

# Biotechnology

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## Biotechnology

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Biotechnology raises not one but two recurring intellectual property issues. The first is that its subject matter is a mix of the natural and the artificial. Drawing the line between the two can be difficult and contentious. The second distinctive problem of biotechnology is that biology is exceptionally complicated; biological systems are unpredictable and hard to model. What's more, the biological systems we most care about – living human bodies – are not just complicated beyond our present understanding but also so precious that experiments on them cannot be undertaken lightly. This means that biological innovation is often slow and amazingly expensive, but also amazingly valuable when successful. These facts inflect the IP system in some important ways. Most importantly, they give rise to an extensive and intensive regulatory regime that restricts how drugs and similar medical technologies are researched and commercialized. Like a supertanker steaming through a boat pond, this regime has drawn the intellectual property system along into its wake.

### A Patent

#### 1 Subject Matter

**Association for Molecular Pathology v. Myriad Genetics, Inc.**  
133 S. Ct. 2107 (2013)

[According to the Supreme Court's summary, human DNA consists of a long string of nucleotides, each of which is one of four molecular fragments commonly abbreviated A, C, T, and G. Each sequence of three nucleotides codes for one of twenty amino acids, the molecules from which the body builds proteins. A gene is sequence of nucleotides that code for the amino acids making up a protein; put another way, a gene contains the information the body uses to make a particular protein. Naturally occurring DNA sequences contain

portions, called "introns," that do not actually code for amino acids; those portions are ignored when the body makes proteins from genes. The remaining portions of DNA, which do code for amino acids and which are used in making proteins, are called "exons."

Myriad discovered that mutations in two human genes, BRCA1 and BRCA2, substantially increased a woman's risk of developing breast cancer. It developed and marketed a test for these mutations. It also obtained multiple patents related to the discovery and the test, which it used to prevent competition from other tests. Claim 1 of patent 5,747,282, for example, claimed "an isolated DNA coding for a BRCA1 polypeptide," with "the amino acid sequence set forth in [an attachment listing a sequence of 1,863 amino acids]." Other claims covered cDNA (short for "complementary DNA"), which is created using synthetic laboratory methods by copying naturally occurring DNA. The resulting molecule differs in that it contains only exons and omits the introns.]

It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. Instead, Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13. The question is whether this renders the genes patentable.

*Chakrabarty*: 443 U.S. 303 (1980)

Myriad recognizes that our decision in *Diamond v. Chakrabarty* is central to this inquiry. In *Chakrabarty*, scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil. The Court held that the modified bacterium was patentable. It explained that the patent claim was "not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter — a product of human ingenuity having a distinctive name, character and use." The *Chakrabarty* bacterium was new "with markedly different characteristics from any found in nature," due to the additional plasmids and resultant "capacity for degrading oil." In this case, by contrast, Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.

Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.

Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a par-

ticular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes. If the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad's patent claims on entire genes (such as claims 1 and 2 of the '282 patent) by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule "invented" by Myriad. But Myriad obviously would resist that outcome because its claim is concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule.

cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. As already explained, creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring. Petitioners concede that cDNA differs from natural DNA in that "the non-coding regions have been removed." They nevertheless argue that cDNA is not patent eligible because "the nucleotide sequence of cDNA is dictated by nature, not by the lab technician." That may be so, but the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a "product of nature" and is patent eligible under § 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.

Justice SCALIA, concurring in part and concurring in the judgment.

I join the judgment of the Court, and all of its opinion except Part I-A and some portions of the rest of the opinion going into fine details of molecular biology. I am unable to affirm those details on my own knowledge or even my own belief. It suffices for me to affirm, having studied the opinions below and the expert briefs presented here, that the portion of DNA isolated from its natural state sought to be patented is identical to that portion of the DNA in its natural state; and that complementary DNA (cDNA) is a synthetic creation not normally present in nature.

**In re Roslin Institute (Edinburgh)**  
750 F.3d 1333 (2014)

On July 5, 1996, Keith Henry Stockman Campbell and Ian Wilmut successfully produced the first mammal ever cloned from an adult somatic cell: Dolly the Sheep. A clone is an identical genetic copy of a cell, cell part, or organism.

"The Court draws a distinction between unpatentable genomic DNA and patentable cDNA, but the difference between these two types of DNA lies in how they are made, not their sequence. A cDNA generated from an organism without introns (e.g. bacteria) will have the exact same sequence as genomic DNA. Furthermore, the splice junctions in human cDNA are natural: they were not designed by an inventor." Eric Grote, *Legal and Scientific Flaws in the Myriad Genetics Litigation* (unpublished draft 2014).



Dolly the Sheep

Campbell and Wilmut obtained a patent on the somatic method of cloning mammals, which has been assigned to Roslin. See U.S. Patent No. 7,514,258. The '258 patent is not before us in this appeal. Instead, the dispute here concerns the Patent and Trademark Office's (PTO) rejection of Campbell's and Wilmut's claims to the clones themselves, set forth in the '233 application, titled Quiescent Cell Populations for Nuclear Transfer.

The '233 application claims the products of Campbell's and Wilmut's cloning method: cattle, sheep, pigs, and goats. Claim 155 and 164 is representative:

155. A live-born clone of a pre-existing, non-embryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs, and goats.

Even before the Supreme Court's recent decision in *Myriad*, the Court's opinions in *Chakrabarty* and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, made clear that naturally occurring organisms are not patentable.

In *Funk Bros*, the Supreme Court considered a patent that claimed a mixture of naturally occurring strains of bacteria that helped leguminous plants extract nitrogen from the air and fix it in soil. The Court concluded that this mixture of bacteria strains was not patent eligible because the patentee did not alter the bacteria in any way. Critically, in *Funk Bros.*, the Court explained:

We do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable. We have here only product claims. The patentee does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.

Thus, while the method of selecting the strains of bacteria might have been patent eligible, the natural organism itself – the mixture of bacteria – was unpatentable because its "qualities are the work of nature" unaltered by the hand of man.

The patent at issue in *Chakrabarty* claimed a genetically engineered bacterium that was capable of breaking down various components of crude oil. The patent applicant created this non-naturally occurring bacterium by adding four plasmids to a specific strain of bacteria. The Court held that the modified bacterium was patentable because it was

*Funk Bros.*: 333 U.S. 127 (1948)

“new” with “markedly different characteristics from any found in nature and one having the potential for significant utility.” As the Court explained, the patentee’s “discovery is not nature’s handiwork, but his own.”

Accordingly, discoveries that possess “markedly different characteristics from any found in nature,” are eligible for patent protection. In contrast, any existing organism or newly discovered plant found in the wild is not patentable. *See also In re Beineke* (holding that a newly discovered type of plant is not eligible for plant patent protection, in part, because such a plant was not “in any way the result of the patent applicant’s creative efforts or indeed anyone’s creative efforts.”).

*Beineke*: 690 F.3d 1344 (Fed. Cir. 2012)

While Roslin does not dispute that the donor sheep whose genetic material was used to create Dolly could not be patented, Roslin contends that copies (clones) are eligible for protection because they are “the product of human ingenuity” and “not nature’s handiwork, but their own.” Roslin argues that such copies are either compositions of matter or manufactures within the scope of § 101. However, Dolly herself is an exact genetic replica of another sheep and does not possess markedly different characteristics from any farm animals found in nature. Dolly’s genetic identity to her donor parent renders her unpatentable.

Supreme Court decisions regarding the preemptive force of federal patent law confirm that individuals are free to copy any unpatentable article, such as a live farm animal, so long as they do not infringe a patented method of copying. In *Sears, Roebuck & Co. v. Stiffel Co.*, the question was whether the defendant could be held liable under state law for copying a lamp design whose patent protection had expired. The Court explained that “when the patent expires the monopoly created by it expires, too, and the right to make the article – including the right to make it in precisely the shape it carried when patented – passes to the public.” The Court further clarified that “an unpatentable article, like an article on which the patent has expired, is in the public domain and may be made and sold by whoever chooses to do so.” Roslin’s claimed clones are exact genetic copies of patent ineligible subject matter. Accordingly, they are not eligible for patent protection.

*Sears, Roebuck*: 376 U.S. 225 (1964)

Roslin argues that its claimed clones are patent eligible because they are distinguishable from the donor mammals used to create them. First, Roslin contends that “environmental factors” lead to phenotypic differences that distinguish its clones from their donor mammals. A phenotype refers to all the observable characteristics of an organism, such as shape, size, color, and behavior, that result from the interaction of the organism’s genotype with its environment. A mammal’s phenotype can change constantly throughout the life of that organism not only due to environmental changes, but also the

physiological and morphological changes associated with aging.

Roslin argues that environmental factors lead to phenotypic differences between its clones and their donor mammals that render their claimed subject matter patentable. However, these differences are unclaimed. Indeed, the word "cloned" in the pending claims connotes genetic identity, and the claims say nothing about a phenotypic difference between the claimed subject matter and the donor mammals. Moreover, Roslin acknowledges that any phenotypic differences came about or were produced quite independently of any effort of the patentee. Contrary to Roslin's arguments, these phenotypic differences do not confer eligibility on their claimed subject matter. Any phenotypic differences between Roslin's donor mammals and its claimed clones are the result of environmental factors, uninfluenced by Roslin's efforts.

Second, Roslin urges that its clones are distinguishable from their original donor mammals because of differences in mitochondrial DNA, which originates from the donor oocyte rather than the donor nucleus. Mitochondria are the organelles (cellular bodies) that produce the energy eukaryotic cells need to function. Mitochondria possess their own DNA, which is distinct from the DNA housed in the cell's nucleus. In the cloning process, the clone inherits its mitochondrial DNA from its donor oocyte, instead of its donor somatic cell. Therefore, Dolly's mitochondrial DNA came from the oocyte used to create her, not her donor mammary cell. Roslin argues that this difference in mitochondrial DNA renders its product claims patent eligible.

But any difference in mitochondrial DNA between the donor and cloned mammals is, too, unclaimed. Furthermore, Roslin's patent application does not identify how differences in mitochondrial DNA influence or could influence the characteristics of cloned mammals.

Finally, Roslin argues that its clones are patent eligible because they are time-delayed versions of their donor mammals, and therefore different from their original mammals. But this distinction cannot confer patentability. The difficulty with the time-delayed characteristic is that it is true of any copy of an original.

### **Ariosa Diagnostics, Inc. v. Sequenom, Inc.**

788 F.3d 1371 (Fed. Cir. 2015)

In 1996, Drs. Dennis Lo and James Wainscoat discovered cell-free fetal DNA ("cffDNA") in maternal plasma and serum, the portion of maternal blood samples that other researchers had previously discarded as medical waste. cffDNA is non-cellular fetal DNA that circulates freely in the blood stream of a pregnant woman. Applying a combination of known laboratory techniques to their discovery, Drs. Lo and Wainscoat implemented a method for detecting the small frac-

tion of paternally inherited cffDNA in maternal plasma or serum to determine fetal characteristics, such as gender. The invention, commercialized by Sequenom as its MaterniT21 test, created an alternative for prenatal diagnosis of fetal DNA that avoids the risks of widely-used techniques that took samples from the fetus or placenta. In 2001, Drs. Lo and Wainscoat obtained U.S Patent No. 6,258,540, which relates to this discovery.

The parties agree that the patent does not claim cffDNA or paternally inherited cffDNA. Instead, the '540 patent claims certain methods of using cffDNA. The steps of the method of claim 1 of the '540 patent include amplifying the cffDNA contained in a sample of a plasma or serum from a pregnant female and detecting the paternally inherited cffDNA. Amplifying cffDNA results in a single copy, or a few copies, generating thousands to millions of copies of that particular DNA sequence. In the amplification step, DNA is extracted from the serum or plasma samples and amplified by polymerase chain reaction ("PCR") or another method. PCR exponentially amplifies the cffDNA sample to detectable levels.

Ariosa makes and sells the Harmony Test, a non-invasive test used for prenatal diagnosis of certain fetal characteristics. [Sequenom threatened suit and Ariosa filed an action seeking a declaratory judgment of noninfringement.]

It is undisputed that the existence of cffDNA in maternal blood is a natural phenomenon. Sequenom does not contend that Drs. Lo and Wainscoat created or altered any of the genetic information encoded in the cffDNA, and it is undisputed that the location of the nucleic acids existed in nature before Drs. Lo and Wainscoat found them. The method ends with paternally inherited cffDNA, which is also a natural phenomenon. The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring.

Because the claims at issue are directed to naturally occurring phenomena, we turn to the second step of *Mayo's* framework. In the second step, we examine the elements of the claim to determine whether the claim contains an inventive concept sufficient to "transform" the claimed naturally occurring phenomenon into a patenteligible application. For process claims that encompass natural phenomenon, the process steps are the additional features that must be new and useful.

Like the patentee in *Mayo*, Sequenom contends that the claimed methods are patent eligible applications of a natural phenomenon, specifically a method for detecting paternally inherited cffDNA. Using methods like PCR to amplify and detect cffDNA was well-understood, routine, and conventional activity in 1997. The method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA. Be-

cause the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful. The only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum.

Sequenom argues that there are numerous other uses of cffDNA aside from those claimed in the '540 patent, and thus, the '540 patent does not preempt all uses of cffDNA. While preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility. In this case, Sequenom's attempt to limit the breadth of the claims by showing alternative uses of cffDNA outside of the scope of the claims does not change the conclusion that the claims are directed to patent ineligible subject matter. Where a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot.

Linn, Circuit Judge, concurring:

I join the court's opinion invalidating the claims of the '540 patent only because I am bound by the sweeping language of the test set out in *Mayo*. In my view, the breadth of the second part of the test was unnecessary to the decision. This case represents the consequence – perhaps unintended – of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain.

The Supreme Court's blanket dismissal of conventional post-solution steps leaves no room to distinguish *Mayo* from this case, even though here no one was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers. Indeed, the maternal plasma used to be routinely discarded, because, as Dr. Evans testified, "nobody thought that fetal cell-free DNA would be present."

