of the patent because claims set the boundaries of legal protection for an invention.¹³

For an example of patent claims, see the sample patent in Appendix C.



SPECIFICATIONS

Specifications are longer descriptions of the claims, and assist readers in understanding the invention’s use and precisely what attributes the patent protects. Specifications are written in paragraph form, rather than single statements like claims. The primary purpose of specifications is to place claims in context. This includes establishing definitions for terms of art (terms with special meaning in the context of the inventor’s field; for example, “sport” would be a term of art in botany or plant breeding), revealing the intent of the inventor, and providing sufficient explanation so that a person skilled in the art could understand the claims.

There are three components to the specifications: **written descriptions**, **enabling descriptions**, and **best mode**.¹⁴ The **written description** describes the invention in detail, giving additional information about the claim(s) to which it relates. The description has to be specific enough that a person skilled in the art

SPECIFICATIONS

Defining a plant as described in Claim 12

US 9,668,439 B2

yield; altered plant maturity, and altered morphological characteristics. One example of herbicide resistance is glyphosate resistance.

In particular embodiments, a plant of the invention may be further defined as produced by a method comprising the steps of: a) crossing first and second soybean plants, wherein the plants comprise Fad3-1b and Fad3-1c alleles conferring decreased linolenic acid content, wherein the first plant has a mid/low-linolenic acid content, and wherein the second plant comprises a commercially significant yield; b) assaying progeny soybean plants resulting from the crossing for yield and for the presence of polymorphisms located in a soybean plant genomic region within 50 cM of said Fad3-1b and Fad3-1c alleles; and c) selecting at least a first agronomically elite progeny plant comprising said polymorphisms and a commercially significant yield to obtain the plant of claim 1.

linked to Fad3-1a, as the inventors have shown that it is the Fad3-1b and Fad3-1c alleles that contribute a low linolenic acid content.

In certain embodiments of the method, the first polymorphism comprises a single nucleotide polymorphism at a position in the Fad3-1b gene corresponding to nucleotide 2021 of SEQ ID NO:1. The first polymorphism may also comprise a single nucleotide polymorphism at a position in the Fad3-1c gene corresponding to nucleotide 687, 1129, 1203, 2316, 3292, 3360 or 3743 of SEQ ID NO:2. In still other embodiments the first polymorphism comprises a deletion in the Fad3-1c gene sequence and/or a single nucleotide polymorphism at a position in the Fad3-1c promoter corresponding to nucleotide 334, 364, 385, 387, 393, 729 or 747 of SEQ ID NO:3. Selecting at least a first soybean plant comprising the polymorphism may be carried out by any method, such as, for example, PCR, single strand conformational polymorphism analysis, denaturing gradient

U.S. Patent Jun. 6, 2017 Sheet 2 of 2 US 9,668,439 B2

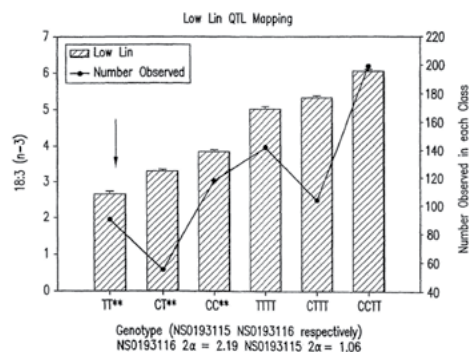


FIG.2

would understand what the claim intends to protect.¹⁵ The **enabling description** is an explanation of how to use the invention.¹⁶ The level of specificity for an enabling description should be such that a person skilled in the art could operate the machine without having to experiment too much.¹⁷ The enabling description does not need to disclose every possible use for the invention but it must show how the invention accomplishes every claimed use. For plants, which are different from machines, an enabling description would more likely focus on the process for creating the plant—which parents and processes to use to create the desired traits. The **best mode** requires disclosure of the best way to achieve the claims.¹⁸ Explained another way, “[a] patent applicant must disclose the best mode of carrying out his claimed invention, not merely a mode of making and using what is claimed.”¹⁹ For example, a hammer inventor would explain that hitting a nail with the head of the hammer is the best way to use it, even if it would also be possible to drive in a nail by hitting it with the handle of the hammer.

REFERENCES

The beginning of each patent includes a list of references the applicant relied on in creating the invention, or which the invention improves upon. These include other patents (from the same inventor and from others), prior patent applications, scholarly and scientific work, and any other source directly cited in the patent. Although it is not a common practice, the patent examiner can add to this list when they review the patent application if they find other references that relate to the patent. When an examiner adds a reference to the list, it is denoted with an asterisk.

“[I]n construing a claim there are two limiting factors—what was invented, and what exactly was claimed. To determine the former—what was invented—we look at the entire patent, with particular attention to the specification (the written description of the invention and the several claims made). To determine the latter—what exactly was claimed—the focus is on the precise words of the particular claim or claims at issue; the written description and preferred embodiments are aids in understanding those words.”

MySpace, Inc., v. GraphOn, Corp., 672 F.3d 1250, 1256 (Fed. Cir. 2012).

III. Defensive Publication

An invention is ineligible for a patent if it is already patented, used by the public, or otherwise considered **prior art** in a particular field (see Table 2). For plant breeders hoping to ensure that no one patents a plant variety that already exists, one strategy is to establish that variety as prior art. **The process of establishing this prior art by creating a printed publication to prevent patenting is called *defensive publication*.**

For example, imagine X and Y are plant breeders, each independently trying to develop a variety

of broccoli with polka dots. If X succeeds first, X could probably get a patent. However, X may not want a patent, but may want to prevent Y from getting a patent on the same invention. In this instance, X might try to ensure that X's polka dotted broccoli is documented as prior art before Y's plant breeding is successful. To do this, X could create a defensive publication that describes the new broccoli variety. Merely developing the new variety is not enough for X to preempt Y's patent—X's invention must be somehow shared with the public to establish it as prior art.

A. What is Defensive Publication?

Defensive publication is a preventive strategy used to preempt patents by including specific information about an invention in a publication. By publishing enough information about an invention, defensive publications put inventions into the public domain. This strategy targets the law's novelty requirement, preempting the possibility of that invention being patented. Recall that patents cannot be issued for any invention that is already “patented, *described in a printed publication*, or in public use, on sale, or otherwise available to the public” (emphasis added).²⁰ When an invention is sufficiently described in a “printed publication,” that invention is considered prior art, and thus the invention is ineligible for patent protection. Printed publications are discussed in more detail on pages 17-20.

B. Why is Defensive Publication Used?

Defensive publications prevent potential patent holders from enforcing the typical protections a patent offers, such as exclusivity. This makes an invention publicly available without use restrictions, liability for patent infringement, or the need to pay royalties to the patent holder. For plant breeders, this means a plant's genetic material might be more widely available for research. For farmers, it means seeds might be cheaper or have fewer restrictions on their use.

Effective defensive publications should prevent litigation and patent disputes entirely by preventing new patents from being issued for preexisting plant varieties and traits. However, a secondary goal of defensive publication is to defend the publication's author against allegations of patent infringement if a later inventor does obtain a patent.

C. How is Defensive Publication Related to Prior Art?

As explained above, prior art is the body of knowledge available to the public in a certain field. Defensive publications are published resources that serve to expand that body of knowledge—a strategy used to stop patent applications from being approved. By law, patented inventions are required to *be novel*. That is, the invention must be a new improvement or addition to the current state of the art. If the invention is known by the public already, it is not novel, and is considered prior art. The America Invents Act expanded the relevant scope of prior art to include *all* knowledge “otherwise available to the public.”

Prior art does not necessarily need to take any specific form. Prior art can be a printed publication, another patent, a patent application, public sale, speech, video, or any other format that makes the invention accessible. **Defensive publication refers specifically to creating printed publications as a means to expand the body of prior art.**

Printed Publications in General

While there are many formats prior art can take (see Table 2, reproduced below), this guide focuses primarily on using printed publications as defensive publications. Printed publications are generally cheaper and easier to create than acquiring a patent, and some plant breeders prefer not to patent their inventions. Printed publications do not require the level of production or business infrastructure needed to offer new varieties for sale. Printed publications provide a less nebulous standard for establishing prior art than public use or “otherwise available to the public.” For these reasons, expanding the prior art through defensive publication of printed publications is a promising strategy for preempting patents.

Table 2: Forms of Prior Art

An invention cannot be patented if it falls into one or more of the categories of prior art described below.

Patented Invention	<ul style="list-style-type: none">• Current patents, expired patents, and some published patent applications.• Unless you are the inventor and the patent application is less than one year old, published patent applications are considered prior art.
Printed Publication	<ul style="list-style-type: none">• Any publicly accessible document that has actually been disseminated to people within the art.• For a more detailed description of printed publications, see Part 2 of this guide: Defensive Publications.
Public Use	<ul style="list-style-type: none">• Inventions that are already used by the public.
Sale	<ul style="list-style-type: none">• Includes inventions that have been sold as well as inventions that are being offered for sale.• Actual purchase of the invention is not necessary if the invention is at least being offered for sale.
Otherwise Available to the Public	<ul style="list-style-type: none">• Includes third-party submissions, disclosures to the public, and any other method by which the public would know of the invention, how to use it, and how to create it.

What Qualifies as a Printed Publication?

Neither the courts, Congress, nor the USPTO have settled on a clear and specific definition of *printed publication*. However, there are a few consistent interpretations. Generally, a *printed* document is one that is **physically accessible**. A *publication* is a printed document that has been **disseminated**. The distinction between accessibility and dissemination is slight. However, the USPTO examiner's manual still draws a distinction between the two.

Printed = physically accessible

Publication = actually disseminated

Printed Publication = A physically accessible document that has been disseminated

What does it mean to be “printed”?

For a document to be printed the document must be accessible to a person of ordinary knowledge within the field. Accessibility has no concrete measure. The law does not specify a number of persons who must be able to access the document nor a particular means of accessing it.²¹ Rather, accessibility is “simply distribution to any segment of the public.”²² A document can be considered accessible even if readers are required to pay for access to it, such as a subscription-based scientific journal.

Attention to accessibility is particularly relevant for online publications. While not literally printed, online and internet publications are considered printed publications *because* they are accessible.²³ Social media posts and chat room comments may be considered printed publications because “while not specifically indexed, newsgroups are organized hierarchically such that someone interested in a topic could easily locate a list of posts, and thus these posts are publicly *accessible*.” Other examples of “printed” documents include admissions, affidavits, declarations, and existing patents. Admissions are statements by the patent applicant identifying someone else's work as prior art.²⁴ Affidavits are written sworn

statements.²⁵ Declarations are formal statements,²⁶ similar to affidavits but not sworn to. Less formally, printed documents can include publicly accessible slides from presentations,²⁷ photographs of inventions made available without restriction,²⁸ highly detailed sales brochures, and catalogs within technical and scientific libraries.²⁹

THE KEY TO ACCESSIBILITY IS THE ABILITY TO FIND AND RECEIVE THE DOCUMENT UPON REQUEST.

Conversely, confidential documents—or documents that are intended to be confidential—are not accessible, and therefore are *not* printed publications. Confidential documents in private libraries or those distributed internally within a company or other institution are insufficient as printed publications. Similarly, unreasonably obscure documents are not printed publications. For example, “[s]tudent theses that were indexed only through index cards, filed alphabetically by author's name, and kept only in a shoebox in the college's chemistry department library” were not considered printed publications because a reasonable researcher could not find them with due diligence.³⁰

What does it mean to be “published”?

To be considered *published* the document must be *disseminated* to a segment of the relevant population. Dissemination requires that members of the relevant field could actually know of the document's existence. To determine whether the dissemination is adequate, the question is whether someone who “exercis[ed] reasonable diligence” would have located it.³¹ For example, when an author disseminated six copies of a research document after presenting it at a trade conference where 50-100 attendees had the opportunity to learn of the document's contents, a court considered this sufficient dissemination to find that the paper was “published.”³² Consequently, the information in the research document was considered prior art since it was included in a printed publication.

In sum, a printed publication is any document that is reasonably accessible and is, in fact, disseminated to the public. However, there is no formal measure of accessible or disseminated. For this reason, it is best for someone trying to create a defensive publication to make the document as accessible as possible to the public and actually distribute it to practitioners in the relevant field.

Table 3: Is a Document a “Printed Publication”?