It is hard to deny that Sequenom's invention is truly meritorious. Prior to the '540 patent, prenatal diagnoses required invasive methods, which presented a degree of risk to the mother and to the pregnancy. The available techniques were time-consuming or required expensive equipment. In a groundbreaking invention, Drs. Lo and Wainscoat discovered that there was cell-free fetal DNA in the maternal plasma. The Royal Society lauded this discovery as "a paradigm shift in non-invasive prenatal diagnosis," and the inventors' article describing this invention has been cited well over a thousand times. The commercial embodiment of the invention, the MaterniT21 test, was the first marketed non-invasive prenatal diagnostic test for fetal aneuploidies, such as Down's syndrome, and presented fewer risks and a more dependable rate of abnormality detection than other tests.

Unlike in *Mayo*, the '540 patent claims a new method that should be patent eligible. While the instructions in the claims at issue in *Mayo* had been widely used by doctors – they had been measuring metabolites and recalculating dosages based on toxicity/inefficacy limits for years – here, the amplification and detection of cffDNA had never before been done. The new use of the previously discarded maternal plasma to achieve such an advantageous result is deserving of patent protection.

In short, Sequenom's invention is nothing like the invention at issue in *Mayo*. But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.

### DNA Copyright Problem

Two law professors collaborated with a biotechnology company to create what they called "Prancer":

a DNA sequence that provides a set of instructions for the synthesis of a protein comprising 231 amino acids linked together in a specific order. The set of instructions is coded in the standard genetic code, and is interpretable by most living biological systems. The encoded protein is fluorescent, which is a useful functional attribute in biotechnology.

The Copyright Office said "no." Its reasoning, along with the professors' response, are detailed in Christopher M. Holman, Claes Gustafsson, & Andrew W. Torrance, *Are Engineered Genetic Sequences Copyrightable?*, 35 *Biotech. L. Rep.* 103 (2016). But try not to peek before you try your hand at coming up with the best reasons for and against!

Is Prancer a copyrightable work of authorship?

## 2 Ownership

The doctrines here are familiar. *Schering* illustrates some of the inherent difficulty in determining novelty (and also infringement) given that biological systems transform substances in complex ways. *Eli Lilly v. Zenith* considers the novelty implications of clinical drug testing.

### Schering Corp. v. Geneva Pharmaceuticals

339 F.3d 1373 (Fed. Cir. 2003)

The District Court correctly determined that that U.S. Patent No. 4,282,233 inherently anticipates claims 1 and 3 of Patent No. 4,659,716.

Schering owns the '233 and '716 patents on antihistamines. Antihistamines inhibit the histamines that cause allergic symptoms.

The prior art '233 patent covers the antihistamine loratadine, the active component of a pharmaceutical that Schering markets as CLARITIN. Unlike conventional antihistamines when CLARITIN was launched, loratadine does not cause drowsiness.

The more recent '716 patent at issue in this case covers a metabolite of loratadine called descarboethoxyloratadine (DCL). A metabolite is the compound formed in the patient's body upon ingestion of a pharmaceutical. The ingested pharmaceutical undergoes a chemical conversion in the digestion process to form a new metabolite compound. The metabolite DCL is also a non-drowsy antihistamine. The '716 patent issued in April 1987 and will expire in April 2004 (the '233 patent issued in 1981 and has since expired).

A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. Inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure.

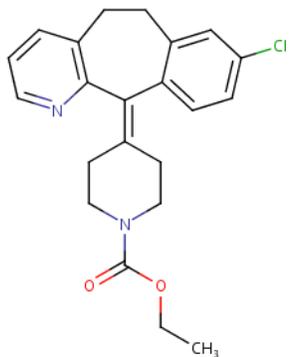
DCL is not formed accidentally or under unusual conditions when loratadine is ingested. The record shows that DCL necessarily and inevitably forms from loratadine under normal conditions. DCL is a necessary consequence of administering loratadine to patients.

This court recognizes that this may be a case of first impression, because the prior art does not disclose any compound that is identifiable as DCL. In this court's prior inherency cases, a single prior art reference generally contained an incomplete description of the anticipatory subject matter, i.e., a partial description missing certain aspects. Inherency supplied the missing aspect of the description.

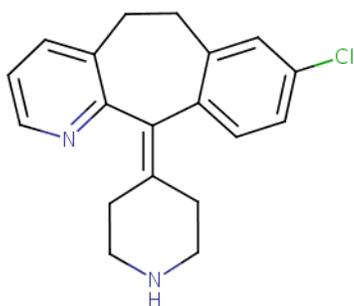
This court sees no reason to modify the general rule for inherent anticipation in a case where inherency supplies the entire anticipatory subject matter. The patent law principle "that which would literally infringe if later in time anticipates if earlier," bolsters this conclusion. Similarly, if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle. Thus, inherency operates to anticipate entire inventions as well as single limitations within an invention.

Turning to this case, the use of loratadine would infringe claims 1 and 3 of the '716 patent covering the metabolite DCL. This court has recognized that a person may infringe a claim to a metabolite if the person ingests a compound that metabolizes to form the metabolite. An identical metabolite must then anticipate if earlier in time than the claimed compound.

This court's conclusion on inherent anticipation in this case does



Loratadine



Descarboethoxyloratadine

not preclude patent protection for metabolites of known drugs. With proper claiming, patent protection is available for metabolites of known drugs. Cf. *In re Kratz* (stating that a naturally occurring strawberry constituent compound does not anticipate claims to the substantially pure compound); *In re Bergstrom* (stating that a material occurring in nature in less pure form does not anticipate claims to the pure material).

But those metabolites may not receive protection via compound claims. In this case, for instance, claims 1 and 3 broadly encompass compounds defined by structure only. Such bare compound claims include within their scope the recited compounds as chemical species in any surroundings, including within the human body as metabolites of a drug. As this case holds, these broad compound claims are inherently anticipated by a prior art disclosure of a drug that metabolizes into the claimed compound.

A skilled patent drafter, however, might fashion a claim to cover the metabolite in a way that avoids anticipation. For example, the metabolite may be claimed in its pure and isolated form, as in *Kratz* and *Bergstrom*, or as a pharmaceutical composition (e.g., with a pharmaceutically acceptable carrier). The patent drafter could also claim a method of administering the metabolite or the corresponding pharmaceutical composition. The '233 patent would not provide an enabling disclosure to anticipate such claims because, for instance, the '233 patent does not disclose isolation of DCL.

### **Eli Lilly and Co. v. Zenith Goldline Pharm. Inc.**

364 F. Supp. 2d 820 (S.D. Ind. 2005)

Defendants have failed to prove by clear and convincing evidence that the HGAA, HGAB, and HGAC Phase I clinical trials of olanzapine were public. These studies were conducted by Lilly personnel in the Lilly clinic. Lilly restricted access to the facility and provided full-time security. In addition, the studies were fully controlled by Lilly. The volunteers, who were healthy and not suffering from schizophrenia, were paid by Lilly for their services, remained in the research ward for the duration of the study, and were closely monitored by doctors and medical staff employed by Lilly. Only Lilly employees administered the drug. The fact that the volunteers were allowed visitors does not change the analysis.

Defendants' argument that the clinical trials were "public" because the patients did not sign a confidentiality agreement is unpersuasive and legally unsound. First, because the patients were not informed of the identity of the compound they were taking and were kept at Lilly facilities at all times, a confidentiality agreement would have been superfluous. Second, the presence or absence of a confidentiality agreement is not controlling. It is simply one of many factors

*Kratz*: 592 F.2d 1169 (CCPA 1979)

*Bergstrom*: 427 F.2d 1394 (CCPA 1970)

Olanzapine is an antipsychotic approved for the treatment of schizophrenia and bipolar disorder; Eli Lilly marketed it under the brand name ZYPREXA.

to be taken into consideration.

Even if Lilly's Phase I clinical trials of olanzapine constituted a public use of the compound more than one year prior to Lilly's application for its patent, it was an experimental use. The evidence demonstrates that the art with respect to this type of atypical antipsychotic drug was highly unpredictable. Small structural changes led to very different properties. Furthermore, the art was plagued with unpredictable side effects that rendered otherwise promising compounds useless in the clinical setting. These side effects could only be understood when the compounds were tested in actual patients. Olanzapine was conceived as a compound that would have antipsychotic activity but not produce flumezapine's toxic effects in schizophrenic patients. Accordingly, testing olanzapine in actual schizophrenic patients was required to prove it would "work for its intended purpose," i.e., as a safe, atypical antipsychotic drug used to treat human patients suffering from or susceptible to psychotic disorders. These Phase I clinical trials in healthy human volunteers were required by regulatory agencies before the compound could be tested in schizophrenic patients. For these reasons, the clinical tests constitute an experimental use and negate a finding that they were a "public use" as defined in patent law.

### 3 Infringement: Similarity

When are two substances the "same" for purposes of patent infringement? In the biotechnology context, the answer is not always straightforward.

#### **Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.** 320 F.3d 1339 (Fed. Cir. 2003)

Porcine Reproductive Respiratory Syndrome (also known as "Mystery Swine Disease" or Swine Infertility and Respiratory Syndrome), swept through commercial pig herds in the 1980s. A previously unknown disease, PRRS had its most pronounced effect on young and newborn piglets. Up to thirty percent of the piglets in litters from infected sows were stillborn, and up to eighty percent of piglets in infected herds died before weaning. The financial consequences to the commercial pig industry were severe.

Researchers seeking a cause for PRRS could not identify any known pathogen behind the epidemic (hence the name "Mystery Swine Disease"). Scientists at Boehringer were the first to solve the mystery, discovering that a previously unknown virus was responsible for the disease.

Boehringer began with a homogenate of lung, brain, spleen, liver, and kidney tissues from an infected piglet. Samples of this combined

homogenate were then added to a panel of 15 different cultured mammalian cell lines. While viruses themselves are too small to see without the aid of an electron microscope, a viral infection often gives rise to morphological changes in the host cell. An observable change in a host cell due to viral infection is known as a cytopathic effect, or CPE. These changes may include cell rounding, disorientation, swelling or shrinking, death, or detachment from the culture surface, and are visible with ordinary microscopes as perturbations of the cultured cell monolayer. Boehringer's scientists found evidence of a virus present in PRRS-infected animals when they observed a CPE in cultured MA-104 embryonic monkey kidney cells, one of the 15 cell lines inoculated with PRRS homogenate.

Continued propagation of a virus requires that the virus be passaged, which entails removing [a portion] of the culture and adding it to a fresh culture of cells. Boehringer scientists passaged the PRRS virus eight times on MA-104 cells, and deposited a sample of the virus from the eighth passage with the American Type Culture Collection (ATCC), which assigned it deposit number VR-2332.

The '778 patent claims this process for growing and isolating the PRRS virus: inoculating cultured monkey cells with the PRRS virus, and incubating the inoculated cells until a CPE is observed. Claim 2 is the only claim at issue in this case, and depends from claim 1:

1. A method of growing and isolating swine infertility and respiratory syndrome virus, ATCC-VR2332, which comprises inoculating the virus on a full or partial sheet of simian cells in the presence of serum in a suitable grown medium and incubating the inoculated cell sheet at about 34 C. to 37 C. until CPE is observed.
2. The method as recited in claim 1 wherein the simian cell line is MA-104.

Schering, like Boehringer, developed a vaccine against PRRS by attenuating the PRRS virus in cell culture. Attenuation is a process wherein a virus is repeatedly passaged on a cultured cell line, sometimes under altered culture conditions (such as lowered temperature). Variant viruses that are better adapted to grow on the cultured cell line will grow faster than the original virus; after many serial passages, such a variant will completely replace the original in the culture. Frequently, however, those variants adapted to grow in a particular environment (such as cultured monkey kidney cells) are ill-suited to grow or cause disease in the original environment (a live pig). If the attenuated virus will not productively infect pigs, but retains enough structural similarity to the original virus such that an immune response mounted against the attenuated virus will protect the pig against the original virus, then the attenuated virus may be

used as a vaccine to protect against PRRS. Both Boehringer and Schering developed attenuated viruses effective as vaccines against PRRS.

Boehringer filed suit against Schering, alleging that Schering's vaccine virus, which is also grown on MA-104 monkey kidney cells, was prepared by a process that infringed the method claimed by the '778 patent.

Boehringer argues that the term "ATCC-VR2332" should be understood as a "prototype" or "generic" term for all PRRS viruses, rather than as a reference to the deposited strain. Boehringer chose to claim its virus using the term "ATCC-VR2332," a term on its face referring to a particular ATCC deposit. Boehringer did not use the broader term "PRRS virus," nor did Boehringer attempt to claim the virus in terms of the more general functional and structural properties disclosed by the specification. Boehringer did not choose to define the term "ATCC-VR2332" in the specification, nor did Boehringer state that ATCC-VR2332 was a "generic" or "prototype" virus, nor did Boehringer assert that viruses related to but not identical to the isolated strain were within the scope of the invention. These choices must be held against it. We therefore conclude that the district court properly construed "ATCC-VR2332" to refer to the strain of virus deposited with the ATCC.

Schering argues that no reasonable jury could find that Schering's VR2525 virus is equivalent to the ATCC-VR2332 viral strain recited by the claim in suit. Under the "function-way-result" analysis, Schering focuses on the fact that ATCC-VR2332 is a pathogenic virus, causing PRRS, while Schering's VR2525 is not. Schering argues that this distinction precludes a finding of equivalence, because Schering's virus generates a protective immune response when administered to pigs, while a pig inoculated with ATCC-VR2332 develops PRRS. Thus, when administered to pigs, VR2525 resembles ATCC-VR2332 in neither function, way, nor result. Schering's argument, however, flies in the face of the basic principle that the relevant analysis is of the role played by each element in the context of the specific patent claim, not whether the accused element is capable of performing different roles than the claim element in other contexts. What happens when the virus is administered to a pig is irrelevant to the assessment of whether the two viral strains are equivalent in the *in vitro* culture method defined by claim 2. The jury was presented with expert testimony from which it could conclude that VR2525 plays the same role as VR2332 in performance of the claimed method. The fact that, in other contexts, VR2525 can perform other functions in different ways to yield a different result is not relevant.