Is it Printed?	Is it a Publication?
<div><div><input type="checkbox"/> Accessibility</div><div>If someone wanted to read this document, could they do so?</div><div>• What barriers exist for a potential reader in actually reading this document?</div></div> <div><div><input type="checkbox"/> Non-Confidentiality</div><div>Is this document intended to be read by anyone?</div><div>• Or, is this document only supposed to be read by a limited number of people? Is there information in this document that is not supposed to be shared with the public?</div></div> <div><div><input type="checkbox"/> Findability</div><div>Could an interested person actually find this document once they knew of it?</div><div>• How hard would they need to search to find this document?</div></div>	<div><div><input type="checkbox"/> Publicized</div><div>Would a reasonably diligent researcher know this document exists?</div></div> <div><div><input type="checkbox"/> Disseminated</div><div>Was this document actually shared with the public?</div></div>

Sales as a Form of Prior Art

Printed publications are not the only legal means by which to establish prior art. Another method that may appeal to plant breeders is *sales*. According to U.S. patent law, if an invention is sold or offered for sale prior to a patent’s filing, that sale is considered prior art. A sale is considered prior art because it effectively discloses the invention to the public. Someone can buy and use the plant or the seeds, negating the need for the USPTO to facilitate a public disclosure through a patent.

However, as a practical matter, a single unpublicized sale is an unreliable method to establish prior art. It is highly unlikely that a patent examiner would come across evidence that the invention is for sale. So the sale of a particular plant variety likely would not preempt a patent unless sales were widespread and highly publicized. Proof of sale is evidence of prior art, but the likelihood of a sale actually being cited as prior art is very low.

Best Practice: Sales and Printed Publications

Even if printed publications and sales are individually unlikely to be found by a patent examiner and used to disqualify a patent, they may be useful in conjunction with one another. The Manual on Patent Examination Procedure notes that, especially where a printed publication is considered insufficient due to its publication date, the publication “may be competent evidence of a previous public use, sale activity, or other availability of a claimed invention to the public where [the prior activity] does have a sufficiently early date to qualify as prior art.”³³ As an added layer of evidence, including proof of sale (or offer for sale) in a defensive publication may be a wise strategy. A best practice is to include the date the seeds or plant were offered for sale, as well as the date of any sale. Sales should be publicized to some extent, and open to the public. Publicity and public sale are not *required* but they add one more layer of evidence that an invention was known within its field before a patent application was filed.

D. Creating Defensive Publications

Once a plant breeder decides to create a defensive publication to prevent anyone else from patenting their plant variety, the next question is how the document should be drafted. This section discusses important considerations for defensive publication authors to maximize the effectiveness of their efforts.

Format

There is no required format for a defensive publication. The publication could be a printed journal article, an online publication, or it could take another format that is sufficiently accessible to the public. However, authors should consider the kinds of documents and publications with which they are already familiar, as well as the kinds of documents and publications most familiar to patent examiners. For example, a plant breeder might already have experience writing about plant varieties for seed catalogs. However, a patent examiner is unlikely to search seed catalogs looking for prior art. Similarly, patent examiners are accustomed to reading patents, but many plant breeders do not regularly draft patent applications. However, drafting a defensive document like a scholarly article may be a good compromise for plant breeders familiar with that medium. Ultimately, to be the most effective, the format of the document should be accessible to a wide audience.

Timing

Defensive documents are only *defensive* if they pre-date the patent in question. Defensive documents are meant to be a clear demonstration of prior art so the invention cannot later be patented by someone else. This necessarily requires inventors to publish their defensive publication *before* someone else files a patent for the same invention. Clearly including a date of publication on every defensive publication ensures that the document can be considered prior art for any patent application filed after that date. The given date should be as specific as possible; including only the year is inadequate.

For further assurance, the inventor/author should keep a receipt of publication. When publishing online, ensure that the web application, host website, or website developer includes a time stamp on the publication. Time stamps are standard for most consumer-facing web applications. For print publications, a physical receipt from the publisher should be sufficient. A receipt is not legally required for a document to be a defensive publication. But in the event that the publication's date is contested, a date of publication from a third party (like a publishing company or web application) is useful.



Why are specific dates better?

The **America Invents Act** changed the American patent system from a first-to-invent system to a first-to-file system. Practically, this means that when someone challenges a patent for failing to meet the novelty requirement, the **filing date** determines whether the patent is invalidated by prior art. Effective defensive publications need to clearly pre-date the patent's filing date, which is specific down to the day.

Table 4: Components to Consider Including in a Defensive Publication

<ul style="list-style-type: none"> • Title • Authors/Inventors • Date of Publication: this is particularly important for defensive publications because it can establish that the publication occurred before a patent application was filed • Abstract: a short summary of the entirety of the invention, including methods, product, prior art, and best use • Introduction: a brief description of the invention and why the invention is an important contribution to the art • Enabling description: this should teach other practitioners in the field how they could recreate the invention. It should be detailed enough that recreation would not require “undue experimentation.” Where relevant, include a discussion of the prior art upon which you relied 	<ul style="list-style-type: none"> • Results: a description of the invention • Tables and Graphs: may be helpful to include photographs of the invention as well • Discussion: describe the best possible use of your invention as well as any other good uses. Consider things like marketability, aesthetic, and resilience. This section should explain the details of your invention • Acknowledgments: possibly co-inventors or the authors of prior art upon which you relied heavily • References: include prior art on which you relied, or find useful in understanding your invention • Offer for sale (if applicable)
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Scope and Depth: Enabling

For prior art to invalidate patent claims the prior art must be specific enough that it is **enabling**.³⁴ In other words, the description of the invention should be written in a manner that could teach an ordinary practitioner in the art how to recreate and use it. The defensive publication should describe the inventor's process for developing the invention. The description does not need to teach the very basics of the art—but also should not be drafted for experts only. Keep “the ordinary practitioner” in mind when drafting the description. For example, consider whether a plant breeder of ordinary skill would know to do x before y. The description should be detailed enough that the ordinary practitioner could recreate the invention without unreasonably difficult or excessive experimentation. Actual duplication of the invention is not necessary. Further, a failed duplication does not mean that the description is insufficient. However, several failed experiments, especially when there was significant confusion in the re-creation process, may be indicative of an insufficient description. These factors could influence whether a description needs to be more specific, but actual experimentation is not necessary.

The publication should also teach the reader how to use the invention. In other words, the publication should explain the invention's most practical uses and particularly, highlight its best use. The publication does not need to describe every possible use for the invention. At a minimum, the publication should include the invention's best

use and those uses that are not obvious to the ordinary practitioner. For ideas on how to describe inventions, see the **USDA and NRCS PLANTS Database list of plant characteristics** in Appendix D.

Terminology

For a defensive publication to effectively preempt a patent, a USPTO examiner must find the publication and recognize that it preempts the invention in the patent application they are examining. In other words, the language a defensive publication uses is critical—ideally, it should use the same terms that a patent examiner uses to search for prior art. In plant breeding, multiple terms are sometimes used to describe the same thing. If a defensive publication author uses one of those terms or phrases and a patent examiner searches for a different term, the publication might be overlooked.

Describing a plant in several different ways in the defensive publication increases the likelihood the defensive publication will show up in a patent examiner's search. Consequently, plant and seed breeders should consider the many ways in which a plant could be described and which of those terms an examiner is most likely to use. Using only trade names and plant breeding terms of art may reduce the likelihood that an examiner will see a publication. Using terms commonly used in patents for similar plant varieties may increase the likelihood that an examiner will see a defensive publication.



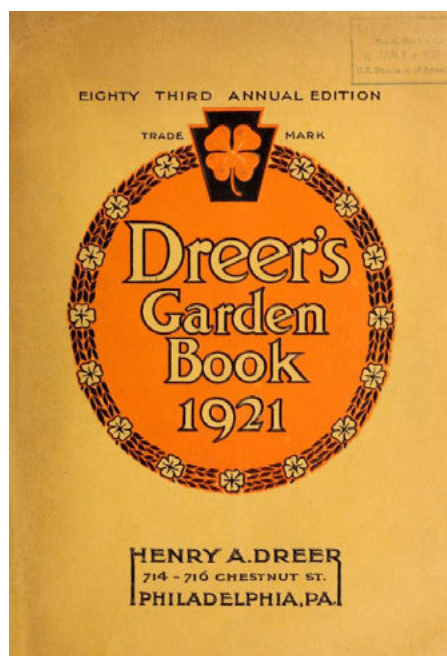
Deborah Griscom Passmore, 1903. Scientific name: *Fragaria*, Common name: Strawberries.



Bertha Heiges, 1904 Scientific name: *Citrus limon*, Common name: Lemons

Table 5: Defensive Publication Checklist

DATE
<input type="checkbox"/> Is there a clear date and time on the document establishing when it was published? <input type="checkbox"/> Is there a receipt or record of publication you and/or readers can access? <input type="checkbox"/> Was the document published before the filing date of the patent in question?
PRINTED
<input type="checkbox"/> Accessibility If someone wanted to read the document, could they do so? What barriers exist for a potential reader in actually reading it? <input type="checkbox"/> Non-confidentiality Is the document intended to be read by anyone? Or is it only supposed to be read by a limited number of people? Is there information in the document that is not supposed to be shared with the public? <input type="checkbox"/> Findability Could an interested person actually find the document once they knew of it? How hard would they need to search to find it?
PUBLISHED
<input type="checkbox"/> Disseminated Was the document actually shared with the public? <input type="checkbox"/> Publicized Would a reasonably diligent researcher know the document exists?
ENABLING
<input type="checkbox"/> Teaching Does the document teach the reader: <ul style="list-style-type: none"> • how to use the invention? • the best use of the invention? • how the invention was created, such that that a regular practitioner could recreate the invention without encountering significant challenge? <input type="checkbox"/> Disclosure Does the document disclose in detail other prior art which is useful in understanding, using, and recreating the invention?
SALE (if applicable)
<input type="checkbox"/> Actual Sale <ul style="list-style-type: none"> • Was the invention sold publicly (not confidentially)? • Was the invention sold with any restrictions on future sale or use? <input type="checkbox"/> Offered for Sale <ul style="list-style-type: none"> • Was the invention offered for sale to the public? • Was the offer publicized such that members of the public would have known it was for sale? <input type="checkbox"/> Inclusion <ul style="list-style-type: none"> • What printed publications, if any, were included with the purchase of the invention?
DISCLOSURE (if applicable)
<input type="checkbox"/> Was the invention, printed publication, or sale disclosed to the U.S. Patent and Trademark Office through a third-party submission?



Third-party Submissions as a Form of Defensive Publication

Defensive publications may be publications for a general or a trade audience (as described above) but it is also possible to communicate directly with the USPTO to submit prior art for their review. This process is called *third-party submission*. A detailed discussion of this option is outside the scope of this guide, but a basic understanding of the process may help plant breeders determine whether this option is right for them.

WHAT IS A THIRD-PARTY SUBMISSION?

A third-party submission is a form of communication with the USPTO where someone who is not the inventor or applicant can attach relevant documents to a patent's file. There are two types of third-party submission: a *third-party preissuance submission* and a *prior art submission*. A preissuance submission must be made before the patent becomes enforceable. A prior art submission can be made at any time. The two types of third-party submissions require different processes and documentation. However, both can be filed electronically through the USPTO website.