Schering further argues that a finding of no substantial differences is precluded by the evidence that there are at least 73 nucleotide differences between VR2525 and ATCC-VR2332 in a particular region

of their RNA genomes. Schering's expert (as well as Boehringer's) noted that even a single nucleotide substitution can have a substantial effect on viral function. Schering proposes that in the face of this evidence, no reasonable jury could have concluded that two viruses having at least 73 nucleotide divergences lack substantial differences.

However, the uncontroversial fact that even a single nucleotide or amino acid substitution may drastically alter the function of a gene or protein is not evidence of anything at all. The mere possibility that a single mutation could affect biological function cannot as a matter of law preclude an assertion of equivalence, and Schering made no showing that any of these substitutions actually affected any property of the virus relevant to the claim at hand. While it may be reasonable to assume that genetic similarity is a relevant comparison between the viruses for purposes of the claimed method, the jury was presented with expert testimony that the two viral genomes are highly similar overall and that any differences between the two are insignificant. A reasonable jury could easily rely on this testimony to conclude that the genetic differences between VR2525 and ATCC–VR2332 are insubstantial in the context of the claimed method.

## 4 Defenses

### **Bowman v. Monsanto Co.** 133 S. Ct. 1761 (2013)

Under the doctrine of patent exhaustion, the authorized sale of a patented article gives the purchaser, or any subsequent owner, a right to use or resell that article. Such a sale, however, does not allow the purchaser to make new copies of the patented invention. The question in this case is whether a farmer who buys patented seeds may reproduce them through planting and harvesting without the patent holder's permission. We hold that he may not.

#### I

Respondent Monsanto invented a genetic modification that enables soybean plants to survive exposure to glyphosate, the active ingredient in many herbicides (including Monsanto's own Roundup). Monsanto markets soybean seed containing this altered genetic material as Roundup Ready seed. Farmers planting that seed can use a glyphosate-based herbicide to kill weeds without damaging their crops. Two patents issued to Monsanto cover various aspects of its Roundup Ready technology, including a seed incorporating the genetic alteration.

Monsanto sells, and allows other companies to sell, Roundup Ready soybean seeds to growers who assent to a special licensing agreement. That agreement permits a grower to plant the purchased

seeds in one (and only one) season. He can then consume the resulting crop or sell it as a commodity, usually to a grain elevator or agricultural processor. But under the agreement, the farmer may not save any of the harvested soybeans for replanting, nor may he supply them to anyone else for that purpose. These restrictions reflect the ease of producing new generations of Roundup Ready seed. Because glyphosate resistance comes from the seed's genetic material, that trait is passed on from the planted seed to the harvested soybeans: Indeed, a single Roundup Ready seed can grow a plant containing dozens of genetically identical beans, each of which, if replanted, can grow another such plant – and so on and so on. The agreement's terms prevent the farmer from co-opting that process to produce his own Roundup Ready seeds, forcing him instead to buy from Monsanto each season.

Petitioner Vernon Bowman is a farmer in Indiana who, it is fair to say, appreciates Roundup Ready soybean seed. He purchased Roundup Ready each year, from a company affiliated with Monsanto, for his first crop of the season. In accord with the agreement just described, he used all of that seed for planting, and sold his entire crop to a grain elevator (which typically would resell it to an agricultural processor for human or animal consumption).

Bowman, however, devised a less orthodox approach for his second crop of each season. Because he thought such late-season planting "risky," he did not want to pay the premium price that Monsanto charges for Roundup Ready seed. He therefore went to a grain elevator; purchased "commodity soybeans" intended for human or animal consumption; and planted them in his fields. Those soybeans came from prior harvests of other local farmers. And because most of those farmers also used Roundup Ready seed, Bowman could anticipate that many of the purchased soybeans would contain Monsanto's patented technology. When he applied a glyphosate-based herbicide to his fields, he confirmed that this was so; a significant proportion of the new plants survived the treatment, and produced in their turn a new crop of soybeans with the Roundup Ready trait. Bowman saved seed from that crop to use in his late-season planting the next year – and then the next, and the next, until he had harvested eight crops in that way. Each year, that is, he planted saved seed from the year before (sometimes adding more soybeans bought from the grain elevator), sprayed his fields with glyphosate to kill weeds (and any non-resistant plants), and produced a new crop of glyphosate-resistant – i.e., Roundup Ready – soybeans.

After discovering this practice, Monsanto sued Bowman for infringing its patents on Roundup Ready seed. Bowman raised patent exhaustion as a defense, arguing that Monsanto could not control his use of the soybeans because they were the subject of a prior au-

thorized sale (from local farmers to the grain elevator). The District Court rejected that argument, and awarded damages to Monsanto of \$84,456.

## II

The doctrine of patent exhaustion limits a patentee's right to control what others can do with an article embodying or containing an invention. Under the doctrine, the initial authorized sale of a patented item terminates all patent rights to that item. And by exhaust[ing] the [patentee's] monopoly" in that item, the sale confers on the purchaser, or any subsequent owner, the right to use [or] sell" the thing as he sees fit. ?? We have explained the basis for the doctrine as follows: "[T]he purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward ... by the sale of the article"; once that "purpose is realized the patent law affords no basis for restraining the use and enjoyment of the thing sold." *Id.*

Consistent with that rationale, the doctrine restricts a patentee's rights only as to the "particular article" sold; it leaves untouched the patentee's ability to prevent a buyer from making new copies of the patented item. The purchaser of the patented machine does not acquire any right to construct another machine either for his own use or to be vended to another. Rather, a second creation of the patented item calls the monopoly, conferred by the patent grant, into play for a second time. That is because the patent holder has "received his reward" only for the actual article sold, and not for subsequent recreations of it. If the purchaser of that article could make and sell endless copies, the patent would effectively protect the invention for just a single sale. Bowman himself disputes none of this analysis as a general matter: He forthrightly acknowledges the "well settled" principle "that the exhaustion doctrine does not extend to the right to 'make' a new product."

Unfortunately for Bowman, that principle decides this case against him. Under the patent exhaustion doctrine, Bowman could resell the patented soybeans he purchased from the grain elevator; so too he could consume the beans himself or feed them to his animals. Monsanto, although the patent holder, would have no business interfering in those uses of Roundup Ready beans. But the exhaustion doctrine does not enable Bowman to make additional patented soybeans without Monsanto's permission (either express or implied). And that is precisely what Bowman did. He took the soybeans he purchased home; planted them in his fields at the time he thought best; applied glyphosate to kill weeds (as well as any soy plants lacking the Roundup Ready trait); and finally harvested more (many more) beans than he started with. That is how "to 'make' a new product,"

to use Bowman's words, when the original product is a seed. Because Bowman thus reproduced Monsanto's patented invention, the exhaustion doctrine does not protect him.

Were the matter otherwise, Monsanto's patent would provide scant benefit. After inventing the Roundup Ready trait, Monsanto would, to be sure, receive its reward for the first seeds it sells. But in short order, other seed companies could reproduce the product and market it to growers, thus depriving Monsanto of its monopoly. And farmers themselves need only buy the seed once, whether from Monsanto, a competitor, or (as here) a grain elevator. The grower could multiply his initial purchase, and then multiply that new creation, ad infinitum – each time profiting from the patented seed without compensating its inventor. Bowman's late-season plantings offer a prime illustration. After buying beans for a single harvest, Bowman saved enough seed each year to reduce or eliminate the need for additional purchases. Monsanto still held its patent, but received no gain from Bowman's annual production and sale of Roundup Ready soybeans. The exhaustion doctrine is limited to the "particular item" sold to avoid just such a mismatch between invention and reward.

Bowman principally argues that exhaustion should apply here because seeds are meant to be planted. The exhaustion doctrine, he reminds us, typically prevents a patentee from controlling the use of a patented product following an authorized sale. And in planting Roundup Ready seeds, Bowman continues, he is merely using them in the normal way farmers do. Bowman thus concludes that allowing Monsanto to interfere with that use would "creat[e] an impermissible exception to the exhaustion doctrine" for patented seeds and other "self-replicating technologies.

But it is really Bowman who is asking for an unprecedented exception – to what he concedes is the "well settled" rule that "the exhaustion doctrine does not extend to the right to 'make' a new product." Reproducing a patented article no doubt "uses" it after a fashion. But as already explained, we have always drawn the boundaries of the exhaustion doctrine to exclude that activity, so that the patentee retains an undiminished right to prohibit others from making the thing his patent protects. See, e.g., *Cotton-Tie Co. v. Simmons* (holding that a purchaser could not "use" the buckle from a patented cotton-bale tie to "make" a new tie). That is because, once again, if simple copying were a protected use, a patent would plummet in value after the first sale of the first item containing the invention. The undiluted patent monopoly, it might be said, would extend not for 20 years (as the Patent Act promises), but for only one transaction. And that would result in less incentive for innovation than Congress wanted. Hence our repeated insistence that exhaustion applies only to the particular item sold, and not to reproductions.

Nor do we think that rule will prevent farmers from making appropriate use of the Roundup Ready seed they buy. Bowman himself stands in a peculiarly poor position to assert such a claim. As noted earlier, the commodity soybeans he purchased were intended not for planting, but for consumption. Indeed, Bowman conceded in deposition testimony that he knew of no other farmer who employed beans bought from a grain elevator to grow a new crop. So a non-replicating use of the commodity beans at issue here was not just available, but standard fare. And in the more ordinary case, when a farmer purchases Roundup Ready seed qua seed – that is, seed intended to grow a crop – he will be able to plant it. Monsanto, to be sure, conditions the farmer’s ability to reproduce Roundup Ready; but it does not – could not realistically – preclude all planting. No sane farmer, after all, would buy the product without some ability to grow soybeans from it. And so Monsanto, predictably enough, sells Roundup Ready seed to farmers with a license to use it to make a crop. Applying our usual rule in this context therefore will allow farmers to benefit from Roundup Ready, even as it rewards Monsanto for its innovation.

Still, Bowman has another seeds-are-special argument: that soybeans naturally “self-replicate or ‘sprout’ unless stored in a controlled manner,” and thus “it was the planted soybean, not Bowman” himself, that made replicas of Monsanto’s patented invention. But we think that blame-the-bean defense tough to credit. Bowman was not a passive observer of his soybeans’ multiplication; or put another way, the seeds he purchased (miraculous though they might be in other respects) did not spontaneously create eight successive soybean crops. As we have explained, Bowman devised and executed a novel way to harvest crops from Roundup Ready seeds without paying the usual premium. He purchased beans from a grain elevator anticipating that many would be Roundup Ready; applied a glyphosate-based herbicide in a way that culled any plants without the patented trait; and saved beans from the rest for the next season. He then planted those Roundup Ready beans at a chosen time; tended and treated them, including by exploiting their patented glyphosate-resistance; and harvested many more seeds, which he either marketed or saved to begin the next cycle. In all this, the bean surely figured. But it was Bowman, and not the bean, who controlled the reproduction (unto the eighth generation) of Monsanto’s patented invention.

Our holding today is limited – addressing the situation before us, rather than every one involving a self-replicating product. We recognize that such inventions are becoming ever more prevalent, complex, and diverse. In another case, the article’s self-replication might occur outside the purchaser’s control. Or it might be a necessary but incidental step in using the item for another purpose. *Cf.* 17 U.S.C. § 117(a)(1) (“[I]t is not [a copyright] infringement for the owner of a

In the Canadian case of *Monsanto Canada Inc. v. Schmeiser*, 2001 FCT 256, a farmer argued that Roundup Ready seeds had blown onto his fields, or been carried by insects. But the court did not have to consider the legal consequences of these possibilities, because “none of the suggested sources could reasonably explain the concentration or extent of Roundup Ready canola of a commercial quality evident from the results of tests on Schmeiser’s crop.”

copy of a computer program to make ... another copy or adaptation of that computer program provide[d] that such a new copy or adaptation is created as an essential step in the utilization of the computer program"). We need not address here whether or how the doctrine of patent exhaustion would apply in such circumstances. In the case at hand, Bowman planted Monsanto's patented soybeans solely to make and market replicas of them, thus depriving the company of the reward patent law provides for the sale of each article. Patent exhaustion provides no haven for that conduct.

§ 287(c)(1)

*Limitation on damages and other remedies; marking and notice*

Why are doctors special?

With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 [i.e., all meaningful remedies] shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

## B Plants

### 1 Plant Patents

#### **Imazio Nursery, Inc. v. Dania Greenhouses**

69 F.3d 1560 (Fed. Cir. 1995)

(Rich, J.)

At least as early as 1892, legislation was proposed to grant patent rights for plant-related inventions. Plant patent legislation was supported by such prominent individuals as Thomas Edison who stated that "nothing that Congress could do to help farming would be of greater value and permanence than to give to the plant breeder the same status as the mechanical and chemical inventors now have through the law." It was also supported by Luther Burbank, a leading plant breeder of the day, whose widow stated that her late husband "said repeatedly that until Government made some such provision [for plant patent protection] the incentive to create work with plants was slight and independent research and breeding would be discouraged to the great detriment of horticulture."

The Townsend-Purnell Plant Patent Act was passed by Congress on May 13, 1930 and was signed by President Hoover on May 23, 1930. It was the first legislation anywhere in the world to grant patent rights to plant breeders and was enacted to "afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given to industry, and thus assist in placing agriculture on a basis of economic equality with industry."

Before enactment of the Plant Patent Act, two factors were thought to prevent plants from being patentable subject matter. The first was the belief that plants, even those bred by man, were products of na-

ture and therefore not subject to patent protection. The second factor was that plants were not considered amenable to the "written description" requirement of the predecessor of 35 U.S.C. § 112, first paragraph. In promulgating the Plant Patent Act, Congress addressed both concerns. It explained that the work of the plant breeder "in aid of nature" was subject to patent protection. Additionally, the written description requirement, applicable to utility patents, was relaxed in favor of a "description ... as complete as is reasonably possible."

As originally enacted, the provisions for plant patent protection were made as amendments to the general patent law. With the promulgation of the 1952 Patent Act, the plant patent provisions were included as a separate chapter of the statute. It should be noted that although the plant patent provisions were separated from the utility patent provisions with the enactment of the 1952 Patent Act, the statute explicitly states that "the provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided."

The only amendment to the plant patent provisions since enactment of the 1952 Patent Act came in 1954 when section 161 was amended to preclude patent protection for plants found in an uncultivated state, thereby broadening the statute to include plants found in a cultivated state and subsequently asexually reproduced.

**Mark D. Janis & Jay P. Kesan, *U.S. Plant Variety Protection: Sound and Fury ... ?***

**39 Houston L. Rev. 727 (2002)**

Congress never adopted explicit legislation implementing fully the patent approach to the problem of incentives for plant breeding. Instead, in the Townsend-Purnell Plant Patent Act of 1930, Congress created a plant patent regime limited to varieties that had been asexually reproduced.

The House Report accompanying the plant patent legislation acknowledged that the asexual reproduction requirement "greatly narrows the scope of the bill." The bill proposed "to give the necessary incentive to preserve new varieties" by encouraging breeders to multiply asexually the new and valuable varieties that they discovered, but the bill did not "give any patent protection to the right of propagation of the new variety by seed, irrespective of the degree to which the seedlings come true to type."

For U.S. law purposes, then, the plant patent legislation created a distinction between plants propagated asexually and plants reproduced via seed. It might be tempting to view the distinction as inevitable, flowing as a matter of necessity from the intrinsic qualities of plants. By extension, the appearance of *sui generis* plant variety regimes would likewise seem to rest on a straightforward, biological

rationale.

In fact, the introduction of the asexual/sexual distinction in U.S. plant intellectual property law was as much a matter of political expediency as it was a matter of biology, as a careful analysis of the history of the plant patent legislation reveals.<sup>38</sup> Major nursery operators – whose varieties were easily propagated asexually – comprised the chief lobbying influence advocating patent protection for plant innovation, and put recognition of plant breeding as “invention” on equal footing with invention in other industrial sectors. By contrast, seed companies saw themselves predominantly as brokers rather than as developers of new varieties. In addition, the nursery operators dealt in ornamentals and fruits, while the seed companies dealt in staples of the food supply. One may assume that patent protection extending to the latter may have been politically unpalatable at the outset of the Great Depression.

### Patent Act

35 U.S.C. § 161  
*Patents for plants*

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.

The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.

35 U.S.C. § 162  
*Description, claim*

No plant patent shall be declared invalid for noncompliance with section 112 if the description is as complete as is reasonably possible.

35 U.S.C. § 163  
*Grant*

In the case of a plant patent, the grant shall include the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States.

### Code of Federal Regulations

37 C.F.R. § 1.164  
*Claim*

The claim shall be in formal terms to the new and distinct variety of the specified plant as described and illustrated, and may also recite the principal distinguishing characteristics. More than one claim is not permitted.

37 C.F.R. § 1.165  
*Plant drawings*

<sup>38</sup>Professor Cary Fowler has provided an insightful study of the subject. *See generally* Cary Fowler, *The Plant Patent Act of 1930: A Sociological History of its Creation*, 82 J. Pat. & Trademark Off. Soc’y 621 (2000).

- (a) Plant patent drawings should be artistically and competently executed and must comply with the requirements of § 1.84. View numbers and reference characters need not be employed unless required by the examiner. The drawing must disclose all the distinctive characteristics of the plant capable of visual representation.
- (b) The drawings may be in color. The drawing must be in color if color is a distinguishing characteristic of the new variety. Two copies of color drawings or photographs must be submitted.

The applicant may be required to furnish specimens of the plant, or its flower or fruit, in a quantity and at a time in its stage of growth as may be designated, for study and inspection. Such specimens, properly packed, must be forwarded in conformity with instructions furnished to the applicant. When it is not possible to forward such specimens, plants must be made available for official inspection where grown.

37 C.F.R. § 1.166  
*Specimens*



US00PP15399P3

(12) **United States Plant Patent**  
**Zaiger et al.**

(10) **Patent No.:** **US PP15,399 P3**  
(45) **Date of Patent:** **Dec. 7, 2004**

(54) **CHERRY TREE NAMED ‘ROYAL KAY’**

(58) **Field of Search** ..... Plt./181

(50) Latin Name: *Prunus avium*  
Varietal Denomination: **Royal Kay**

*Primary Examiner*—Anne Marie Grunberg

(57) **ABSTRACT**

(76) Inventors: **Gary Neil Zaiger**, 1907 Elm Ave., Modesto, CA (US) 95358; **Leith Marie Gardner**, 1207 Grimes Ave., Modesto, CA (US) 95358; **Grant Gene Zaiger**, 4005 California Ave., Modesto, CA (US) 95358

A new and distinct variety of cherry tree (*Prunus avium*). The following features of the tree and its fruit are characterized with the tree budded on ‘Mahaleb’ Rootstock (non-patented), grown on Handford sandy loam soil with Storie Index rating 95, in USDA Hardiness Zone 9, near Modesto, Calif., with standard commercial fruit growing practices such as pruning, thinning, spraying, irrigation and fertilization. Its novelty consist of the following combination of desirable features:

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 93 days.

1. Vigorous, upright tree growth.
2. Fruit maturing in the early season.
3. Fruit with attractive red skin color.
4. Heavy and regular production of large size fruit.
5. Fruit with very good flavor and eating quality.
6. Fruit with good handling and storage quality.

(21) Appl. No.: **10/302,701**

(22) Filed: **Nov. 25, 2002**

(65) **Prior Publication Data**

US 2004/0103463 P1 May 27, 2004

(51) **Int. Cl.**<sup>7</sup> ..... **A01H 5/00**

(52) **U.S. Cl.** ..... **Plt./181**

**1 Drawing Sheet**

**1**

**BACKGROUND OF THE VARIETY**

1. Field of the Invention

In the field of plant genetics, we conduct an extensive and continuing plant-breeding program including the organization and asexual reproduction of orchard trees, and of which plums, peaches, nectarines, apricots, cherries and interspecifics are exemplary. It was against this background of our activities that the present variety of cherry tree was originated and asexually reproduced by us in our experimental orchard located near Modesto, Stanislaus County, Calif.

2. Prior Varieties

Among the existing varieties of cherry trees, which are known to us, and mentioned herein, are ‘Stella’ Cherry (non-patented) and ‘Early Burlat’ Cherry (non-patented).

**STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH AND DEVELOPMENT**

Not applicable.

**ORIGIN OF THE VARIETY**

The present new variety of cherry tree (*Prunus avium*) was developed by us in our experimental orchard located near Modesto, Calif. The new cherry tree was selected in 1992 from a group of open pollinated seedlings grown from seed of a selected seedling with the field identification number 13HA431. The seedling cherry tree (13HA431) originated as a third generation seedling from open pollinated seed of ‘Stella’ Cherry (non-patented) and was selected to be used as a parent in our cherry breeding program. We grew a large number of these open pollinated seedlings on their own root under careful observation and selected the present variety for asexual reproduction due to

**2**

it’s heavy fruit production, early maturity, and good fruit quality.

**ASEXUAL REPRODUCTION OF THE VARIETY**

Asexual reproduction of the new and distinct variety of cherry tree was by budding to ‘Mahaleb’ Rootstock (non-patented), as performed by us in our experimental orchard located near Modesto, Calif., and shows that reproductions run true to the original tree and all characteristics of the tree and its fruit are established and transmitted through succeeding asexual propagations.

**SUMMARY OF THE NEW VARIETY**

The present new variety of cherry tree is of large size, vigorous, upright growth and a regular bearer of large fruit with medium firmness, very good flavor and eating quality. The fruit is further characterized by its attractive red skin color and early fruit maturity. In comparison to the standard commercial cherry variety ‘Early Burlat’ (non-patented), the new variety blooms approximately 7 days earlier and the fruit is approximately 3 days earlier in maturity. In comparison to ‘Stella’ Cherry (non-patented), the new variety blooms approximately 7 days earlier and the fruit matures approximately 25 days earlier. In comparison to its parent plant, the instant plant ripens earlier.

**PHOTOGRAPH OF THE VARIETY**

The accompanying color photographic illustration shows typical specimens of the foliage and fruit of the present new cherry variety. The illustration shows the upper and lower surface of the leaves, an exterior and sectional view of a fruit divided in its suture plane to show flesh color, pit cavity and the stone remaining in place. The photographic illustration was taken shortly after being picked (shipping ripe) and the

colors are as nearly true as is reasonably possible in a color representation of this type.

#### DESCRIPTION OF THE VARIETY

The following is a detailed botanical description of the new variety of cherry tree, 7 years of age, its flowers, foliage and fruit, as based on observations of specimens grown near Modesto, Calif., with color in accordance with Munsell Book of Color.

#### Tree:

*Size*.—Large. Tree pruned to 4 to 5 meters in height for economical harvesting of fruit.

*Vigor*.—Vigorous. Tree growth reaching 1 to 2 meters the first growing season. Growth rate varies with soil type and depth, cultural practices and climatic conditions.

*Form*.—Upright. During the first and second growing seasons scaffolds are selected and tied down to increase crotch angle and help spread tree to desired width of 3 to 4 meters.

*Branching habit*.—Upright. Crotch angle approximately 40° when juvenile, upon maturity the weight of the fruit tends to increase the branch angles.

*Productivity*.—Very productive. Produces adequate fruit set annually.

*Bearer*.—Regular. Adequate fruit set for three consecutive years.

*Fertility*.—Self sterile, pollinator required.

*Density*.—Medium dense. Usually pruned to form open vase shape to enhance health of fruit spurs and fruit color throughout the tree.

*Hardiness*.—Hardy. Tree grown in USDA Hardiness Zone 9. Winter chilling requirement is approximately 750 hours at or below 45° F.

#### Trunk:

*Size*.—Large. Measured 20.3 cm in circumference at 25.4 cm above ground on a 7 year old tree. Varies with soil type, climatic conditions and cultural practices.

*Stocky*.—Medium stocky.

*Texture*.—Medium rough, increases slightly with age of tree.

*Color*.—Varies from 5Y 6/2 to 7.5Y 6/2.

#### Branches:

*Size*.—Medium. Average circumference 12.1 cm at 1.2 meters above ground.

*Surface texture*.—Smooth on new growth, becomes medium rough on mature growth.

*Lenticels*.—Numerous. Average of 35 in a 25.8 square cm section. Average length 3.1 mm, increases in size as branches grow larger. Average width 1.6 mm. Color — 5YR 5/8.

*Color*.—New growth varies from 5Y 4/6 to 5Y 5/4. Old growth 7.5R 5/2, varies with age of growth.

#### Leaves:

*Size*.—Large. Average length 126.1 mm. Average width 60.9 mm.

*Form*.—Varies between ovate and lanceolate.

*Apex*.—Acuminate.

*Base*.—Cuneate.

*Margin*.—Serrate.

*Thickness*.—Medium.

*Surface texture*.—Upper surface relatively smooth, slight indentation over leaf veins, glabrous. Lower

surface relatively smooth, slight ridges created by midrib and pinnate venation, glabrous.

*Petiole*.—Average length 38.1 mm. Average width 1.6 mm. Grooved longitudinally. Color of upper surface varies from 5R 2/4 to 5R 2/6. Color of lower surface varies from 2.5GY 5/6 to 2.5GY 5/8.

*Glands*.—Reniform. Large size. Number varies from 1 to 2. Average number 2. Average length 1.5 mm. Average width 1.3 mm. Located primarily on the upper portion of the petiole. Color varies from 2.5GY 8/4 to 7.5R 3/8 when exposed to the sun.

*Color*.—Upper surface varies from 5GY 3/4 to 5GY 4/4. Lower surface varies from 2.5GY 4/4 to 2.5GY 5/4.

*Midvein*.—Color varies from 5Y 5/6 to 5Y 6/6.

#### Flower buds:

*Size*.—Large. Average length 15.5 mm. Average diameter 6.9 mm.

*Hardiness*.—Hardy in all stone fruit growing areas in California.

*Form*.—Plump, conical.

*Pedicel*.—Average length 25.4 mm. Average width 2.5 mm. Color varies from 2.5GY 5/4 to 2.5GY 6/4.

*Color*.—N 9.5/.

*Number of buds per spur*.—Average 5, varies from 3 to 8.

#### Flowers:

*Size*.—Large. Average height 21.2 mm. Average diameter 34.7 mm.

*Petals*.—Number — 5, alternately arranged to sepals. Nearly orbicular, narrows at point of attachment. Outer edge slightly cleft. Average length 16.5 mm. Average width 15.6 mm.

*Sepals*.—Number — 5, alternately arranged to petals. Triangular shape. Both upper and lower surfaces glabrous. Average length 7.3 mm. Average width 4.6 mm. Color — upper surface 2.5GY 5/4, lower surface 2.5GY 6/4.

*Stamens*.—Average number per flower 30. Average filament length 11.8 mm. Filament color N 9.5/. Color of anthers 1.25Y 8/12.

*Pollen*.—Abundant, pollinator required — not self-fertile. Color — 1.25Y 8/12.

*Pistil*.—Number per flower — usually one. Average length 16.5 mm, stigma is usually at the same height as the anthers. Surface — glabrous. Color — 2.5GY 9/6.

*Fragrance*.—Slight to moderate aroma.

*Blooming period*.—Date of First Bloom Mar. 9, 2002. Date of Petal Fall Mar. 22, 2002. Varies slightly with climatic conditions.

*Color*.—N 9.5/.

*Number flowers per flower bud*.—Average 4, varies from 2 to 4.

*Pedicel*.—Medium length. Average length 26.1 mm. Average width 2.7 mm. Color 2.5GY 8/4.

#### Fruit:

*Maturity when described*.—Firm ripe.

*Date of first picking*.—May 2, 2002.

*Date of last picking*.—May 9, 2002. Varies slightly with climatic conditions.

*Size*.—Large. Average diameter axially 28.5 mm. Average transversely in suture plane 25.4 mm. Average weight 6.9 grams. Average weight varies slightly with fertility of the soil, amount of fruit set and climatic conditions.