COSTS AND CHALLENGES OF THIRD-PARTY SUBMISSIONS

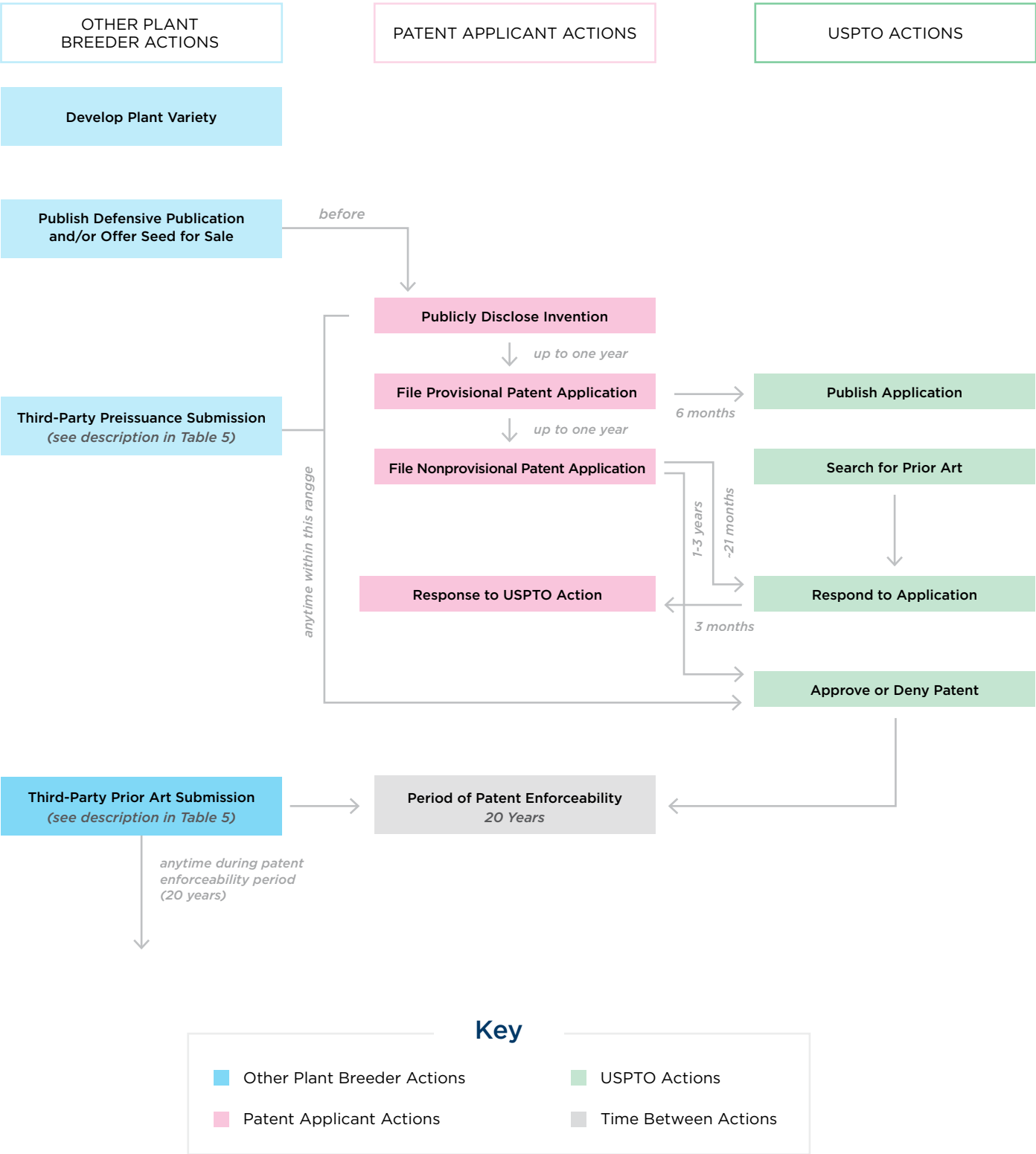
The first hurdle to making a third-party submission is knowing that a relevant patent application has been filed. A plant breeder can find this information either by searching for relevant applications on the USPTO website³⁵ on a regular basis, or by signing up for the Patent Application Alert Service,³⁶ which allows users to customize search criteria so that links to relevant patent applications will be sent to the user as soon as the applications are published.

The price of third-party submission can be prohibitive for some plant breeders, especially if they do not have small entity status or need to file more than three documents (see cost information in Table 5). Moreover, if the documents are submitted incorrectly or at the wrong time, the submission is completely discarded, and the submission fees are not refundable. This is a considerable risk, especially for non-attorneys who may reasonably misinterpret the regulations for submission. While e-filing makes the submission process easier, there is still room for error. The submission also alerts the patent applicant. If the patent is approved, this could notify the patent owner of what they may believe is infringement—inviting litigation or limiting the use of the third party's own invention to avoid costly litigation.

Table 6: Third-party Preissuance Submissions vs. Prior Art Submissions

Third-party Preissuance Submissions (35 U.S.C. § 122(e))	Prior Art Submissions (37 C.F.R. § 1.501)
WHAT ARE THEY?	
Third parties can submit potentially relevant printed publications to the USPTO while a patent application is awaiting approval.	At any time, any person can submit a printed publication they believe has bearing on the enforceability of a particular patent.
TIMING	
<ul style="list-style-type: none"> • Must be submitted while the patent is being examined. Printed publications cannot be submitted for a patent that is already approved. • Must be submitted before the later of two dates: either <ul style="list-style-type: none"> • 6 months after the date the patent application is published or • the date the USPTO rejects any claims in the patent (note: USPTO can reject patent claims individually, allowing the remainder of a patent's claims to be granted). • Regardless of the point above, must be filed before the date the patent is approved. 	<ul style="list-style-type: none"> • May be submitted at any time while the patent is in effect. • Depending on whether the patent is currently being formally re-examined by the patent office, the submission may be subject to more specific regulations.
EFFECT	
<ul style="list-style-type: none"> • If properly submitted, and the document effectively proves that there is disqualifying prior art, the patent application may be denied. At a minimum, the submission should notify the patent examiner of potentially disqualifying prior art. • The applicant is notified of the submission. 	<ul style="list-style-type: none"> • If filed correctly, the printed publication is attached to the patent's file. The patent's owner is notified of the printed publication and whether it was admitted into the file.
COST	
<ul style="list-style-type: none"> • Regularly, \$180 per every 10 documents. • \$90 per 10 documents for a "small entity." A plant breeder qualifies as a small entity if they file as a person who has no ownership or rights to the patent in question. Nonprofits also qualify. • Free if the submission is less than three documents and it is the only submission the submitter files for that application. 	<ul style="list-style-type: none"> • No statutory fee, but the submitter must also serve notice of the submission to the patent owner, which will incur some cost.
REQUIREMENTS (WHAT TO INCLUDE)	
<ul style="list-style-type: none"> • Document list. • Description of relevance of each document. • The document referenced. • Submission statement. • Payment of fee. 	<ul style="list-style-type: none"> • A copy of a certification that the submission was served to the patent's owner (proof of service). • An explanation of how the prior art in the printed publication affects or invalidates at least one specific claim in the patent.
PROS	
<ul style="list-style-type: none"> • Has a greater possible effect than a prior art submission. 	<ul style="list-style-type: none"> • Ability to file anonymously.
CONS	
<ul style="list-style-type: none"> • If the submission is noncompliant it is discarded with no refund of fees. 	<ul style="list-style-type: none"> • May not have any practical effect on the enforceability of the patent.

Table 7: Patent Process Timeline



This schematic shows the patent application and approval process, along with points in the process for engagement by other plant breeders.

IV. Practical Considerations

A. Current USPTO Search Techniques Overlook Many Defensive Publications

Patent Examining Procedure: Standards versus Practice

The Manual of Patent Examining Procedure (MPEP) has standards that, ideally, should lead to examiners finding and noting defensive publications. However, the reality is that non-patent literature (NPL) like defensive publications is often going unrecognized. The only NPL that seems to be regularly included in the patent review process is the NPL disclosed by patent applicants. In other words, the USPTO may be relying solely on information submitted with the application, without doing any additional research into NPL. Even when a patent applicant discloses NPL, there is no guarantee that the patent examiner will consult that prior art, despite the MPEP's directive to "fully consider all the prior art references cited in the application."³⁷

The problem does not appear to be a lack of defensive publications, or a lack of *quality* defensive publications. The primary problem is that, no matter how good the defensive publication might be, it will not have the intended effect of preventing the patent unless a patent examiner sees it in time.

According to the MPEP, examiners should be searching within the art (for example, plant breeding) and analogous arts, based on what is claimed by the patent and what *could* be claimed by the patent, and including both U.S. and foreign materials.³⁸ Furthermore, according to the MPEP, examiners should have access to several comprehensive databases which allow them to search for prior art using words as well as genetic sequences and chemical structures.³⁹ There is even a service of trained professionals who search for NPL, which examiners are encouraged to use, called the Scientific and Technical Information Center.⁴⁰

Some private organizations have established online databases as clearinghouses for defensive publications, although they tend not to focus on plants. Unfortunately, this approach requires a significant investment in ongoing maintenance

and updates to keep databases from becoming obsolete. Even when they are maintained, there is no guarantee that USPTO will consult them. Although patent examiners *can* use internet searches to find NPL, there is no guarantee that they will search online. But the USPTO's online presence is growing, which may mean that there will be a growing dependence on internet searches for NPL.

Patent examiners tend to be specialized in the types of patents they examine because patents are highly technical. For this reason, examiners become experts in their field and build private libraries of relevant information. Examiners can, and do, call upon resources from their collections while examining patent applications. Getting a defensive publication into an individual examiner's library is one way to make sure the publication is considered, but targeting examiners' libraries is likely an impractical approach for plant breeders.

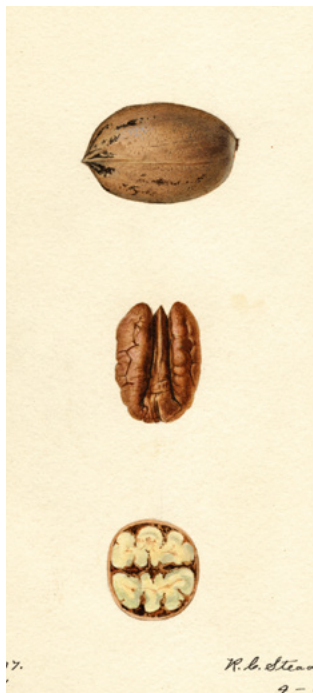
Despite the range of tools at their disposal, patent examiners' actual practice still overlooks most NPL. This oversight is mostly due to the volume of patent applications they review—as of February 2019, the backlog of unexamined applications was over 500,000.⁴¹

Value of Defensive Publication Given Current USPTO Practice

Despite this bleak outlook, there are several reasons to draft defensive publications with the expectation that a patent examiner will see them. First, the USPTO has recently attempted to update its examination procedure to make prior art searches more efficient. This efficiency update may mean that NPL will soon be more easily found, and defensive publications will thus be more likely to be effective.

Second, a well-drafted defensive publication may be useful as evidence in a lawsuit. A defensive publication may protect the author against

allegations of patent infringement. Note that authors should not rely solely on defensive publications to protect them in patent infringement actions. Similarly, should there be a larger advocacy push for courts to order the USPTO to enforce the MPEP, having a body of well-documented defensive publications will be very helpful. If advocates can show examples where USPTO examiners could have easily uncovered a defensive publication that invalidates a patent, it will go to show the need for the MPEP to be enforced.



B. Practical Publishing Considerations

Effective defensive publications should help their authors avoid litigation and patent disputes. To accomplish this, defensive publications need to be seen by patent examiners. Making publications easy to find makes it more likely an examiner will see them, despite the noted backlog.

But defensive publication strategies should also take into account plant breeders' other motivations for publishing. Many plant breeders choose to publish in peer-reviewed journals. These journals are good options for defensive publications because they can be recognizable and reputable sources for patent examiners to search. However, the peer-review process is time-consuming, which can delay a defensive publication's publication date. Additionally, peer-reviewed journals are unlikely to allow a plant breeder to publish in multiple venues. One way of circumventing these downsides to peer-reviewed publishing is to pre-print a defensive

publication using a service such as bioRxiv, which allows users to upload research before peer review is complete, giving them a date stamp to establish priority of their publication. Before using pre-printing services, it is best to research the policies of your preferred peer-reviewed journals, as some may not accept pre-printed submissions.

If publishing in peer-reviewed journals is not a concern, a best practice is to distribute a defensive publication over a wide variety of sources and media. Consider publishing in trade journals, Google Scholar, SSRN, personal blogs, LinkedIn, and institutional websites; submitting print copies to local libraries and specialty libraries; contributing to seed repositories; and including defensive publications with sales. Note that some forms of publishing may come with a significant price tag.⁴² More information on publishing is available in Appendix E.

C. Issues to Consider Before Publishing Defensively

Keep in mind that effective defensive publication teaches other people how to create an invention. In many cases, authors will not have control over how readers use that information. They may sell and market the author's invention, for which the author/inventor does not have a right to royalties. Further, someone may use this information to expand upon the original work and patent their own invention. Publication also puts competitors on notice. If this level of disclosure, and having limited (if any) ownership rights to an invention is concerning, defensive publication may not be the best way to manage your intellectual property.

Defensive Publications are Not Complete Defenses to Infringement Challenges

In the event someone is accused of patent infringement, a defensive publication may not be a complete, or even a partial, defense. In the best-case scenario, a judge could find that a patent is partially or completely invalidated by prior art, specifically, the defensive publication. However, by that point the accused individual has likely spent

a significant amount of time, money, and energy in litigation. On the other hand, a judge might find that the defensive publication is insufficient, and in that case the accused individual would be liable for patent infringement. In short, a defensive publication is useful evidence to have in a patent dispute, but should not be relied on alone to defend against potential liability. For personalized advice on how to protect against liability, consult a licensed attorney.

Defensive Publications Carry No Property Rights

Publishing your invention in a defensive publication does not grant an individual the same rights a patent does. Through a defensive publication alone, an inventor may not be able to limit readers' use of the invention or require royalties related to that use. Before choosing to publish defensively, an inventor should consider how much control they wish to have over the invention, as defensive publication is not an effective means to exert ongoing control over intellectual property.



V. Conclusion



For plant breeders concerned about agribusiness “locking up” stores of plant genetic diversity in utility patents, the current state of defensive publication is discouraging but not hopeless. Current USPTO practices are largely ineffective at capturing non-patent literature, the type of defensive publication that many plant breeders are best equipped to create. However, there are still several valid reasons to believe that defensive publication is worthwhile and that change is possible within the patent examining process.

Drafting defensive publications may protect plant breeders from patent litigation by creating a credible timeline showing when they created the plant in controversy. Defensive publications also help the plant breeding community as a whole by facilitating open sharing of plant breeding knowledge. The sum of defensive publication literature amounts to a library of valuable knowledge on which plant breeders can rely, both in a practical sense and as a possible defense to a charge of patent infringement.

Opportunities for change to the patent examining process present themselves in agency rulemaking procedures, requests for public input, and internal agency motivation. Defensive publications can play a role in any of these agents of change. For example, the USPTO offers an online tool allowing members of the public to comment on the Manual of Patent Examining Procedure.⁴³ Additionally, a

strong body of well-drafted defensive publications may serve as a catalyst for plant breeders, legislators, and USPTO examiners to initiate change in the patent field. When legislators’ constituents want to create and engage with IP, but are blocked from doing so, legislators may initiate change for the benefit of their constituents. Legislators may recognize this growing body of defensive publications and become more motivated to initiate much-needed change in the USPTO examination process. Finally, with a growing mass of credible, well-drafted defensive publications, USPTO examiners will find it easier to find (and harder to ignore) defensive publications that invalidate patents attempting to monopolize the plant breeding field.

This guide serves as one resource plant breeders can use to create a library of defensive publications. Defensive publication authors should seek out more information on how to create exemplary publications, as this guide is just an introduction. For this reason, an appendix follows with more resources for defensive publication authors to expand their understanding, answer unresolved questions, and engage with the subject. Plant breeders interested in pursuing IP protection for their own work, or in developing a legal strategy based on defensive publication, should consult an attorney licensed in their state for individualized advice.

VI. Appendices

Appendix A: Relevant Sections of Patent Law

Below are the relevant portions of patent law referenced in this guide.

This section should serve as a quick reference.

35 U.S.C § 101 - INVENTIONS PATENTABLE

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 102 - CONDITIONS FOR PATENTABILITY; NOVELTY

(a) Novelty; Prior Art.—A person shall be entitled to a patent unless—

- (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
- (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

(b) Exceptions.—

- (1) Disclosures made 1 year or less before the effective filing date of the claimed invention.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—
 - (A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
 - (B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.
- (2) Disclosures appearing in applications and patents.—A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if—
 - (A) the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;
 - (B) the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
 - (C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the

claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

(c) Common Ownership Under Joint Research

Agreements.—Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—

- (1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;
- (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
- (3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(d) Patents and Published Applications Effective as Prior Art.

—For purposes of determining whether a patent or application for patent is prior art to a claimed invention under subsection (a)(2), such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application—

- (1) if paragraph (2) does not apply, as of the actual filing date of the patent or the application for patent; or
- (2) if the patent or application for patent is entitled to claim a right of priority under section 119, 365(a), 365(b), 386(a), or 386(b), or to claim the benefit of an earlier filing date under section 120, 121, 365(c), or 386(c), based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.

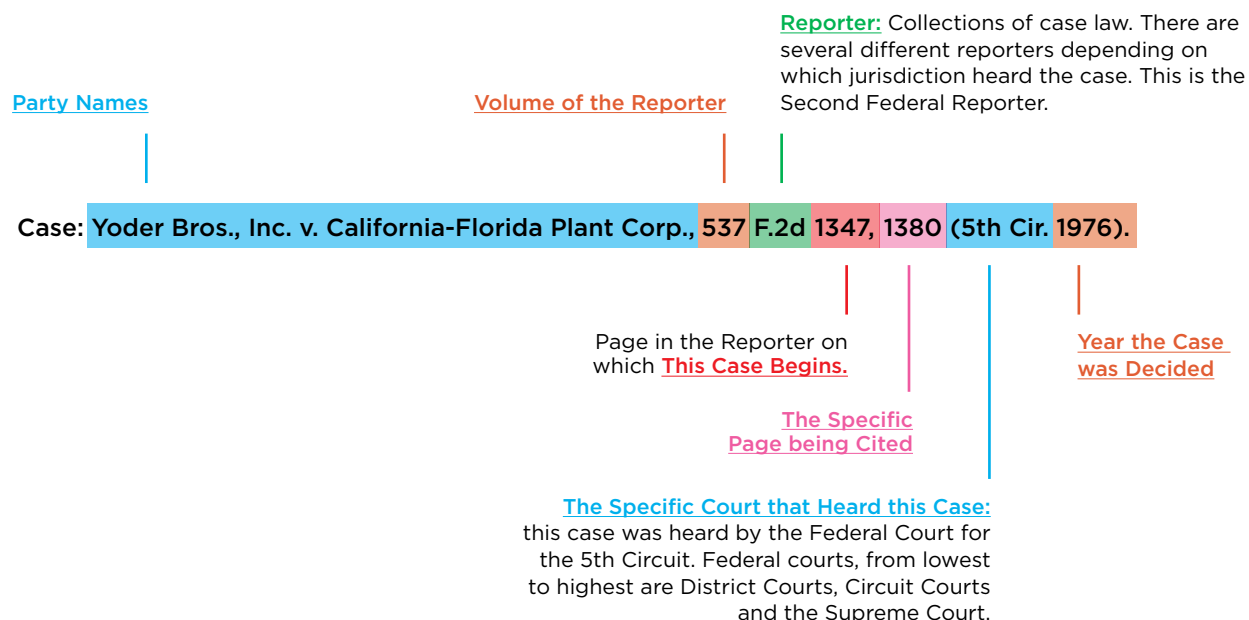
35 U.S.C. § 103 - CONDITIONS FOR PATENTABILITY; NON-OBVIOUS SUBJECT MATTER

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Appendix B: How to Read Legal Citations

The following graphics show what each part of a legal citation denotes. Statutes and case citations are listed.

Case: Yoder Bros., Inc. v. California-Florida Plant Corp., 537 F.2d 1347, 1380 (5th Cir. 1976).



Statute: 35 U.S.C. § 161 Patents for Plants

Title 35: All patent statutes are in Title 35 of the USC. Titles are split further into Parts, Sections, and Subsections

Of the **United States Code:** The United States Code (USC) is the body of all federal statutory law for the United States. Regulations are not included in the USC.

Statute: 35 U.S.C. § 161 Patents for Plants

Section 161:
There can be smaller subsections to the law.

Title of the Section: Laws may have different names than what is given to the name of the statute. For example, this section is titled Patents for Plants, but the law itself is called the Plant Patent Act. Statutes are named before they are added to the USC.

*The United States Code can be found at: <http://uscode.house.gov/>
or <https://www.law.cornell.edu/uscode/text>*

Appendix C: Sample Utility Patent

The sample provided shows portions of a utility patent annotated to describe how different parts of a patent function together.



US009668439B2

(12) **United States Patent**
Wu et al.

(10) **Patent No.:** **US 9,668,439 B2**

(45) **Date of Patent:** ***Jun. 6, 2017**

(54) **HIGH YIELDING SOYBEAN PLANTS WITH LOW LINOLENIC ACID**

(71) Applicant: **Monsanto Technology LLC**, St. Louis, MO (US)

(72) Inventors: **Kunsheng Wu**, Ballwin, MO (US); **Paul McLaird**, Kirkwood, MO (US); **Joseph Byrum**, West Des Moines, IA (US); **Robert Reiter**, Ballwin, MO (US); **Mark Erickson**, Slater, IA (US)

(73) Assignee: **Monsanto Technology LLC**, St. Louis, MO (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 180 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/517,662**

(22) Filed: **Oct. 17, 2014**

(65) **Prior Publication Data**

US 2015/0096075 A1 Apr. 2, 2015

Related U.S. Application Data

(60) Continuation of application No. 13/676,077, filed on Nov. 13, 2012, now Pat. No. 8,901,375, which is a continuation of application No. 13/174,753, filed on Jun. 30, 2011, now Pat. No. 8,378,170, which is a continuation of application No. 12/212,624, filed on Sep. 17, 2008, now Pat. No. 8,013,217, which is a division of application No. 11/239,676, filed on Sep. 29, 2005, now Pat. No. 7,442,850.

(60) Provisional application No. 60/614,331, filed on Sep. 29, 2004.

(51) **Int. Cl.**

A01H 5/10 (2006.01)
A01H 1/04 (2006.01)
A23D 9/00 (2006.01)
A01H 1/02 (2006.01)
C12N 5/04 (2006.01)
C12Q 1/68 (2006.01)
A23K 10/30 (2016.01)
A23K 20/147 (2016.01)
A23K 20/158 (2016.01)
A23L 11/00 (2016.01)
A23L 33/115 (2016.01)

(52) **U.S. Cl.**

CPC **A01H 5/10** (2013.01); **A01H 1/02** (2013.01); **A01H 1/04** (2013.01); **A23D 9/00** (2013.01); **A23K 10/30** (2016.05); **A23K 20/147** (2016.05); **A23K 20/158** (2016.05); **A23L 11/03** (2016.08); **A23L 11/07** (2016.08); **A23L 33/115** (2016.08); **C12N 5/04** (2013.01); **C12Q 1/6895** (2013.01); **A23V 2002/00** (2013.01); **C12Q 2600/13** (2013.01); **C12Q 2600/156** (2013.01); **Y02P 60/877** (2015.11)

(58) **Field of Classification Search**

None

See application file for complete search history.

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Primary Examiner — Elizabeth McElwain

(74) Attorney, Agent, or Firm — Dentons US LLP;
Chunping Li, Esq.

(57) **ABSTRACT**

The invention overcomes the deficiencies of the prior art by providing methods for marker assisted selection to create plants of a soybean variety that exhibit a mid/low linolenic acid content with a commercially significant yield and an agronomically elite phenotype. The invention also provides derivatives and plant parts of these plants. Further provided by the invention are methods for the use of these plants. The invention is significant in that oil with decreased linolenic acid exhibits numerous beneficial characteristics yet prior art varieties with decreased linolenic acid also exhibited decreased yield and poor agronomic quality.

36 Claims, 2 Drawing Sheets

PRIOR ART

Appendix C: Sample Utility Patent

The sample provided shows portions of a utility patent annotated to describe how different parts of a patent function together.