- Form.*—Globose. Slightly flattened at apex and base.  
*Suture.*—Shallow, relatively smooth.  
*Ventral surface.*—Smooth, nearly rounded.  
*Apex.*—Varies from slightly retuse to rounded.  
*Base.*—Retuse.  
*Cavity.*—Rounded. Average depth 1.8 mm. Average diameter 2.2 mm.
- Stem:  
*Size.*—Medium. Average length 34.9 mm. Average width 1.6 mm.  
*Color.*—Varies from 2.5GY 4/4 to 2.5GY 5/4.
- Flesh:  
*Ripens.*—Evenly.  
*Texture.*—Smooth, relatively meaty.  
*Fibers.*—Few, small and tender.  
*Firmness.*—Medium firm, comparable to ‘Early Burlat’ Cherry (non-patented).  
*Aroma.*—Slight.  
*Amydgalin.*—Undetected.  
*Eating quality.*—Good.  
*Flavor.*—Very good, good balance between acid and sugar.  
*Juice.*—Moderate amount, enhances flavor.  
*Brix.*—Average of 13.5°, varies slightly with amount of fruit per tree and climatic conditions.  
*Color.*—Varies from 2.5R 4/8 to 5R 3/8. Varies with fruit maturity. Pit cavity color 5R 2/6.
- Skin:  
*Thickness.*—Medium.  
*Surface.*—Smooth.  
*Bloom.*—Wanting.  
*Tendency to crack.*—None during dry weather, only slight tendency to crack in wet weather, varies with stage of fruit maturity.  
*Color.*—Varies from 2.5R 2/4 to 5R 3/10.  
*Tenacity.*—Tenacious to flesh.  
*Astringency.*—None.
- Stone:  
*Type.*—Clingstone.  
*Size.*—Medium. Average length 11.3 mm. Average width 8.9 mm. Average thickness 7.2 mm.  
*Form.*—Ovoid.  
*Base.*—Slightly rounded.  
*Apex.*—Round to slight apical point.  
*Surface.*—Smooth, except for ridges near suture.  
*Sides.*—Equal to unequal. Some stones have one side extending further from suture plane.

- Ridges.*—A small, narrow ridge on each side of suture, extending from base to apex.  
*Tendency to split.*—None.  
*Color.*—Varies from 10YR 7/6 to 10YR 7/8 when dry.
- Kernal:  
*Form.*—Ovoid.  
*Taste.*—Bitter.  
*Viability.*—Viable. Good embryo development.  
*Size.*—Average length 7.9 mm. Average width 5.1 mm. Average depth 4.4 mm.  
*Skin color.*—Varies from 10YR 5/6 to 10YR 6/8 when dry.
- Use: Dessert. Market — local and long distance.  
 Keeping quality: Good. Held well for 21 days in cold storage at 38° to 42° F. and maintained good appearance and eating quality.  
 Shipping quality: Good. Minimal bruising or scarring in packing and shipping trials.  
 Plant disease resistance/susceptibility: No specific testing for relative plant/fruit disease has been designed. Under close observation during planting, growing and harvesting of fruit, under normal cultural and growing conditions near Modesto, Calif., no particular plant/fruit disease resistance or susceptibility has been observed. Any variety or selection observed during indexing of plant characteristics with abnormal susceptibility is destroyed and eliminated from our breeding program.
- The present new variety of cherry tree, its flowers, foliage and fruit herein described may vary in slight detail due to climate, soil conditions and cultural practices under which the variety may be grown. The present description is that of the variety grown under the ecological conditions prevailing near Modesto, Calif.
- It is claimed:  
 1. A new and distinct variety of cherry tree, substantially as illustrated and described, characterized by its large size, vigorous, upright growth and being a regular and productive bearer of large size fruit with very good flavor and eating quality; the fruit is further characterized by its attractive red skin color and by maturing in the early season with good handling and shipping qualities, and in comparison to ‘Early Burlat’ Cherry (non-patented), the new variety blooms approximately 7 days earlier and the fruit is approximately 3 days earlier in maturity.

\* \* \* \* \*

U.S. Patent

Dec. 7, 2004

Plant 15,399



## a Subject Matter

### In re Arzberger 112 F.2d 834 (CCPA 1940)

This is an appeal from a decision rejecting the single claim of appellant's application for a plant patent. The alleged invention is described by the examiner in his statement to the Board of Appeals as follows:

This application relates to a species of bacteria. This species of bacteria is named by applicant *Clostridium saccharo-butyl-aceticum-liquefaciens* and cultured by him from Louisiana cane field soil. These bacteria are useful for producing butyl alcohol, acetone, and ethyl alcohol when grown in a suitable nutrient carbohydrate medium. Reproduction of these bacteria is asexual, by binary fission.

We are of the opinion that, while bacteria possess some of the characteristics of plants and some of the characteristics of animals, it is generally recognized by scientists that the characteristics of plants predominate in bacteria, and bacteria are usually scientifically classified as plants.

Times and taxonomies change. Today, plants are classified as eukaryotes (whose cells have organelles with membranes), along with animals, fungi, many amoebas and algae, and much more. Bacteria are prokaryotes (which lack such organelles) and make up their own domain of life. Asking whether bacteria are plants or animals is like asking whether Africans are from Mexico or Ecuador.

In Webster's New International Dictionary the first definition of "plant" reads as follows: "1. A young tree, shrub, or herb, planted or ready to plant; a slip, cutting, or sapling; \* \* \*." The third definition is a lengthy description of plants from a scientific standpoint, and in this definition bacteria are mentioned.

We think it may fairly be said that in the common language of the people, the meaning of the word "plant" is as stated in the first definition, above quoted. At any rate, whether Congress intended to include in the term "plant" all organic matter which may be scientifically classified as plants is open to such doubt as to warrant resort to the legislative history of the provision here involved. It is sufficient to say that it fairly appears therefrom that the word "plant" as used therein was used in its popular sense and not in its scientific sense, and that the bill was designed for the benefit of agriculturalists and horticulturalists.

It will be observed that the reports of the Committees state that the bill provides that any person who invents or discovers a new and distinct variety of plant shall be given by patent an exclusive right to propagate that plant by asexual reproduction, and propagation by asexual reproduction is defined in the reports to be "by grafting, budding, cuttings, layering, division, and the like, but not by seeds." While it is true that the bacteria here involved are asexually repro-

duced, it is not here claimed that appellant propagates them by any of the methods above set out, and we do not understand that appellant claims that the bacteria here involved are capable of being reproduced by any of such methods. This, we think, is a strong indication of the character of plants intended to be embraced in the enactment of the legislation under consideration.

That the scientific meaning of a word is not always controlling in the interpretation of statutes was established in the case of *Nix v. Hedden*, where, in the interpretation of a tariff statute, the Supreme Court held that a tomato is a vegetable, although it is scientifically classified as a fruit. The court in its opinion stated: "Botanically speaking, tomatoes are the fruit of a vine, just as are cucumbers, squashes, beans, and peas. But in the common language of the people, whether sellers or consumers of provisions, all these are vegetables which are grown in kitchen gardens, and which, whether eaten cooked or raw, are, like potatoes, carrots, parsnips, turnips, beets, cauliflower, cabbage, celery, and lettuce, usually served at dinner in, with, or after the soup, fish, or meats which constitute the principal part of the repast, and not, like fruits generally, as dessert."

*Nix*: 149 U.S. 304 (1893)

So here, we think that Congress, in the use of the word "plant," was speaking "in the common language of the people," and did not use the word in its strict, scientific sense. The Patent Office tribunals were correct in holding that the subject matter of the claim before us is not within the plant provision.

## b Procedures

### In re Greer

484 F.2d 488 (CCPA 1973)

Appellant's invention relates to a variety of Bermuda grass found growing in a bed of, and allegedly distinct from, a variety of Bermuda grass known as Zimmerly Select. The particular characteristics relied upon by appellant to distinguish his grass from known varieties of Bermuda grass are set forth in the claim which reads as follows:

1. A new and distinct variety of BERMUDA GRASS PLANT, substantially as shown and described, characterized particularly by its outstanding reproductive properties, its large, glossy rhizomes, its high level of resistance to common Bermuda grass diseases and the large percentage of above ground stolons which remain green in freezing weather.

With regard to the "outstanding reproductive" characteristics of the claimed grass, the specification, in substance, indicates that when the

stolons<sup>2</sup> of the grass are planted they cover the soil surface as quickly as do the rhizomes when planted (in fact faster).

In support of the claim that the plant produces "large, glossy rhizomes" the specification states that "some are almost as large in diameter as a lead pencil." Additionally it states that they "penetrated the soil from one inch to two and one-half inches deeper than Coastal Bermuda [grass] rhizomes grown under identical conditions." The specification also indicates that by visual observation of rhizomes, it could be seen that the rhizomes of the claimed grass were larger than those of other Bermuda grasses grown the same way. However, no actual measurements are reported.

To support the claim that the new grass is distinct from others because of the large percentage of stolons remaining green in freezing weather, the specification indicates that a test plot of the claimed grass remained green under the same winter conditions where Zim-merly Select, Coastal Bermuda, and native Bermuda had become dormant.

The claim that the grass is disease resistant is based on the failure of the applicant and other growers of his grass to observe disease in plots of the grass. However, the specification also reveals that other varieties of Bermuda grass grown at the same locations also remained free of disease.

In conformance with the usual procedure for the examination of applications for plant patents, the application was submitted by the Patent Office to the Department of Agriculture for its evaluation of the assertions made in the specification supporting the claim that the grass was a distinct and new variety of plant. In due course a report was provided by the Department of Agriculture to the Patent Office.

1. The claimed grass is reported as superior to five other varieties of bermudagrass in its ability to withstand freezing weather. No comparative data were included in the application to show the relative winter survival of the claimed grass vs. other varieties. In addition to the lack of survival data, it [is] not clear from the application that all varieties were planted and managed in the same fashion.
2. The claimed grass is reported to have a high level of resistance to common bermudagrass diseases. It is stated,

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<sup>2</sup>Webster's Third New International Dictionary, 1971 edition, provides the following definitions: stolon - a horizontal branch from the base of a plant that is either above or below ground and produces new plants from buds at its tip or nodes (as in the strawberry); rhizome - a more or less elongate stem or branch of a plant that is often thickened or tuber shaped as a result of deposits of reserve food material, is usu. horizontal and underground, produces shoots above and roots below, and is distinguished from a true root in possessing buds, nodes and usu. scalelike leaves - called also rootstalk.

however, that no disease was noted on bermudagrass varieties grown at the same locations as the claimed grass. This information does not support the claim for disease resistance as the named varieties differ greatly in their reaction to disease (from highly susceptible to highly resistant). ...

In support of its conclusion that the rejection under § 112 should be affirmed the board cited the following excerpt from the legislative history of the Plant Patent Act of 1930:

Modern methods of identification, together with such amplification thereof as may reasonably be expected, will render it possible and practicable to describe clearly and precisely the characteristics of a particular variety. When this can not be done by an applicant for a patent, the variety is not clearly distinguishable as a distinct variety, and no patent would issue.

From it the board reasoned as follows:

Accordingly, we believe it to be clear that the instant failure to adequately differentiate the claimed grass from other known varieties of Bermuda grass must result in the denial of a patent. We will sustain the rejection.

Appellant has attacked the soundness of the board's decision principally on the ground that § 162 relieves the applicant for a plant patent of the strict requirements of § 112.

In view of the statute, we must agree with appellant that a disclosure containing a description not fully in compliance with § 112 might still be adequate under § 162. In this regard this court, recognizing present technological limitations, has concluded that there is no requirement for a how-to-make disclosure in a plant patent application. *See LeGrice*.

Nevertheless, we do not agree that it was contemplated by Congress that § 162 would operate to allow an applicant to allege characteristics which might be capable of distinguishing one variety of plant from another without sufficient disclosure to establish that these characteristics are indeed present in the claimed plant and absent in the varieties to which it is most closely related.

In the instant case we do not doubt that Bermuda grass having different reproductive properties, disease resistance, etc., when compared to the same properties of known varieties, would be a distinct variety of Bermuda grass. However, if, as is true in this case, the characteristics chosen to define the new plant are meaningless unless compared with predecessor plant varieties, it is incumbent upon the

applicant to provide information of such a character that a meaningful comparison can be made. It is our view that the Patent Office in this case was justified in its conclusion that the criteria used to support the claim did not allow for such a meaningful comparison.

### c Ownership

#### **Ex parte Moore**

115 U.S.P.Q. 145 (BPAI 1957)

This is an appeal from the final rejection of the following claim:

The new and distinct variety of peach tree as shown and described, characterized by its hardiness and resistance to cold and the late time of ripening of the fruit.

Mr. Francis Miller built a house in 1918 and the following year he noticed a small peach tree growing in his yard which he believed sprang from a peach seed planted by one of the men who worked on the house the preceding year. He protected the tree from injury and watered and fertilized it along with the grass and other vegetation in the yard. The tree lived some twelve years or more and before annual crops of large, luscious peaches. During all of this time Miller had no idea that the peach tree in his yard was a new variety. In so far as he was concerned, it was just a peach tree.

In 1928, when the tree was about ten years old and after it had borne seven annual crops, Mr. William Moore, the applicant in the application here on appeal, who was a friend of Miller and an orchardist and developer of new varieties of orchard trees by profession, saw the peach tree in Miller's yard and recognized that it was a new variety. He requested permission to take grafts for the purpose of asexually reproducing the tree on his own farm and with Miller's consent he took ten scions and grafted them on native root stock and had produced several successive generations from the original tree at the time the instant application was filed, thus demonstrating that the peach tree was in fact a new variety.

The issue in this appeal turns about the meaning to be given the word "discovers" in 35 U.S.C. § 161. It is the examiner's view that Miller is the one who discovered the new seedling peach tree rather than appellant because, according to two affidavits by Miller of record, Miller "noticed" or "took notice" of the existence of the new seedling growing in his yard and cultivated it long before appellant Moore observed it and recognized it as a new variety. That the seedling was growing in Miller's yard and that Miller was aware of its existence is corroborated by an affidavit by appellant, also of record in the case. The examiner's position, as we understand it, is that it was the intent of Congress that the word "discovers" in 35 U.S.C. 161 be read as

meaning "finds", and Miller is the one who found the peach tree, not appellant.