PRIOR ART

US 9,668,439 B2

Page 2

(56)

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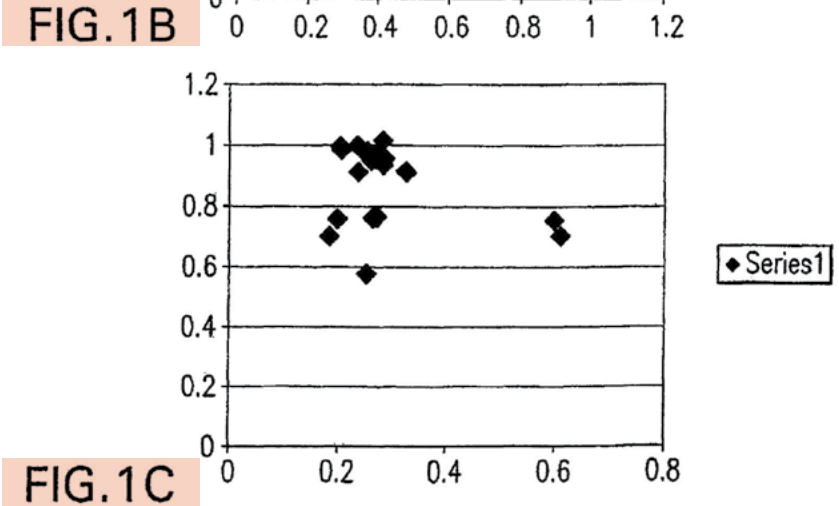
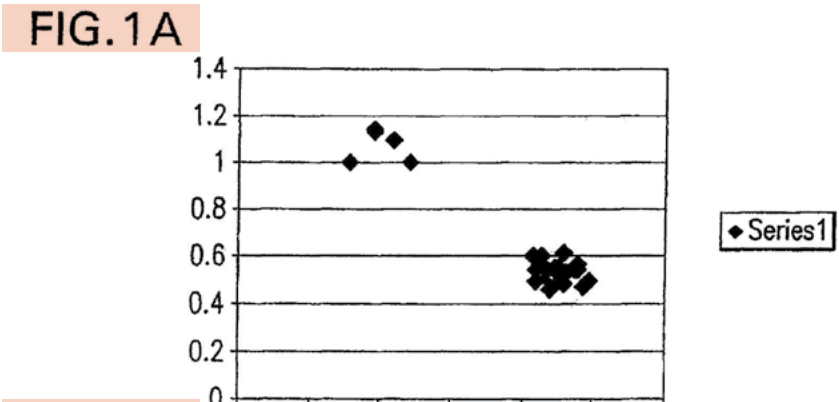
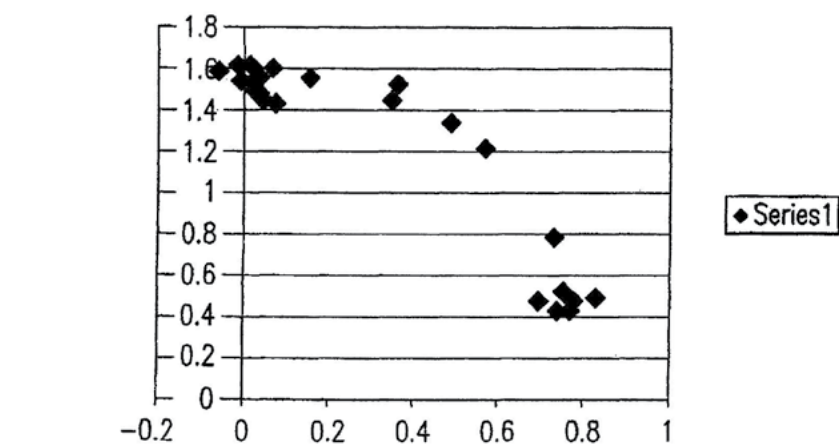
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Appendix C: Sample Utility Patent

The sample provided shows portions of a utility patent annotated to describe how different parts of a patent function together.

SPECIFICATIONS



Appendix C: Sample Utility Patent

The sample provided shows portions of a utility patent annotated to describe how different parts of a patent function together.

SPECIFICATIONS

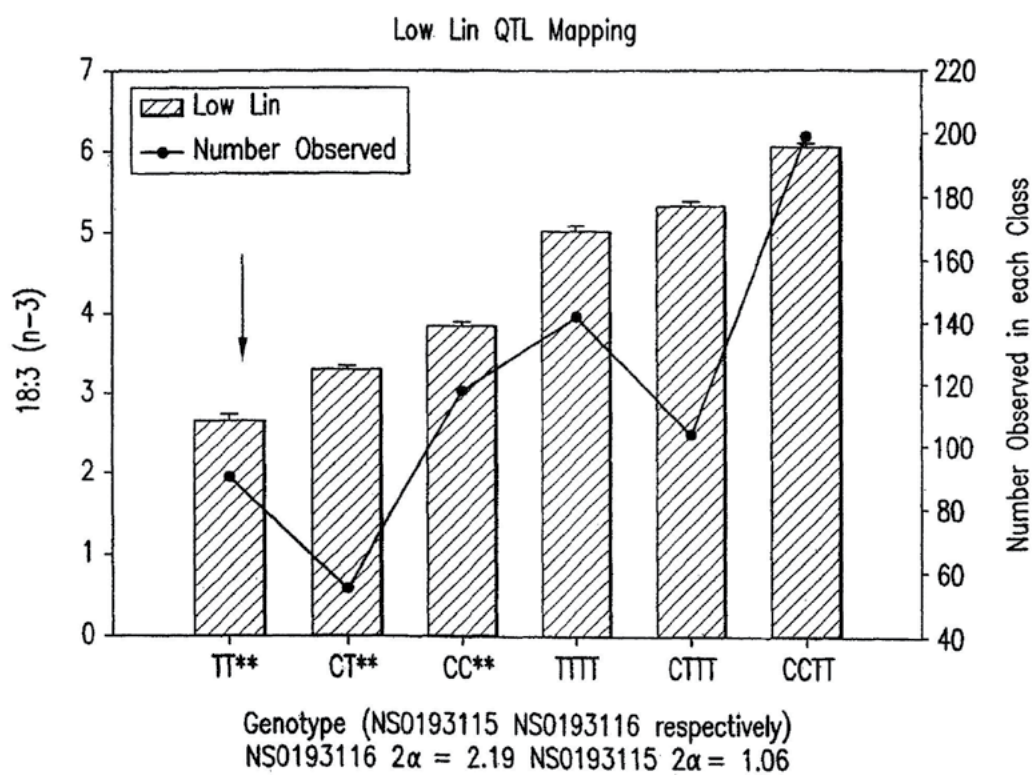


FIG.2

Appendix C: Sample Utility Patent

The sample provided shows portions of a utility patent annotated to describe how different parts of a patent function together.

SPECIFICATIONS

US 9,668,439 B2

1

HIGH YIELDING SOYBEAN PLANTS WITH LOW LINOLENIC ACID

BACKGROUND OF THE INVENTION

This application is a continuation of co-pending U.S. application Ser. No. 13/676,077, filed Nov. 13, 2012, issued as U.S. Pat. No. 8,901,375, which is a continuation of U.S. application Ser. No. 13/174,753, filed Jun. 30, 2011; issued as U.S. Pat. No. 8,378,170, which is a continuation of U.S. application Ser. No. 12/212,624, filed Sep. 17, 2008, issued as U.S. Pat. No. 8,013,217; which is a divisional of U.S. application Ser. No. 11/239,676, filed Sep. 29, 2005, issued as U.S. Pat. No. 7,442,850; which claims the priority of U.S. Provisional Patent Application Ser. No. 60/614,331, filed Sep. 29, 2004; the entire disclosures of which are specifically incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to the field of plant breeding. In particular, the invention relates to agronomically elite soybean varieties with commercially significant yield and a mid/low-linolenic acid content.

2. Description of Related Art

Soybean seeds are an important source of vegetable oil, which is used in food products throughout the world. The relatively high level (usually about 8%) of linolenic acid (18:3) in soybean oil reduces its stability and flavor.

Hydrogenation of soybean oil is used to lower the level of linolenic acid (18:3) and improve both stability and flavor of soybean oils (Dutton et al., 1951; Lui and White, 1992). However, hydrogenation results in the production of trans fatty acids, which increases the risk for coronary heart disease when consumed (Hu et al., 1997).

Varieties of low linolenic acid soybean have been produced through mutation, screening and breeding (Fehr et al., 1992; Rahman and Takagi, 1997; Ross et al., 2000; Byrum et al., 1997; Stoisin et al., 1998). Varieties with a linolenic acid content on the order of 1% or lower in particular have been produced (U.S. Pat. Nos. 5,534,425 and 5,714,670). However, the low linolenic acid lines produced to date have been plagued poor seed yield and other agronomic characteristics desired for commercial production. The problem has been difficult to solve and is complicated by the quantitative nature of agronomic traits such as linolenic acid content and yield. The usefulness of low linolenic acid content soybean has therefore been limited in most commercial settings.

Developing a product with commercial significance seed yield is a high priority in most soybean cultivar development programs. Yield is controlled by many genes and strongly influenced by the environment. It is a characteristic of central importance to the commercial value of a variety and breeders continually attempt to improve yield beyond that presently available. It is a difficult challenge to incorporate low linolenic acid content into high yielding cultivars.

Likely because of the difficulty, the prior art has failed to provide high yielding soybean varieties that also possess low linolenic acid and agronomically elite characteristics. However, there is a great need in the art for such soybean plants. The Food and Drug Administration (FDA) has proposed regulations on nutrition labeling to require that the amount of trans fatty acids in a food be included in the Nutrition Facts panel. In addition to the health benefits of reducing our

2

reliance on hydrogenation of soybean oils, the aforementioned proposal by FDA has sparked great interest in the production of low linolenic acid (less than 3%) soybean that does not require, or requires less hydrogenation. Decreased linolenic acid can significantly improve the value of a soybean harvest. For the decreased linolenic acid to have commercial significance, yield and/or elite agronomic traits must not be substantially impacted. Therefore, providing soybean plants that are agronomically elite while both high yielding and possessing decreased linolenic acid would represent a substantial advance in the art and benefit farmers and consumers alike.

SUMMARY OF THE INVENTION

In one aspect, the invention provides a soybean plant of an agronomically elite variety having a mid/low-linolenic acid content and a commercially significant yield. Also provided are the parts of this plant, including, but not limited to, pollen, an ovule, a cell and a seed. Further provided is a tissue culture of regenerable cells of the plant, wherein the tissue culture regenerates soybean plants capable of expressing all the physiological and morphological characteristics of the plant. In one embodiment of the invention, the regenerable cells are embryos, meristematic cells, pollen, leaves, roots, root tips or flowers or are protoplasts or callus derived therefrom. Further provided by the invention is a soybean plant regenerated from the tissue culture capable of expressing all the physiological and morphological characteristics of the starting plant.

In certain embodiments of the invention, a mid/low-linolenic acid content is defined as a linolenic acid content of from about 1.0% to about 3.0% by weight of total seed fatty acids, including from about 1.5% to about 3.0%, about 2% to about 2.6%, about 2% to about 3%, about 1% to about 2.6%, about 1% to about 2.2%, about 1.6% to about 2.6% and about 2% to about 2.4% by weight of total seed fatty acids. Such plants may further be defined as having a grain yield of, for example, at least about 90%, 94%, 98%, 100%, 103%, 105% or about 110% of the check lines AG2703 and DKB23-51. Line AG2703, which also has the designations SN79553 and 9323265446452, was patented in U.S. Pat. No. 6,184,442, the disclosure of which is incorporated herein by reference in its entirety. The line designated DKB23-51, which also has the designations 02122920 and 958361722350, was patented in U.S. Pat. No. 6,369,302, the disclosure of which is incorporated herein by reference in its entirety. Seeds of AG2703 and DKB23-51 have been deposited with the ATCC under ATCC accession numbers PTA-2577 and PTA-3933, respectively.

In yet another aspect, the invention provides plant parts of a plant of the invention. Examples of such parts include pollen, an ovule, a meristem or a cell. The invention also provides seeds of a plant described herein, as well as tissue cultures comprising cells of such a plant, wherein the tissue culture regenerates soybean plants expressing the physiological and morphological characteristics of the plant. The tissue culture may be comprised of regenerable cells such as embryos, meristematic cells, pollen, leaves, roots, root tips or flowers.

In still another aspect, the invention provides a soybean plant of the invention comprising a transgene. The transgene may in one embodiment be defined as conferring a trait selected from the group consisting of herbicide tolerance; disease resistance; insect or pest resistance; altered fatty acid, protein or carbohydrate metabolism; increased grain

Defines mid/low linolenic acid content which is used in interpreting Claim 1.

Appendix C: Sample Utility Patent

The sample provided shows portions of a utility patent annotated to describe how different parts of a patent function together.

SPECIFICATIONS

US 9,668,439 B2

3

yield; altered plant maturity, and altered morphological characteristics. One example of herbicide resistance is glyphosate resistance.