Appellant's view, on the other hand, is that although Miller may have found the seedling in the sense that he became aware of its presence in his yard, he did not "find" the new variety because he had no appreciation that the tree was different from other peach trees in the vicinity and, lacking such appreciation, he did not asexually reproduce it and thus establish that the tree was in fact a new variety. In contrast to this he argues that appellant was the one who realized that the tree might perhaps be a new variety and took steps to determine that fact by asexual reproduction through five generations. Since appellant was the first to discover the fact that the tree in Miller's yard was a new variety and then took steps by asexual reproduction to establish the fact that it was a new variety, it is appellant's view that he is the one who really was the discoverer of the new variety under the meaning of the statute.

After careful consideration of the examiner's position as developed at length in his answer, as well as that of appellant, we are of the opinion that appellant Moore is the one who discovered the new variety according to the intent of the statute.

If the word "discovers," as used in the statute, is to be construed as meaning "finds," and "finds" is construed as merely becoming aware of the existence of a plant without any appreciation that it is a new variety and no attempt is made to perpetuate the variety by asexual reproduction, it seems to us that the constitutional objective of advancing the progress of science and useful arts will to a large degree be nullified in so far as found seedlings are concerned. To illustrate; had the matter been left entirely in Miller's hands he would have done nothing to preserve the variety because, although he knew it was a peach tree, so far as he was aware, it had no unusual characteristics and was just an ordinary peach tree. When it had lived out its life span of twelve years and died, the new variety would have been lost for all time. Miller found a peach tree but he did not discover a new variety.

### **Dunn v. Ragin v. Carlile**

**50 U.S.P.Q. 472 (BPI 1941)**

This is an interference involving an application filed March 1, 1940, by Arthur A. Dunn, an application filed October 14, 1939, by Robert Lee Ragin and an application filed May 8, 1937, by Charles W. Carlile. Dunn and Carlile are represented by the same attorney and the Dunn application is assigned to Carlile.

The invention relates to a new variety of seedless orange and orange tree of the so-called pineapple type. The new variety of orange tree defined in the issue count originated as a mutation or bud varia-

tion, commonly called a bud sport, on a pineapple orange tree growing in a cultivated orange grove located in Brevard County, Florida. All the parties to this interference rely upon the propagation of trees from the same bud variation as establishing their respective rights to a patent. While this fact might appear to present a question of originality it is believed that the real issue is purely one of priority among the applicants.

It has long been held that an invention comprises two main inventive acts, conception, and reduction to practice. The question of what constitutes a conception and reduction to practice has been dealt with and decided in an abundance of cases and this question is so well defined in these cases as to require no further comment or citation. In each of these previously decided cases the inventions involved related to a new and useful art, machine, manufacture, or composition of matter. None have related to a new variety of plant. By analogy, however, it may be said that there must be a conception and reduction to practice in cases involving the invention or discovery of a new plant as well as in the previously referred to cases.

The question of what constitutes a reduction to practice is not believed to present any real problem. A reduction to practice may ordinarily be an actual reduction to practice, that is an actual successful building of a machine or performance of the art or process and so on, or it may be a constructive reduction to practice by the filing of a valid allowable application for a patent describing and claiming the invention. The principle of a constructive reduction to practice is a pure fiction of law and came into being as a result of judicial interpretation on the theory that a valid application for a patent completes the invention and makes it available to the public enabling any one of this group skilled in the art to which it relates to reproduce or perform the invention disclosed.

It should be noted that the statute provides as a prerequisite to the filing of an application for a plant patent that the alleged new variety of plant be asexually reproduced. It seems evident therefore that the filing of an application could not complete the invention but that an actual reduction to practice prior to the filing date of the application is an essential requirement. The mere filing of an application for a patent for a new variety of plant would not enable anyone to reproduce such a plant. The plant must actually be in being and reproductions thereof must be obtainable by one of the usual forms of asexual propagation as for example grafting, budding, inarching, division or the like. It would appear therefore that the filing of an application for a plant patent by itself can not properly be considered a constructive reduction to practice because of the statutory prerequisite.

It is believed that an actual reduction to practice is completed when the new variety is actually reproduced by any satisfactory

method of asexual propagation and it is determined that the progeny in fact possess the characteristic or characteristics which distinguish it as a new variety. In the case under consideration an actual reduction to practice would be established when by asexual propagation citrus trees were produced which bore fruits having all the attributes of the variety known as a pineapple orange with the exception of its habit of containing seeds.

A new variety may popularly be said to be conceived or discovered when an individual becomes aware of its existence. An inventor can not properly be said to have discovered a new variety of plant until he is certain that it is in fact a new variety. In cases like the instant case, where the new variety is produced by bud variation it is believed the conception or discovery occurs when the asexual reproduction establishes the bud variation to be in fact a true bud variation or new variety, since the only real test of a true bud variety is its ability to be perpetuated through bud propagation.

The facts as related in the Dunn record are that in 1930 or at least sometime prior to 1933 R. V. Williams, an employee on the grove adjoining that owned by Dunn, discovered a seedless orange growing on a tree in the Dunn grove. He communicated knowledge of his discovery to Dunn and Dunn went to the location designated and found that one limb of the tree bore seedless oranges, while the remainder of the tree bore fruit heavily seeded in accordance with the standard characteristics of the variety. Dunn testified that he observed the tree from year to year until 1937 in order to determine if the habit was fixed. In January of that year the senior party Carlile was at the Dunn grove picking fruit, his company having purchased the crop. Dunn informed Carlile of the seedless tree and allegedly requested him to reproduce the same. Later the tree and all rights in it were sold to Carlile who ultimately removed it and transplanted it in his own nursery. Carlile cut budwood from the tree and budded the same to root stock in order to produce additional specimens. In November 1938 the trees thus reproduced had fruit sufficiently matured to determine that they were in fact seedless orange trees of the pineapple type. At least three generations of such trees had been produced and had borne fruit by the time the testimony was given in this case. Trees were sold as early as July, 1938 to a Mr. MacDonald in Miami and all have since produced seedless oranges.

The Ragin story is as follows: In 1934 Ragin obtained permission from Dunn to cut budwood on the Dunn grove. While cutting budwood he met the witness Williams who informed him that he had found a seedless orange. Williams did not designate the exact tree and Ragin sought it out while cutting budwood. Ragin took budwood and budded some to root stock but also top-worked several trees in order to get more rapid growth. Top-working consists of

cutting out the crown of a mature tree and budding or grafting to it the new growth desired. In 1935 the trees thus top-worked were shown to Springer, nursery inspector for the Florida Plant Board. At that time Ragin told Springer that the new growth was of seedless oranges. The following year Springer again inspected the same trees which were then bearing fruit. He cut fruit and found it to be in fact seedless. He later inspected other trees and found the fruit thereon to be seedless. Springer's testimony stands unchallenged and must be accepted as true. Since Springer testified that he cut fruit the following summer it must be held that Ragin actually reduced to practice no later than the end of the summer of 1936 that is September 15, 1936.

The party Dunn first learned of the seedless oranges sometime prior to 1933 according to the testimony in his behalf. Thereafter he did nothing until he sold the tree to Carlile. Dunn insists that Carlile was his agent in reducing the invention to practice and that he not only sold the tree but also sold his rights in the invention. Since there was no conception until the invention was reduced to practice Dunn could not have sold anything except the tree for he had nothing else to sell. Since Dunn did nothing he can not be held to be an inventor. Even if it were held that the reduction to practice by Carlile did inure to the benefit of Dunn his effective date for conception and reduction to practice would not be earlier than November, 1938. This date is considerably later than September 15, 1936, the date established for Ragin.

Dunn contends however that the finding of the parent tree constituted the conception or discovery contemplated by the statute. If it be assumed without so holding that this contention is correct, Dunn could not prevail since it is not believed that he has established any diligence during the required period. If Dunn's testimony is to be accepted at its face value it would appear that he did absolutely nothing beyond merely observing the tree for a period of seven years. . . . Dunn's excuse for failure to act is not believed to be either convincing or adequate and award must be made in favor of Ragin.

### **In re LeGrice**

301 F.2d 929 (CCPA 1962)

The issue on these consolidated appeals is whether appellant is entitled under 35 U.S.C. § 161 to a patent on each of his applications serial numbers 709,127 and 709,128, filed January 15, 1958, each entitled 'Rosa Floribunda Plant.' The Patent Office Board of Appeals affirmed the final rejection of both applications under 35 U.S.C. § 102(b) on the ground that the inventions had been described in printed publications in England more than one year prior to the dates of filing of the said applications. The publications occur in the National Rose So-

ciety Annual of England and in catalogues. The Annual describes appellant as having raised the roses described and the catalogues show color pictures of these roses. There is no dispute that the publications relate to and picture the identical roses which were originated by appellant and which he now seeks to patent.

We think it is sound law, consistent with the public policy underlying our patent law, that before any publication can amount to a statutory bar to the grant of a patent, its disclosure must be such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention.

In view of the long line of cases dealing with other types of inventions antedating 1930, we think Congress, by failing to provide otherwise, intended that the provisions of section 102(b), as applied to plant patents, should not be interpreted otherwise than they had been with respect to other inventions, i.e., that only an 'enabling' publication is effective as a bar to a subsequent patent.

While man can and does assist nature by the cross-pollination of selected parent plants, the actual creation of the new plant, because of the almost infinite number of possible combinations between the genes and chromosomes, is not presently subject to a controlled reproduction by act of man. While those skilled in this art now understand the mechanics of plant reproduction and the general principles of plant heredity, they are not presently able to control the factors which govern the combinations of genes and chromosomes required to produce a new plant having certain predetermined desired properties.

Appellant in his brief points out:

The description of a plant in a plant patent or in a printed publication at best can only recite, as historical facts, that at one time a certain plant existed, was discovered in a certain manner, and was asexually reproduced. This information may be interesting history, but cannot enable others to reproduce the plant. Prior public use and sale of a plant are the avenues by which a plant enters the public domain.

In the case of manufactured articles, processes and chemical compositions, a different situation prevails. Written descriptions and drawings in publications can often enable others to manufacture the article, practice the process or produce the chemical composition.

We therefore hold that the descriptions in the printed publications here in issue do not meet the requirement of an 'enabling' description, as the statute has been interpreted in numerous cases.

We do not agree with the examiner and the board that this creates an "anomaly" when dealing with plant patents which requires that

“plant publications must be totally ignored as printed publications.” Instead, it requires that the facts of each case be carefully considered to determine whether the description in the printed publication in question does in fact place the invention in the possession of the public. Each case must be decided on its own particular facts in determining whether, in fact, the description in the printed publication is adequate to put the public in possession of the invention and thus bar patentability of a plant under the conditions stated in section 102(b). While the present knowledge of plant genetics may mean as a practical matter, that the descriptions in such general publications as are here involved cannot be relied upon as a statutory bar under section 102(b), we must be mindful of the scientific efforts which are daily adding to the store of knowledge in the fields of plant heredity and plant eugenics which one skilled in this art will be presumed to possess.

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

Normally, the three requirements for patentability are novelty, utility, and nonobviousness. For plant patents, the requirement of distinctness replaces that of utility, and the additional requirement of asexual reproduction is introduced.

The concept of novelty refers to novelty of conception, rather than novelty of use; no single prior art structure can exist in which all of the elements serve substantially the same function. As applied to plants, the Patent Office Board of Appeals held that a “new” plant had to be one that literally had not existed before, rather than one that had existed in nature but was newly found, such as an exotic plant from a remote part of the earth. *Ex parte Foster* In *Greer*, the court indicated that the Board believed that novelty was to be determined by a detailed comparison with other known varieties.

*Foster*: 90 U.S.P.Q. 16 (BPAI 1951)

The legislative history of the Plant Patent Act is of considerable assistance in defining “distinctness.” The Senate Report said:

In order for the new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties and it is immaterial whether in the judgment of the Patent Office the new characteristics are inferior or superior to those of existing varieties. Experience has shown the absurdity of many views held as to the value of new varieties at the time of their creation.

The characteristics that may distinguish a new variety would include, among others, those of habit; immunity from disease; or soil conditions; color of flower, leaf, fruit or stems; flavor; productivity, including ever-bearing

qualities in case of fruits; storage qualities; perfume; form; and ease of asexual reproduction. Within any one of the above or other classes of characteristics the differences which would suffice to make the variety a distinct variety, will necessarily be differences of degree.

A definition of "distinctness" as the aggregate of the plant's distinguishing characteristics seems to us a sensible and workable one.

The third requirement, nonobviousness, is the hardest to apply to plants, though we are bound to do so to the best of our ability. Rephrasing the *John Deere* tests for the plant world, we might ask about (1) the characteristics of prior plants of the same general type, both patented and nonpatented, and (2) the differences between the prior plants and the claims at issue. We see no meaningful way to apply the third criterion to plants – i. e. the level of ordinary skill in the prior art. Criteria one and two are reminiscent of the "distinctness" requirement already in the Plant Patent Act. Thus, if we are to give obviousness an independent meaning, it must refer to something other than observable characteristics.

We think that the most promising approach toward the obviousness requirement for plant patents is reference to the underlying constitutional standard that it codifies – namely, invention.

The general thrust of the "invention" requirement is to ensure that minor improvements will not be granted the protection of a seventeen year monopoly by the state. In the case of plants, to develop or discover a new variety that retains the desirable qualities of the parent stock and adds significant improvements, and to preserve the new specimen by asexually reproducing it constitutes no small feat.

This Court's case dealing with the patent on the chemical compound commonly known as the drug "Darvon," *Eli Lilly & Co. v. Generix Drug Sales*, provides some insight into the problem of how to apply the "invention" requirement to a new and esoteric subject matter. The court first noted that

analogical reasoning is necessarily restricted in many chemical patent cases because of the necessity for physiological experimentation before any use can be determined. In fact, such lack of predictability of useful result from the making of even the slightest variation in the atomic structure or spatial arrangement of a complex molecule deprives the instant claims of obviousness and anticipation of most of their vitality.

The court resolved the apparent dilemma by looking to the therapeutic value of the new drug instead of to its chemical composition:

Reason compels us to agree that novelty, usefulness and

*Eli Lilly v. Generix, Inc.*: 460 F.2d 1096  
(5th Cir. 1972)

non-obviousness inhere in the true discovery that a chemical compound exhibits a new needed medicinal capability, even though it be closely related in structure to a known or patented drug.

The same kind of shift in focus would lead us to a more productive inquiry for plant patents. If the plant is a source of food, the ultimate question might be its nutritive content or its prolificacy. A medicinal plant might be judged by its increased or changed therapeutic value. Similarly, an ornamental plant would be judged by its increased beauty and desirability in relation to the other plants of its type, its usefulness in the industry, and how much of an improvement it represents over prior ornamental plants, taking all of its characteristics together.

#### **d Infringement**

### **Imazio Nursery, Inc. v. Dania Greenhouses** 69 F.3d 1560 (Fed. Cir. 1995)

#### I. BACKGROUND

Bruno Imazio, the owner of Imazio Nursery, Inc. (Imazio), is the inventor of the U.S. Plant Patent No. 5,336, which is entitled "Heather Named Erica Sunset." According to the '336 patent, Mr. Imazio discovered Erica Sunset heather in 1978 "as a seedling of unknown pollen parentage growing in a cultivated field of Erica persoluta, the variety believed to be the seed parent, where it was noticed because of its early blooming and particularly because of its reaching full bloom, from base to tip, more than a month before the parent plant begins to bloom." It was the early blooming of the Erica Sunset, during the Christmas and Valentine's Day seasons, that distinguished the Erica Sunset from other known varieties.

The sole claim of the '336 patent recites:

A new variety of Heather persoluta, substantially as herein shown and described, particularly characterized by its profuse production of blooms over the entire length of the stem beginning in early December.

In April 1992, Imazio sued Coastal for patent infringement alleging that Coastal's "Holiday Heather" infringed the '336 patent.

The trial court adopted the standard that the Plant Patent Act "bars the asexual reproduction and sale of any plant which is the same variety (i.e., has the same essential characteristics) as the patented plant, whether or not the infringing plant was originally cloned from the patented plant." The district court also addressed whether independent creation could be a defense to plant patent infringement.

The district court stated that "independent creation is not a proper defense to patent infringement" and asserted that "the courts' recognition of an independent creation defense would inadvertently entice deliberate infringement, with a fraudulent defense of independent creation asserted."

On the merits of the infringement charge, the trial court reviewed the testimony of both parties' experts and found that the "undisputed evidence thus shows that the patented Erica Sunset heather and the Holiday Heather are the same plants both morphologically (internal and external characteristics) and phenologically (blooming cycle)." The trial court concluded that Imazio had "successfully demonstrated that the Holiday Heather is an asexual reproduction of the Erica Sunset."

#### IV. STATUTORY CONSTRUCTION

We first consider the scope of protection of plant patents.

##### 1. *The meaning of the term "variety"*

The parties dispute the meaning of the term "variety" in section 161. Imazio argues that in providing plant patent protection for "any distinct and new variety of plant," it was intended that a plant patent cover "all plants of that new and distinct variety, i.e., all plants having the same essential and distinctive characteristics." Thus, argues Imazio, "variety" should be construed in its technical, taxonomical sense and should be interpreted to encompass more than just clones of a single plant. Coastal, on the other hand, contends that "variety" should be construed in the vernacular sense as "something different from others of the same general kind." Coastal maintains that by use of the term "variety" Congress did not intend to afford plant patent protection to a range of plants but intended only to protect a single plant.

The Plant Patent Act does not define "variety." However, the legislative history of the Plant Patent Act states:

new and distinct varieties fall into three classes – sports, mutants, and hybrids. In the first class of cases, the sports, the new and distinct variety results from bud variation and not seed variation. A plant or portion of a plant may suddenly assume an appearance or character distinct from that which normally characterizes the variety or species. In the second class of cases, the mutants, the new and distinct variety results from seedling variation by self pollenization of species. In the third class of cases, the hybrids, the new and distinct variety results from seedlings of cross pollenization of two species, two varieties, or a species and a variety.

Thus, upon passage of the Plant Patent Act, a patentable variety could be either a sport, mutant, or hybrid. In addition, by amendment in 1954, Congress added another class of plants, newly found seedlings, subject to the exception that such seedlings found in an uncultivated state cannot be patented.

Section 161 also requires that a patentable variety be new. Additionally, the variety must be distinct. As to this requirement, the legislative history states that

in order for the new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties. The characteristics that may distinguish a new variety would include, among others, those of habit; immunity from disease; resistance to cold, drought, heat, wind, or soil conditions; color of flower, leaf, fruit, or stems; flavor; productivity, including ever-bearing qualities in case of fruits; storage qualities; perfume; form; and ease of asexual reproduction. Within any one of the above or other classes of characteristics the differences which would suffice to make the variety a distinct variety, will necessarily be differences of degree.

The legislative history is clear that Congress intended that distinct and new cultivated sports, mutants, hybrids, and newly found seedlings be entitled to plant patent protection.

Although the legislative history does not answer the question of what "variety" means in terms of whether a single plant or a range of plants is protected by a plant patent, in addition to being distinct and new, a patentable plant must also be asexually reproduced. As discussed below, this additional requirement informs the scope of protection of plant patents and hence directs the meaning of "variety" in § 161.

## *2. The significance of the asexual reproduction requirement*

The legislative history defines asexual reproduction as reproduction by "grafting, budding, cuttings, layering, division, and the like, but not by seeds." The legislative history further states that

whether the new variety is a sport, mutant, or hybrid, the patent right granted is a right to propagate the new variety by asexual reproduction. It does not include the right to propagate by seeds. This limitation in the right granted recognizes a practical situation and greatly narrows the scope of the bill. Whether the new variety is a hybrid, mutant or sport, there is never more than one specimen of it produced except through asexual reproduction. For

example, without asexual reproduction there would have been but one true McIntosh or Greening apple tree. These varieties of apples could not have been preserved had it not been through human effort in the asexual reproduction of the two original trees. They could not have been reproduced true to the type by nature through seedlings.

The legislative history additionally sets forth that plants sought to be patented

must be asexually reproduced in order to have their identity preserved. This is necessary since seedlings either of chance or self-pollenization from any of these would not preserve the character of the individual.

It is clear from the legislative history that as a result of the asexual reproduction requirement, only a single plant, i.e., reproduction from one original specimen in the words of Congress, is protected by a plant patent. At the time of enactment, Congress recognized that the asexual reproduction prerequisite greatly narrowed the scope of protection of plant patents but found such a limitation necessary to ensure that the characteristics of the plant to be patented were maintained. Additionally, it has since been recognized that as intimated by Congress, asexual reproduction confirms the existence of a new variety by separating variations resulting from fluctuations in environmental conditions from true plant variations.

Due to the asexual reproduction prerequisite, plant patents cover a single plant and its asexually reproduced progeny. *See* Senate Report at 6 (Plant patent protection encourages "those who own the single specimen to reproduce it asexually and create an adequate supply."). Thus, the term "variety" in section 161 must be interpreted consistently with this requirement. Accordingly, "variety" in section 161 cannot be read as affording plant patent protection to a range of plants, as asserted by Imazio.

#### V. INFRINGEMENT

As to the first step, consistent with our analysis above, the scope of the claim of the '336 patent is the *asexual progeny* of the Heather persoluta shown and described in the '336 patent specification. To perform the second step of the infringement analysis, we first look to the language of the statute.

Section 163 grants to plant patentees the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced. 35 U.S.C. § 163. As stated above, the trial court held that asexual reproduction is shown if the patentee can prove that the alleged infringing plant has the same essential characteristics as the patented plant. We disagree.

We must construe the term "asexual reproduction" in section 163 in the same way as we did in section 161. Thus, for purposes of plant patent infringement, the patentee must prove that the alleged infringing plant is an asexual reproduction, that is, that it is the progeny of the patented plant.

Below, the parties disputed whether independent creation is a proper defense to plant patent infringement. The trial court refused to recognize such a defense stating that the "patent holder would have great difficulties enforcing his patent rights if a defendant were allowed to raise independent creation as an affirmative defense." The trial court reasoned that it would be hard for the patentee to refute evidence of independent creation because all such evidence would be in the defendant's control.

We must reject the trial court's analysis of the independent creation defense because it is contrary to the plain meaning of the statute. The statute requires asexual reproduction of the patented plant for there to be infringement. It is necessarily a defense to plant patent infringement that the alleged infringing plant is not an asexual reproduction of the patented plant. Part of this proof could be, thus, that the defendant independently developed the allegedly infringing plant. However, the sine qua non is asexual reproduction. That is what the patentee must prove and what the defendant will seek to disprove.

The judgment of infringement of the '336 patent is reversed. The case is remanded for further proceedings consistent with this opinion.

### **Armstrong Nurseries, Inc. v. Smith**

170 F. Supp. 519 (E.D. Tex. 1958)

In 1955, Defendant Dyess requested Defendant Hood to grow roses for him and agreed to furnish Defendant Hood or make available for Defendant Hood's use the requisite budwood. In accordance with such agreement Defendant Dyess did subsequently furnish and make available to Defendant Hood a quantity of budwood for different varieties with which Defendant Hood dormant budded or caused to be dormant budded approximately 73,000 rose plants in a certain field in his possession and under his control.

Among said 73,000 rose plants were approximately 1,500 rose plants, more or less, characterized by a vigorous upright-growing habit; the production of flat glossy, dark green, medium size foliage during spring growing with increase in size until attainment of large proportions during late summer and fall; high resistance to mildew and anthracnose; by long moderately heavy stems having a fairly large number of medium to large thorns in the spring diminishing in late season until relative freedom of thorns is reached; by the shape of

bud and open bloom combined with wide contrast between outer surface petal color and inner surface petal color and extreme brilliance of the latter in the opening bud and newly opening flower, substantially as shown and described in Plant Patent No. 792, being of the variety of rose plant commonly known as 'Forty-Niner'.

Defendant Hood was unaware when he first budded the aforesaid 73,000 rose plants that any of them were of the aforesaid patented varieties. Later when the crop came on and Defendant Hood questioned Defendant Dyess in respect of the varieties of said patented rose plants, Defendant Dyess told Defendant Hood that those plants which were in fact of the variety shown and described in the Plant Patent No. 792 and commonly known as 'Forty-Niner' were a new variety known as 'Fifty-Five.'

Defendant Hood has never possessed and does not now possess a proper license or sub license (grower) authorizing him to asexually reproduce, grow, sell, or use the aforesaid patented rose plants.

By reason of his unauthorized dormant budding and cultivation of the aforesaid patented rose plants, Defendant Hood has infringed Plant Patent No. 792.

At the time Defendant Dyess furnished Defendant Hood the aforesaid budwood Defendant Dyess did not possess a current valid growing license or sub license, and by his dealings with Defendant Hood in respect of said budwood and the rose plants subsequently grown by Defendant Hood, he actively induced the infringement of said Plant Patents by Defendant Hood and is an infringer of the rights of said patentees under said respective plant patents.

## 2 Plant Variety Protection Act

### **Senate Report No. 1246, 91st Congress, 2d Session (1970) Plant Variety Protections Act**

Under the patent law, patent protection is limited to those varieties of plants which reproduce asexually, that is, by such methods as grafting or budding. No protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. Thus, patent protection is not available with respect to new varieties of most of the economically important agricultural crops, such as cotton or soybeans.

Subsequently, legislation was introduced to encourage the development of novel varieties of sexually reproduced plants by the issuance of certificates of plant variety protection by the Department of Agriculture to establish such protection, was reported by the Committee on Agriculture and Forestry, and on August 24 this legislation was referred to this committee for the purpose of reviewing its im-

pact on the plant patent statute. The committee recommends the bill, S. 3070, favorably as amended.

No.



# THE UNITED STATES OF AMERICA

**TO ALL TO WHOM THESE PRESENTS SHALL COME:**

## Seminis Vegetable Seeds, Inc.

Whereas, THERE HAS BEEN PRESENTED TO THE

Secretary of Agriculture

An application requesting a certificate of protection for an alleged distinct variety of sexually reproduced, or tuber propagated plant, the name and description of which are contained in the application and exhibits, a copy of which is hereunto annexed and made a part hereof, and the various requirements of LAW in such cases made and provided have been complied with, and the title thereto is, from the records of the PLANT VARIETY PROTECTION OFFICE, in the applicant(s) indicated in the said copy, and Whereas, upon due examination made, the said applicant(s) is (are) adjudged to be entitled to a certificate of plant variety protection under the LAW.

Now, therefore, this certificate of plant variety protection is to grant unto the said applicant(s) and the successors, heirs or assigns of the said applicant(s) for the term of TWENTY years from the date of this grant, subject to the payment of the required fees and periodic replenishment of viable basic seed of the variety in a public repository as provided by LAW, the right to exclude others from selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it, or conditioning it for propagation, or stocking it for any of the above purposes, or using it in producing a hybrid or different variety therefrom, to the extent provided by the PLANT VARIETY PROTECTION ACT. (84 STAT. 1542, AS AMENDED, 7 U.S.C. 2321 ET SEQ.)

CARROT

'RF714911A'

In Testimony Whereof, *I have hereunto set my hand and caused the seal of the Plant Variety Protection Office to be affixed at the City of Washington, D.C. this twenty-second day of June, in the year two thousand and ten.*

Attest:

Commissioner  
Plant Variety Protection Office  
Agricultural Marketing Service

Secretary of Agriculture

U.S. DEPARTMENT OF AGRICULTURE  
 AGRICULTURAL MARKETING SERVICE  
 SCIENCE AND TECHNOLOGY - PLANT VARIETY PROTECTION OFFICE

The following statements are made in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and the Paperwork Reduction Act (PRA) of 1995.

Application is required in order to determine if a plant variety protection certificate is to be issued (7 U.S.C. 2421). Information is held confidential until certificate is issued (7 U.S.C. 2426).