Defining a plant
as described in
Claim 12

In particular embodiments, a plant of the invention may be further defined as produced by a method comprising the steps of: a) crossing first and second soybean plants, wherein the plants comprise Fad3-1b and Fad3-1c alleles conferring decreased linolenic acid content, wherein the first plant has a mid/low-linolenic acid content, and wherein the second plant comprises a commercially significant yield; b) assaying progeny soybean plants resulting from the crossing for yield and for the presence of polymorphisms located in a soybean plant genomic region within 50 cM of said Fad3-1b and Fad3-1c alleles; and c) selecting at least a first agronomically elite progeny plant comprising said polymorphisms and a commercially significant yield to obtain the plant of claim 1.

In still yet another aspect, the invention provides a method of obtaining soybean germplasm, comprising the steps of: a) identifying at least a first polymorphism in a soybean plant genomic region within 50 cM of a Fad3-1b or Fad3-1c allele conferring decreased linolenic acid content; b) assaying soybean plants for the presence of the polymorphism; and c) selecting at least a first soybean plant comprising the polymorphism. The method may comprise identifying polymorphisms in a soybean plant genomic region within 50 cM of both of said Fad3-1b and Fad3-1c alleles and assaying for the presence of said polymorphisms. In one embodiment, the first polymorphism comprises a single nucleotide polymorphism at a position in the Fad3-1b gene sequence corresponding to nucleotide 2021 of SEQ ID NO: 1. In another embodiment, the first polymorphism comprises a single nucleotide polymorphism at a position in the Fad3-1c gene sequence corresponding to nucleotide 687, 1129, 1203, 2316, 3292, 3360 or 3743 of SEQ ID NO:2. The first polymorphism may also comprise a deletion in the Fad3-1c gene sequence, and may comprise a polymorphism in the Fad3-1c promoter, such as a single nucleotide polymorphism at a position corresponding to nucleotide 334, 364, 385, 387, 393, 729 or 747 of SEQ ID NO:3. Detecting the polymorphism may be carried out by any method, including PCR, single strand conformational polymorphism analysis, denaturing gradient gel electrophoresis, cleavage fragment length polymorphism analysis and/or DNA sequencing.

In still yet another aspect, the invention provides a method of plant breeding comprising the steps of: a) assaying soybean plants for the presence of at least a first polymorphism in a soybean plant genomic region within 50 cM of a Fad3-1b or Fad3-1c allele conferring decreased linolenic acid content; b) selecting at least a first soybean plant comprising the polymorphism; and c) crossing the first soybean plant to a second soybean plant to produce progeny plants comprising the polymorphism. The method may further comprise the step of: d) selecting a progeny plant comprising the polymorphism and crossing the progeny plant with a third soybean plant to produce additional progeny plants. In the method the second and third plants may be of the same variety. In certain embodiments, the method further comprises repeating step d) about 2-10 times. The method may still further comprise assaying soybean plants for the presence of polymorphisms in soybean plant genomic regions within 50 cM of said Fad3-1b and Fad3-1c alleles and selecting said first soybean plant may be based on the presence of the polymorphisms. In certain embodiments, markers linked to Fad3-1b and Fad3-1c may be assayed without assaying for markers tightly

4

linked to Fad3-1a, as the inventors have shown that it is the Fad3-1b and Fad3-1c alleles that contribute a low linolenic acid content.

In certain embodiments of the method, the first polymorphism comprises a single nucleotide polymorphism at a position in the Fad3-1b gene corresponding to nucleotide 2021 of SEQ ID NO:1. The first polymorphism may also comprise a single nucleotide polymorphism at a position in the Fad3-1c gene corresponding to nucleotide 687, 1129, 1203, 2316, 3292, 3360 or 3743 of SEQ ID NO:2. In still other embodiments the first polymorphism comprises a deletion in the Fad3-1c gene sequence and/or a single nucleotide polymorphism at a position in the Fad3-1c promoter corresponding to nucleotide 334, 364, 385, 387, 393, 729 or 747 of SEQ ID NO:3. Selecting at least a first soybean plant comprising the polymorphism may be carried out by any method, such as, for example, PCR, single strand conformational polymorphism analysis, denaturing gradient gel electrophoresis, cleavage fragment length polymorphism analysis and/or DNA sequencing.

In still yet another aspect, the invention provides a probe or primer that hybridizes under stringent conditions to a soybean plant genomic region within 50 cM of a Fad3-1b or Fad3-1c allele, wherein the probe or primer is a nucleic acid sequence selected from the group consisting SEQ ID NOs: 4-98.

Still yet another aspect of the invention is a method of producing a food product for human or animal consumption comprising: (a) obtaining a plant of the invention; (b) cultivating the plant to maturity; and (c) preparing a food product from the plant. In certain embodiments of the invention, the food product may be protein concentrate, protein isolate, meal, oil, flour or soybean hulls.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings form part of the present specification and are included to further demonstrate certain aspects of the invention. The invention may be better understood by reference to one or more of these drawings in combination with the detailed description of specific embodiments presented herein:

FIGS. 1A-1C. FIG. 1A shows the allelogram of NS0193117. The allelic patterns from the Taqman assay were consistent with the sequences. FIG. 1B shows the allelogram of NS0193115 on the sequencing panel. All four lines with low linolenic content had a different allele from the wild-type, corresponding well with the sequences. FIG. 1C shows the allelogram of NS0193116, derived from Fad3-1c position 687.

FIG. 2 shows the phenotypic values of Fad3-1b and Fad3-1c.

DETAILED DESCRIPTION OF THE INVENTION

The invention overcomes the deficiencies of the prior art by providing agronomically elite soybean varieties with a mid/low-linolenic acid content and commercially acceptable grain yield. The invention is significant in that, although the benefits of these characteristics have been realized individually, they have not previously been combined in a single variety. The provision of a mid/low linolenic acid content in combination with other desirable characteristics provides many benefits. For example, current soybean oils must typically be at least partially hydrogenated and/or mixed with other oils due to problems with oil stability. Reduced

Enablement: [How to use the invention. Use this invention to yield soybeans with mid/low linolenic acid content; improve stability; eliminate hydrogenation; and/or lower cost of soybean oil production.](#)

Appendix C: Sample Utility Patent

The sample provided shows portions of a utility patent annotated to describe how different parts of a patent function together.

SPECIFICATIONS

US 9,668,439 B2

5

6

[Enablement: see previous page](#)

linolenic acid content reduces the need for either solution by improving stability and, depending upon use, can eliminate the need for hydrogenation. The cost and quality of soybean oil can therefore be markedly improved by decreasing linolenic acid content, making the oil increasingly competitive relative to other seed oils. Low linolenic acid content also reduces off-flavors and thus lines with this characteristic have higher commercial value (Liu and White, 1992). However, widespread adoption of low-linolenic varieties has to date been hampered by poor yields or agronomic quality.

[Best Mode: using genetic markers to create the plant/invention which creates agronomically elite genes](#)

The invention provides genetic markers and methods for their use for the creation of such improved plants. This is significant because of the complex inheritance of quantitative traits, such as yield and linolenic acid content, which is made exponential when attempting to combine the traits. The markers were identified using the candidate gene approach. Locus-specific nested primers were designed to cover the entire FAD3 gene family consisting of three independent loci. Amplicons were generated from 25 different genotypes comprising 9 mutants and 16 wild types. SNPs and Indels were identified through sequence alignment. Genetic segregation analysis confirmed that the markers identified linked to the alleles Fad3-1b and Fad3-1c, which were associated with mutations in the corresponding wildtype sequences yielding low linolenic phenotypes. Analysis of the segregating plants demonstrated that Fad3-1b and Fad3-1c additively control linolenic content in soybean. Therefore, using a combination of markers for Fad3-1b and Fad3-1c, the invention allows accurate prediction of linolenic acid content in plants without the need for expensive biochemical analyses. These markers were successfully demonstrated for use in low linolenic soybean breeding programs and allowed, for the first time, the development of soybean varieties combining a low linolenic acid phenotype with commercially significant yield and agronomically elite characteristics.

The prior art has failed to provide plants of such a variety, presumably because of the difficulty in combining different traits with complex inheritance and lack of means for overcoming these difficulties. By describing methods for the production of such plants and providing examples of these plants, the invention now allows the preparation of a potentially unlimited number of novel soybean varieties exhibiting a commercially significant yield with combined with low linolenic acid content and specifically a mid/low linolenic acid content. Once such an elite variety is produced the combined yield and low linolenic acid content can be transferred to other varieties with appropriate backcross and selection to maintain the desirable traits as described herein below.

i. Plants of the Invention

The invention provides for the first time plants and derivatives thereof of soybean varieties that combine commercially significant yield and mid/low-linolenic acid content with an agronomically elite phenotype. Such plants may be defined as having a commercially significant yield, for example, that is defined as a yield of at least 103% of the check lines AG2703 and DKB23-51. In certain further embodiments, plants are provided having a mid/low-linolenic acid content and a grain yield of at least about 90%, 94%, 98%, 100%, 105% or about 110% of these lines. Such plants may be defined, in certain embodiments of the invention, as having a yield in excess of about 35, 37, 39, 41, 43 or 45 bushels per acre over at least 10 environments. In particular embodiments of the invention, the mid/low-linolenic acid content may be defined as from about 1% to about 3% of seed fatty acid content, including from about

1.3% to about 3%, from about 1.5% to about 3%, from about 1.8% to about 3%, from about 2.1% to about 3%, from about 2.4% to about 3%, from about 2.6% to about 3%, from about 1% to about 2.6%, from about 1.3% to about 2.6%, from about 1.8% to about 2.6%, from about 2% to about 2.6%, from about 2% to about 2.4% and from about 1.6% to about 2.4% of seed fatty acid content.

One aspect of the current invention is therefore directed to the aforementioned plants and parts thereof and methods for using these plants and plant parts. Plant parts include, but are not limited to, pollen, an ovule and a cell. The invention further provides tissue cultures of regenerable cells of these plants, which cultures regenerate soybean plants capable of expressing all the physiological and morphological characteristics of the starting variety. Such regenerable cells may include embryos, meristematic cells, pollen, leaves, roots, root tips or flowers, or protoplasts or callus derived therefrom. Also provided by the invention are soybean plants regenerated from such a tissue culture, wherein the plants are capable of expressing all the physiological and morphological characteristics of the starting plant variety from which the regenerable cells were obtained.

II. Marker Assisted Selection for Production of Soybean Varieties with Mid/Low-Linolenic Acid Content

The current invention provides genetic markers and methods for the introduction of loci conferring a mid/low-linolenic acid content in soybean plants. The invention therefore allows for the first time the creation of plants that combine this linolenic acid content with a commercially significant yield and an agronomically elite genetic background. Using the methods of the invention, loci conferring decreased linolenic acid content may be introduced into potentially any desired soybean genetic background, for example, in the production of new varieties with commercially significant yield and a mid/low-linolenic acid content.

[Best Mode: using genetic markers to create the plant/invention which creates agronomically elite genes](#)

Marker assisted introgression involves the transfer of a chromosome region defined by one or more markers from one germplasm to a second germplasm. The initial step in that process is the localization of the trait by gene mapping, which is the process of determining the position of a gene relative to other genes and genetic markers through linkage analysis. The basic principle for linkage mapping is that the closer together two genes are on the chromosome, the more likely they are to be inherited together. Briefly, a cross is generally made between two genetically compatible but divergent parents relative to traits under study. Genetic markers can then be used to follow the segregation of traits under study in the progeny from the cross, often a backcross (BC1), F₂, or recombinant inbred population.

The term quantitative trait loci, or QTL, is used to describe regions of a genome showing qualitative or additive effects upon a phenotype. The current inventors have identified genetic markers for two such QTLs, Fad3-1b and Fad3-1c. The invention therefore allows the use of molecular tools to combine these QTLs with desired characteristics.

A. Development of Linked Genetic Markers

A sample first plant population may be genotyped for an inherited genetic marker to form a genotypic database. As used herein, an "inherited genetic marker" is an allele at a single locus. A locus is a position on a chromosome, and allele refers to conditions of genes; that is, different nucleotide sequences, at those loci. The marker allelic composition of each locus can be either homozygous or heterozygous. In order for information to be gained from a genetic marker in a cross, the marker must be polymorphic; that is, it must exist in different forms so that the chromosome carrying the

Appendix C: Sample Utility Patent

The sample provided shows portions of a utility patent annotated to describe how different parts of a patent function together.

67

US 9,668,439 B2

68

-continued

cgggtttttt tgttgtcat tggaa

25

<210> SEQ ID NO 96
<211> LENGTH: 32
<212> TYPE: DNA
<213> ORGANISM: Artificial Sequence
<220> FEATURE:
<223> OTHER INFORMATION: Synthetic Primer

<400> SEQUENCE: 96

tcaagatgta ttctattatt ttctgaaacg cg

32

<210> SEQ ID NO 97
<211> LENGTH: 26
<212> TYPE: DNA
<213> ORGANISM: Artificial Sequence
<220> FEATURE:
<223> OTHER INFORMATION: Synthetic Primer

<400> SEQUENCE: 97

ctataaaaat tgaatcaata gaagaa

26

<210> SEQ ID NO 98
<211> LENGTH: 22
<212> TYPE: DNA
<213> ORGANISM: Artificial Sequence
<220> FEATURE:
<223> OTHER INFORMATION: Synthetic Primer

<400> SEQUENCE: 98

aaaaattgaa tcaataaaag aa

22

CLAIMS

Independent Claim

Dependent Claims Relying on Claim 1

What is claimed is:

1. A plant of an agronomically elite soybean variety having a commercially significant yield and a mid/low-linolenic acid content, said plant comprising a Fad3-1b or Fad3-1c allele conferring decreased linolenic acid content, wherein said allele comprises:
(a) a single nucleotide polymorphism at a position in the Fad3-1b gene sequence corresponding to nucleotide 2021 of SEQ ID NO:1;
(b) a single nucleotide polymorphism at a position in the Fad3-1c gene sequence corresponding to nucleotide 687, 1129, 1203, 2316, 3292, 3360 or 3743 of SEQ ID NO:2;
(c) a deletion in the Fad3-1c gene sequence; or
(d) a single nucleotide polymorphism at a position in the Fad3-1c promoter corresponding to nucleotide 334, 364, 385, 387, 393, 729 or 747 of SEQ ID NO:3.
2. The plant of claim 1, wherein the linolenic acid content is further defined as selected from the group consisting of from about 1.2% to about 3.0% by weight of total seed fatty acids, from about 1.5% to about 3.0% by weight of total seed fatty acids, from about 2% to about 2.6% by weight of total seed fatty acids, from about 2% to about 3% by weight of total seed fatty acids, from about 1% to about 2.6% by weight of total seed fatty acids, from about 1% to about 2.2% by weight of total seed fatty acids, from about 1.6% to about 2.6% by weight of total seed fatty acids, and from about 2% to about 2.4% by weight of total seed fatty acids.
3. A plant part of the plant of claim 1.
4. The plant part of claim 3, further defined as pollen, an ovule, a meristem or a cell.

5. A seed that produces the plant of claim 1.
6. A tissue culture of regenerable cells of the plant of claim 1, wherein the tissue culture regenerates soybean plants expressing the physiological and morphological characteristics of the plant of claim 1.
7. The tissue culture of claim 6, wherein the regenerable cells are embryos, meristematic cells, pollen, leaves, roots, root tips or flowers.
8. A soybean plant regenerated from the tissue culture of claim 6, wherein the regenerated soybean plant expresses the physiological and morphological characteristics of the plant of claim 1.
9. The soybean plant of claim 1, further defined as comprising a transgene.
10. The soybean plant of claim 9, wherein the transgene is further defined as conferring a trait selected from the group consisting of herbicide tolerance; disease resistance; insect or pest resistance; altered fatty acid, protein or carbohydrate metabolism; increased grain yield; altered plant maturity, and altered morphological characteristics.
11. The soybean plant of claim 9, wherein the transgene confers tolerance to glyphosate herbicide.
12. The plant of claim 1, defined as prepared by a method comprising the steps of:
a) crossing first and second soybean plants, wherein the first and second plants collectively comprise a Fad3-1b allele and a Fad3-1c allele each of which confer decreased linolenic acid content, wherein the first plant comprises at least one of the Fad3-1b or Fad3-1c alleles, and wherein the second plant comprises a commercially significant yield;
b) assaying progeny soybean plants resulting from the crossing for yield and for the presence of polymor-

Defensive Publication Guide for Plant Breeders

Appendices | 39

Appendix C: Sample Utility Patent

The sample provided shows portions of a utility patent annotated to describe how different parts of a patent function together.

US 9,668,439 B2

69

phisms located in a soybean plant genomic region within 50 cM of said Fad3-1b and Fad3-1c alleles; and
c) selecting at least a first progeny plant comprising said polymorphisms and a commercially significant yield to obtain the plant of claim 1.

13. A method of producing soybean seed, comprising crossing the plant of claim 1 with itself or a second soybean plant.

14. The method of claim 13, further defined as a method of preparing hybrid soybean seed, comprising crossing the plant of claim 1 to a second, distinct soybean plant.

15. A method of producing food or feed comprising:

- (a) obtaining the plant of claim 1;
- (b) cultivating said plant to maturity; and
- (c) preparing food or feed from said plant.

16. The method of claim 15, wherein the food is protein concentrate, protein isolate, soybean hulls, meal or flour.

17. The method of claim 15, wherein the food is oil.

18. The method of claim 17, wherein the food comprises beverages, infused foods, sauces, condiments, salad dressings, fruit juices, syrups, desserts, icings and fillings, soft frozen products, confections or intermediate food.

19. A method of obtaining soybean germplasm, comprising the steps of:

- a) obtaining a plant according to claim 1;
- b) assaying said soybean plant for the presence of the polymorphism; and
- c) selecting said soybean plant comprising the polymorphism.

20. The method of claim 19, wherein said polymorphisms are in a soybean plant genomic region within 50 cM of both of said Fad3-1b and Fad3-1c alleles.

21. The method of claim 19, wherein the first polymorphism comprises a single nucleotide polymorphism at a position in the Fad3-1b gene sequence corresponding to nucleotide 2021 of SEQ ID NO:1.

22. The method of claim 19, wherein the first polymorphism comprises a single nucleotide polymorphism at a position in the Fad3-1c gene sequence corresponding to nucleotide 687, 1129, 1203, 2316, 3292, 3360 or 3743 of SEQ ID NO:2.

23. The method of claim 19, wherein the first polymorphism comprises a deletion in the Fad3-1c gene sequence.

24. The method of claim 19, wherein the first polymorphism comprises a single nucleotide polymorphism at a position in the Fad3-1c promoter corresponding to nucleotide 334, 364, 385, 387, 393, 729 or 747 of SEQ ID NO:3.

25. The method of claim 19, wherein assaying soybean plants for the presence of the first polymorphism comprises PCR, single strand conformational polymorphism analysis,

70

denaturing gradient gel electrophoresis, cleavage fragment length polymorphism analysis and/or DNA sequencing.

26. A method of plant breeding comprising the steps of:

- a) assaying a soybean plant according to claim 1 for the presence of at least a first polymorphism in a soybean plant genomic region within 50 cM of a Fad3-1b or Fad3-1c allele conferring decreased linolenic acid content;

- b) selecting said soybean plant comprising the polymorphism; and

- c) crossing the soybean plant to a second soybean plant to produce progeny plants comprising the polymorphism.

27. The method of claim 26, further comprising the step of:

- d) selecting a progeny plant comprising the polymorphism and crossing the progeny plant with a third soybean plant to produce additional progeny plants.

28. The method of claim 27, wherein the second and third plants are of the same variety.

29. The method of claim 27, further comprising repeating step d) about 2-10 times.

30. The method of claim 26, comprising assaying soybean plants for the presence of polymorphisms in soybean plant genomic regions within 50 cM of said Fad3-1b and Fad3-1c alleles.

31. The method of claim 30, comprising selecting said first soybean plant based on the presence of the polymorphisms.

32. The method of claim 26, wherein the first polymorphism comprises a single nucleotide polymorphism at a position in the Fad3-1b gene sequence corresponding to nucleotide 2021 of SEQ ID NO:1.

33. The method of claim 26, wherein the first polymorphism comprises a single nucleotide polymorphism at a position in the Fad3-1c gene sequence corresponding to nucleotide 687, 1129, 1203, 2316, 3292, 3360 or 3743 of SEQ ID NO:2.

34. The method of claim 26, wherein the first polymorphism comprises a deletion in the Fad3-1c gene sequence.

35. The method of claim 26, wherein the first polymorphism comprises a single nucleotide polymorphism at a position in the Fad3-1c promoter corresponding to nucleotide 334, 364, 385, 387, 393, 729 or 747 of SEQ ID NO:3.

36. The method of claim 26, wherein selecting at least a first soybean plant comprising the polymorphism comprises PCR, single strand conformational polymorphism analysis, denaturing gradient gel electrophoresis, cleavage fragment length polymorphism analysis and/or DNA sequencing.

* * * * *

Appendix D:

For plant descriptions specific to crop species, search the U.S. National Plant Germplasm System database at <https://npgsweb.ars-grin.gov/gringlobal/descriptors.aspx?>

Listed below are some common plant descriptions from the USDA Natural Resource Conservation Service's PLANTS Database list of plant characteristics. These terms may be useful in describing a new plant in a defensive publication. More descriptions and further guidance are available at <https://plants.sc.egov.usda.gov/charinfo.html>.

SUMMARY

Duration
Growth Habit
Duration
Native Status
Federal T/E Status
National Wetland Indicator

MORPHOLOGY/PHYSIOLOGY

Active Growth Period
After Harvest Regrowth Rate
Bloat
C:N Ratio
Coppice Potential
Fall Conspicuous
Fire Resistant
Flower Color
Flower Conspicuous
Foliage Color
Foliage Porosity Summer
Foliage Porosity Winter
Foliage Texture
Fruit/Seed Color
Fruit/Seed Conspicuous
Growth Form
Growth Rate
Height at Base Age, Maximum
Height at Maturity
Known Allelopath
Leaf Retention
Lifespan
Low Growing Grass
Nitrogen Fixation
Resprout Ability
Shape and Orientation
Toxicity

GROWTH REQUIREMENTS

Adapted To Coarse Textured
Soils
Adapted To Medium Textured
Soils
Adapted To Fine Textured
Soils
Anaerobic Tolerance
CaCO₃ Tolerance
Cold Stratification Required
Drought Tolerance
Fertility Requirement
Fire Tolerance
Frost Free Days, Minimum
Hedge Tolerance
Moisture Use
pH, Minimum
pH, Maximum
Planting Density Per Acre,
Minimum
Planting Density Per Acre,
Maximum
Precipitation, Minimum
Precipitation, Maximum
Root Depth, Minimum
Salinity Tolerance
Shade Tolerance
Temperature, Minimum (°F)

REPRODUCTION

Bloom Period
Commercial Availability
Fruit/Seed Abundance
Fruit/Seed Period Begin
Fruit/Seed Period End
Fruit/Seed Persistence
Propagated By Bare Root
Propagated By Bulbs
Propagated By Container
Propagated By Corms
Propagated By Cuttings

Propagated By Seed
Propagated By Sod
Propagated By Sprigs
Propagated By Tubers
Seed Per Pound
Seed Spread Rate
Seedling Vigor
Small Grain
Vegetative Spread Rate

SUITABILITY/USE

Berry/Nut/Seed Product
Christmas Tree Product
Fodder Product
Fuelwood Product
Lumber Product
Naval Store Product
Nursery Stock Product
Palatable Browse Animal
Palatable Graze Animal
Palatable Human
Post Product
Protein Potential
Pulpwood Product
Veneer Product

MORPHOLOGY/PHYSIOLOGY

ACTIVE GROWTH PERIOD:

Plants have their most active growth in which seasonal period?

- Spring
- Spring & Fall
- Spring & Summer
- Spring, Summer & Fall
- Summer
- Summer & Fall
- Fall
- Fall, Winter & Spring
- Year-round

Appendix E: Further Resources

Below are some online resources with more in-depth information on topics discussed in this guide. This selection is not comprehensive and inclusion should not be construed as an endorsement by the authors.

USPTO RESOURCES

Manual of Patent Examining Procedure:

<https://mpep.uspto.gov/RDMS/MPEP/current>

Proposed Rule Changes:

<https://www.federalregister.gov/agencies/patent-and-trademark-office>

Third-party submission:

<https://efs.uspto.gov/EFSWebUIUnregistered/EFSWebUnregistered?preSelTPS=TRUE>

DEFENSIVE PUBLICATION RESOURCES

Defensive Publications: <http://www.defensivepublications.org>

IBM Technical Disclosure Bulletin: <https://priorart.ip.com>

U.S. LAW

Text of U.S. patent statutes, hosted by the Legal Information Institute:

<https://www.law.cornell.edu/patent/patent.overview.html>

Patent Law Basics & Beyond from legal blog IP Watchdog:

<https://www.ipwatchdog.com/patent/>

PUBLISHING

bioRxiv (preprint server for biology): <https://www.biorxiv.org/>

Elsevier's Journal Publishing Tool:

<https://www.elsevier.com/authors/journal-authors>

Create Space self-publishing: <https://wwwcreatespace.com/>

Build your own blog: <http://www.wordpress.org>

Appendix F:

The following is a glossary of legal or specialized language used throughout this guide:

LEGAL TERMS AND SPECIALIZED LANGUAGE:

Accessibility: the ability to find and receive a document upon request

Administrative Law Courts: courts that govern the conduct of administrative agencies (e.g., the USPTO)

Admission: a patent applicant's statement identifying or citing to something as prior art

Affidavit: "A voluntary declaration of facts written down and sworn to by a declarant, [usually] before an officer authorized to administer oaths. A great deal of evidence is submitted by affidavit."⁴⁴

Best Mode: the best way to achieve the result claimed

Claims: one-sentence statements describing the protected features of an invention

Confidential: not intended to be disseminated or otherwise shared with unintended recipients

Copyright: intellectual property protection for works of art

Declaration: a formal statement of fact

Defensive Publication: a publication drafted with the intent to expand the field of public knowledge to prevent future patents of that public knowledge

Dissemination: distributing a document to members in the relevant field to the extent that those members actually know of the document

Due Diligence: exercising reasonable care and attention to the matter at hand

Enabling: teaching the reader how to achieve a stated purpose or recreate an invention

Exclusivity: the right to prohibit a third party from using or acquiring your invention or any rights to it

Filing Date: the date a patent application is filed

Intellectual Property: a field of property rights which comprises all valuable products created through human invention and intellect

Liability: being held accountable for a legal wrong

Litigation: a legal dispute; lawsuit

Manual of Patent Examining Procedure: the United States Patent and Trademark Office's guide for patent examiners on researching and approving patent applications

Nonpatent Literature: printed publications that are not patents or patent applications

Novel: new to a field of art or an improvement upon an existing invention in the art

Obvious: known by an ordinary practitioner in the art because of the prior art that exists at the time

Ownership Rights: legally protected rights that allow a property owner to control their property, including intellectual property

Patent Trial and Appeals Board: the administrative court that rules on issues of patentability

Patentability: the characteristics that an invention must have to gain patent protection

Patents: an intellectual property instrument that grants ownership rights to an inventor

Printed: a physically accessible document

Printed Publication: a physically accessible document that has been disseminated

Prior Art: the body of knowledge the public possesses

Proof of Service: legally sufficient evidence that a person has been notified of

COMMON ACRONYMS:

AMS: Agricultural Marketing Service

IP: Intellectual property

MPEP: Manual of Patent Examining Procedure

NPL: Nonpatent literature

PPA: Plant Protection Act

PTAB: Patent Trials and Appeals Board

PVPA: Plant Variety and Protection Act

USDA: United States Department of Agriculture

USPTO: United States Patent and Trademark Office

a pending legal action

Property Rights: the legally protected rights that an owner acquires by virtue of owning something

Royalties: payment a licensee pays to an inventor for the right to use their invention

Specification: description in a patent that put claims into context

Statutes: laws written by Congress

Terms of Art: specialized language and terms used by practitioners in a particular field

Third-party Submission: a document attached to a patent's file offered by someone other than the patent applicant

Trademark: intellectual property protection for designations (e.g., logos and brand names)

Utility Patents: intellectual property protections for tangible inventions and methods

Written Descriptions: part of a patent that describes the protected parts of an invention

Endnotes

- 1 *What's the Problem?*, CONVENTION ON BIOLOGICAL DIVERSITY, <https://www.cbd.int/agro/whatstheproblem.shtml> (last updated Oct. 8, 2019).
- 2 Philip H. Howard, *Global Seed Industry Changes Since 2013*, <https://philhoward.net/2018/12/31/global-seed-industry-changes-since-2013/> (last updated Oct. 8, 2019).
- 3 35 U.S.C. § 161 (2018).
- 4 According to the statute, distinct means “clearly distinguishable from any other variety the existence of which is publicly known,” uniform means that “any variations are describable, predictable, and commercially acceptable,” and stable means that once the variety is reproduced it “will remain unchanged with regard to the essential and distinctive characteristics of the variety with a reasonable degree of reliability commensurate with that of varieties of the same category in which the same breeding method is employed.” 7 U.S.C. § 2402 (2018).
- 5 See *Manual of Patent Examining Procedure* (MPEP) U.S. PATENT AND TRADEMARK OFFICE, [hereinafter MPEP], <https://www.uspto.gov/web/offices/pac/mpep/index.html> (last updated Oct. 9, 2019) (for a link to the online MPEP).
- 6 Although patent law also requires an invention to be “useful,” that requirement sets a low bar. It merely requires that the invention work for what it claims to do. For example, a plant breeder could not patent glass marbles by claiming that they grow into pumpkin plants because they could not possibly do so in the real world. Gene Quinn, IP WATCHDOG, *Understanding the Patent Law Utility Requirement* (Nov. 7, 2015), <https://www.ipwatchdog.com/2015/11/07/understanding-the-patent-law-utility-requirement/id=63007/>.
- 7 35 U.S.C. §§ 101–103.
- 8 See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (holding that within the meaning of the patent statute, “live human-man microorganism is patentable”).
- 9 35 U.S.C. § 102(a)(1).
- 10 *Id.*
- 11 35 U.S.C. § 112(a)–(b) (stating that [t]he 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 as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.” Further, [t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.”).
- 12 See, e.g., *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2006) (“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’”) (citing *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)).
- 13 Brent A Olson, *Minnesota Practice Series: Business Law Deskbook*, §17.3 The Concept of A Patent (Dec. 2013 update) (West).
- 14 See Appendix C (for a sample utility patent); see also Appendix F (for the definition of “claims”).
- 15 Christopher A. Cotropia, *Patent Claim Interpretation Methodologies and Their Claim Scope Paradigms*, 47 Wm. & Mary L. Rev. 49, 75 (2005).
- 16 *Id.* at 75–77.
- 17 See *id.* at 75 (stating that “[t]he enablement requirement asks the inventor to set forth a working embodiment of the claimed invention in the specification”).
- 18 *Analog Devices, Inc. v. Linear Tech. Corp.*, 479 F.Supp.2d 202, 209 (D. Mass. 2007).
- 19 *Id.* at 205.
- 20 35 U.S.C. § 102(a)(1).
- 21 JOHN GLADSTONE MILLS III ET AL., PATENT LAW FUNDAMENTALS § 10.3 (Nov. 2018) (available on Westlaw); *Suffolk Tech. LLC., v. AOL Inc.*, 752 F.3d 1358, 1364 (2014) (“[a] given reference is ‘publicly accessible’ upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it.” (quoting *SRI Int’l, Inc. v. Internet Sec. Sys., Inc.* 511 F.3d 1186, 1194 (quoting *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006)).
- 22 MILLS ET AL., *supra* note 21, at § 10.3.
- 23 *Id.*; *Suffolk Tech.*, 752 F.3d at 1364 (2014) (holding that an internet post was made publicly accessible, thus considering it a printed source under the relevant statute).
- 24 An admission is “a statement by an applicant during prosecution identifying certain matter not the work of the inventor as ‘prior art’ is an admission that the matter is prior art.” *Riverwood Int’l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354, (Fed. Cir. 2003). However, the admission of prior art by the same inventor does not disqualify the patent application. See MPEP, *supra* note 5, at § 2129.
- 25 An affidavit is “a voluntary declaration of facts written down and sworn to by a declarant, usu[ally] before an officer authorized to administer oaths. A great deal of evidence is submitted by affidavit.” *Affidavit*, BLACK’S LAW DICTIONARY (11th ed. 2019). In patent applications, an affidavit is used as “[e]vidence [. . .] of knowledge and activity that constitute prior art.” Prior Art Rejections – Introduction, U.S. PATENT AND TRADEMARK OFFICE, <https://www.uspto.gov/video/cbt/intropriorartrej/>.
- 26 “A formal statement, proclamation, or announcement.” *Declaration*, BLACK’S LAW DICTIONARY (11th ed. 2019).
- 27 Prior Art Rejections – Introduction, U. S. PATENT AND TRADEMARK OFFICE, <https://www.uspto.gov/video/cbt/intropriorartrej/>.
- 28 *J.A. LaPorte, Inc. v. Norfolk Dredging Co.*, 625 F.Supp. 36, 41 (E.D. Va. 1985).
- 29 *Friction Div. Prods., Inc. v. E.I. DuPont de Nemours & Co.*, 658 F.Supp. 998, 1008, (D. Del. 1987) (citing *In re Hall*, 781 F.2d 897, 900 (Fed. Cir. 1986) and *Mass. Inst. of Tech. v. AB Fortia*, 774 F.2d 1104, 1109 (Fed. Cir. 1985) (“Cataloging a paper in a technical or scientific library makes the publication sufficiently accessible to those interested in the art to satisfy the requirements of § 102(b).” Further, distributing the publication at a conference may also satisfy the publication requirement).
- 30 MILLS ET AL., *supra* note 21, at § 10.3.(citing *In re Cronyn*, 890 F.2d 1158, 1161 (Fed. Cir. 1989)).
- 31 *Suffolk Tech. LLC., v. AOL Inc.*, 752 F.3d 1358, 1364 (Fed. Cir. 2014) (citing *In re Hall*, 781 F.2d at 898–99) (quoting *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006)).
- 32 *Mass. Inst. of Tech.* 774 F.2d at 1109 (1985) (finding prior art where an MIT cellular biologist delivered an oral presentation on “microcarriers.” The conference was attended by between 50 and 500 cell culturists. The presenter gave his paper to the head of the conference and six attendees without restrictions.); MPEP, *supra* note 5, at § 2128.01.
- 33 MPEP, *supra* note 5, at § 2152.
- 34 JORGE A. GOLDSTEIN, US BIOTECHNOLOGY PATENT LAW §9.10–Novelty applied to biotechnology claims (2018).
- 35 *Patent Application Full Text and Image Database*, U.S. Patent & Trademark Office, <http://appft.uspto.gov/netathtml/PTO/search-bool.html> (last updated Oct. 15, 2019).
- 36 *Patent Application Alter Service*, U.S. PATENT AND TRADEMARK OFFICE, <https://www.uspatentappalerts.com/index.php> (last updated Oct. 15, 2019).
- 37 MPEP, *supra* note 5, at § 904.03.

- 38 *Id.* at § 904.01(c).
- 39 *Id.* at § 904.02.
- 40 *Scientific and Technical Information Center*, U.S. PATENT AND TRADEMARK OFFICE, <https://www.uspto.gov/about-us/organizational-offices/office-commissioner-patents/office-deputy-commissioner-patent-4> (last updated Oct. 15, 2019).
- 41 *Unexamined Patent Application Inventory*, U.S. PATENT AND TRADEMARK OFFICE, <https://www.uspto.gov/corda/dashboards/patents/main.dashxml?CTNAVID=1005> (last updated Oct. 15, 2019).
- 42 See, e.g., Richard Van Noorden, *The True Cost of Science Publishing, Cheap Open-Access Journals Raise Questions About the Value Publishers add for Their Money*, 495 NATURE NEWS 426 (2013), https://www.nature.com/news/polopoly_fs/1.126761/menu/main/topColumns/topLeftColumn/pdf/495426a.pdf.
- 43 See MPEP, *supra* note 5 (to view the MPEP website and an online version of the MPEP); *Discuss the Manual of Patent Examination Procedures (MPEP)*, U.S. PATENT AND TRADEMARK OFFICE, <https://uspto-mpep.ideascale.com/a/index>.
- 44 *Affidavit*, BLACK'S LAW DICTIONARY (11th ed. 2019).