APPLICATION FOR PLANT VARIETY PROTECTION CERTIFICATE  
 (Instructions and information collection burden statement on reverse)

1. NAME OF OWNER <b>Seminis Vegetable Seeds, Inc.</b>		2. TEMPORARY DESIGNATION OR EXPERIMENTAL NAME <b>RF 71-4911A</b>	3. VARIETY NAME <b>RF714911A</b>
4. ADDRESS (Street and No., or R.F.D. No., City, State, and ZIP Code, and Country) <b>2700 Camino del Sol Oxnard, CA 93030-7967</b>		5. TELEPHONE (include area code) <b>(805) 647-1572</b>	FOR OFFICIAL USE ONLY PVPO NUMBER <b>#200800282</b> FILING DATE <b>June 5, 2008</b>
		6. FAX (include area code) <b>(805) 918-2545</b>	
7. IF THE OWNER NAMED IS NOT A "PERSON", GIVE FORM OF ORGANIZATION (corporation, partnership, association, etc.) <b>Corporation</b>	8. IF INCORPORATED, GIVE STATE OF INCORPORATION <b>California</b>	9. DATE OF INCORPORATION <b>4 June 1962</b>	

SMS 12/21/09

10. NAME AND ADDRESS OF OWNER REPRESENTATIVE(S) TO SERVE IN THIS APPLICATION. (First person listed will receive all papers)		F E E S  R E C E I V E D	FILING AND EXAMINATION FEES: \$ <b>4382.00</b> DATE <b>6/5/08</b>
<b>Carol Miller Seminis Vegetable Seeds, Inc. 37437 State Hwy 16 Woodland, CA 95695</b>	<b>Sara Boeke Seminis Vegetable Seeds, Inc. P.O. Box 97, NL-6700 AB Wageningen, Netherlands</b>		CERTIFICATION FEE: \$ <b>768.00</b> DATE <b>3/18/10</b>

11. TELEPHONE (Include area code) <b>(530) 669-6274</b>	12. FAX (Include area code) <b>(530) 669-6112</b>	13. E-MAIL <b>carol.l.miller@seminis.com</b>
14. CROP KIND (Common Name) <b>Carrot</b>	16. FAMILY NAME (Botanical) <b>Umbelliferae</b>	18. DOES THE VARIETY CONTAIN ANY TRANSGENES? (OPTIONAL) <input type="checkbox"/> YES <input type="checkbox"/> NO IF SO, PLEASE GIVE THE ASSIGNED USDA-APHIS REFERENCE NUMBER FOR THE APPROVED PETITION TO DEREGULATE THE GENETICALLY MODIFIED PLANT FOR COMMERCIALIZATION.
15. GENUS AND SPECIES NAME OF CROP <b>Daucus carota</b>	17. IS THE VARIETY A FIRST GENERATION HYBRID? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	

19. CHECK APPROPRIATE BOX FOR EACH ATTACHMENT SUBMITTED (Follow instructions on reverse)		20. DOES THE OWNER SPECIFY THAT SEED OF THIS VARIETY BE SOLD AS A CLASS OF CERTIFIED SEED? (See Section 83(a) of the Plant Variety Protection Act)
a. <input checked="" type="checkbox"/> Exhibit A. Origin and Breeding History of the Variety b. <input checked="" type="checkbox"/> Exhibit B. Statement of Distinctness c. <input checked="" type="checkbox"/> Exhibit C. Objective Description of Variety d. <input type="checkbox"/> Exhibit D. Additional Description of the Variety (Optional) e. <input checked="" type="checkbox"/> Exhibit E. Statement of the Basis of the Owner's Ownership f. <input checked="" type="checkbox"/> Exhibit F. Declaration Regarding Deposit g. <input checked="" type="checkbox"/> Voucher Sample (3,000 viable untreated seeds or, for tuber propagated varieties, verification that tissue culture will be deposited and maintained in an approved public repository) h. <input checked="" type="checkbox"/> Filing and Examination Fee (\$4,382), made payable to "Treasurer of the United States" (Mail to the Plant Variety Protection Office)		<input type="checkbox"/> YES (If "yes", answer items 21 and 22 below) <input checked="" type="checkbox"/> NO (If "no", go to item 23)
		21. DOES THE OWNER SPECIFY THAT SEED OF THIS VARIETY BE LIMITED AS TO NUMBER OF CLASSES? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF YES, WHICH CLASSES? <input type="checkbox"/> FOUNDATION <input type="checkbox"/> REGISTERED <input type="checkbox"/> CERTIFIED
		22. DOES THE OWNER SPECIFY THAT SEED OF THIS VARIETY BE LIMITED AS TO NUMBER OF GENERATIONS? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF YES, SPECIFY THE NUMBER 1,2,3, etc. FOR EACH CLASS. <input type="checkbox"/> FOUNDATION <input type="checkbox"/> REGISTERED <input type="checkbox"/> CERTIFIED (If additional explanation is necessary, please use the space indicated on the reverse.)
23. HAS THE VARIETY (INCLUDING ANY HARVESTED MATERIAL) OR A HYBRID PRODUCED FROM THIS VARIETY BEEN SOLD, DISPOSED OF, TRANSFERRED, OR USED IN THE U. S. OR OTHER COUNTRIES? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF YES, YOU MUST PROVIDE THE DATE OF FIRST SALE, DISPOSITION, TRANSFER, OR USE FOR EACH COUNTRY AND THE CIRCUMSTANCES. (Please use space indicated on reverse.)		24. IS THE VARIETY OR ANY COMPONENT OF THE VARIETY PROTECTED BY INTELLECTUAL PROPERTY RIGHT (PLANT BREEDER'S RIGHT OR PATENT)? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO IF YES, PLEASE GIVE COUNTRY, DATE OF FILING OR ISSUANCE AND ASSIGNED REFERENCE NUMBER. (Please use space indicated on reverse.)

25. The owners declare that a viable sample of basic seed of the variety has been furnished with application and will be replenished upon request in accordance with such regulations as may be applicable, or for a tuber propagated variety a tissue culture will be deposited in a public repository and maintained for the duration of the certificate.

The undersigned owner(s) is(are) the owner of this sexually reproduced or tuber propagated plant variety, and believe(s) that the variety is new, distinct, uniform, and stable as required in Section 42, and is entitled to protection under the provisions of Section 42 of the Plant Variety Protection Act.

Owner(s) is (are) informed that false representation herein can jeopardize protection and result in penalties.

SIGNATURE OF OWNER 		SIGNATURE OF OWNER	
NAME (Please print or type) <b>Carol L. Miller</b>		NAME (Please print or type)	
CAPACITY OR TITLE <b>PVP Specialist</b>	DATE <b>4. Jun. 08</b>	CAPACITY OR TITLE	DATE

(See reverse for instructions and information collection burden statement)

**GENERAL INSTRUCTIONS:** To be effectively filed with the Plant Variety Protection Office (PVPO), **ALL** of the following items must be **received** in the PVPO: (1) Completed application form signed by the owner; (2) completed exhibits A, B, C, E, F; (3) for a tuber reproduced variety, verification that a viable (*in the sense that it will reproduce an entire plant*) tissue culture will be deposited and maintained in an approved public repository; and (4) payment by credit card or check drawn on a U.S. bank for \$4,382 (\$518 filing fee and \$3,864 examination fee), payable to "Treasurer of the United States" (*See Section 97.6 of the Regulations and Rules of Practice*). **NEW:** With the application for a seed reproduced variety **or by direct deposit soon after filing**, the applicant must provide at least 3,000 viable untreated seeds of the variety *per se*, and for a hybrid variety at least 3,000 untreated seeds of each line necessary to **reproduce** the variety. Partial applications will be held in the PVPO for not more than 90 days; then returned to the applicant as un-filed. Mail application and other requirements to Plant Variety Protection Office, AMS, USDA, Room 401, NAL Building, 10301 Baltimore Avenue, Beltsville, MD 20705-2351. Retain one copy for your files. All items on the face of the application are self explanatory unless noted below. Corrections on the application form and exhibits must be initialed and dated. **DO NOT** use masking materials to make corrections. If a certificate is allowed, you will be requested to send a payment by credit card or check payable to "Treasurer of the United States" in the amount of \$768 for issuance of the certificate. Certificates will be issued to owner, not licensee or agent.

**NOTES:** It is the responsibility of the applicant/owner to keep the PVPO informed of any changes of address or change of ownership or assignment or owner's representative during the life of the application/certificate. The fees for filing a change of address; owner's representative; ownership or assignment; or any modification of owner's name is specified in Section 97.175 of the regulations. (*See Section 101 of the Act, and Sections 97.130, 97.131, 97.175(h) of the Regulations and Rules of Practice.*)

**Plant Variety Protection Office**  
**Telephone:** (301) 504-5518      **FAX:** (301) 504-5291  
**General E-mail:** PVPOmail@usda.gov  
**Homepage:** <http://www.ams.usda.gov/science/pvpo/PVPindex.htm>

#### SPECIFIC INSTRUCTIONS:

To avoid conflict with other variety names in use, the applicant must check the appropriate recognized authority and **provide evidence** that the permanent name of the application variety (even if it is a parental, inbred line) has been cleared by the appropriate recognized authority before the Certificate of Protection is issued. For example, for agricultural and vegetable crops, contact: U.S. Department of Agriculture, Agricultural Marketing Service, Livestock and Seed Programs, **Seed Regulatory and Testing Branch**, 801 Summit Crossing Place, Suite C, Gastonia, North Carolina 28054-2193 Telephone: (704) 810-8870. <http://www.ams.usda.gov/lsg/seed.htm>.

#### ITEM

- 19a. Give:
- (1) the genealogy, including public and commercial varieties, lines, or clones used, and the breeding method;
  - (2) the details of subsequent stages of selection and multiplication;
  - (3) evidence of uniformity and stability; and
  - (4) the type and frequency of variants during reproduction and multiplication and state how these variants may be identified
- 19b. Give a summary of the variety's distinctness. Clearly state how this application variety may be distinguished from all other varieties in the same crop. If the new variety is most similar to one variety or a group of related varieties:
- (1) identify these varieties and state all differences objectively;
  - (2) attach replicated statistical data for characters expressed numerically and demonstrate that these are clear differences; and
  - (3) submit, if helpful, seed and plant specimens or photographs (prints) of seed and plant comparisons which clearly indicate distinctness.
- 19c. Exhibit C forms are available from the PVPO Office for most crops; specify crop kind. Fill in Exhibit C (Objective Description of Variety) form as completely as possible to describe your variety.
- 19d. Optional additional characteristics and/or photographs. Describe any additional characteristics that cannot be accurately conveyed in Exhibit C. Use comparative varieties as is necessary to reveal more accurately the characteristics that are difficult to describe, such as plant habit, plant color, disease resistance, etc.
- 19e. Section 52(5) of the Act requires applicants to furnish a statement of the basis of the applicant's ownership. An Exhibit E form is available from the PVPO.
20. If "Yes" is specified (*seed of this variety be sold by variety name only, as a class of certified seed*), the applicant **MAY NOT** reverse this affirmative decision after the variety has been sold and so labeled, the decision published, or the certificate issued. However, if "No" has been specified, the applicant may change the choice. (*See Regulations and Rules of Practice, Section 97.103*).
23. *See Sections 41, 42, and 43 of the Act and Section 97.5 of the regulations for eligibility requirements.*
24. *See Section 55 of the Act for instructions on claiming the benefit of an earlier filing date.*

**22. CONTINUED FROM FRONT** (*Please provide a statement as to the limitation and sequence of generations that may be certified.*)

**23. CONTINUED FROM FRONT** (*Please provide the date of first sale, disposition, transfer, or use for each country and the circumstances, if the variety (including any harvested material) or a hybrid produced from this variety has been sold, disposed of, transferred, or used in the U.S. or other countries.*)

**24. CONTINUED FROM FRONT** (*Please give the country, date of filing or issuance, and assigned reference number, if the variety or any component of the variety is protected by intellectual property right (Plant Breeder's Right or Patent).*)

U.S. Patent Application No. 11/874,629 Entitled "Carrots Having Increased Lycopene Content" by Robert V. Maxwell filed 18-Oct-07.

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0055. The time required to complete this information collection is estimated to average 1.4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

To file a complaint of discrimination, write to USDA, Director, Office of Civil Rights, 1400 Independence Avenue, S.W., Washington, D.C. 20250-9410, or call (800) 795-3272 (voice) or (202) 720-6382 (TDD). USDA is an equal opportunity provider and employer.

## EXHIBIT A

RF714911A

Origin and Breeding History of Red Carrot Male Sterile, ~~RF 71-4911A~~SWS  
12/22/09

RF 71-4911A was developed via work based at the Seminis Breeding Station in Payette, Idaho. Reproductive cycles were carried out at Payette, while the vegetative cycles were performed at the Elmore Forms, Inc. property near Brawley, California. Roots are grown at the Southern California location and transported to Idaho for seed production.

Line RF 71-4911A exhibits a number of improved traits including uniform red color throughout an internal root cross-section and high petaloid male-sterility stability. A pedigree breeding system was used for line development and improvement. The development of the line can be summarized as follows.

- Sept. 2000      Planted seeds of 'Nutri-red' and 'USDA line 4367S' (an orange male sterile line released by the USDA) in the Imperial Valley, California.
- Feb. 2001      Harvested roots of 'Nutri-red' and 'USDA line 4367S' for F1 hybrids. Planted individual roots selected from 'Nutri-red' and made crosses with 'USDA line 4367S', establishing new sub-line populations of 'Nutri-red' with their respective hybrids.
- Sept. 2001      Planted hybrid seed and new sub-lines in California.
- Feb. 2002      Harvested hybrids of 'Nutri-red' sub-lines and 'USDA line 4367S' (all orange roots) in preparation of first backcross to the respective sub-lines.
- Sept. 2002      Planted BC1 seed in California with the respective sub-lines.
- Feb. 2003      Selected red roots within the BC1 population and prepared for backcrossing, again, to the 'Nutri-red' sub-lines.
- Sept. 2003      Planted BC2 seed in California with the respective sub-lines.
- Feb. 2004      Most backcrosses appeared to be nearly stable, though some orange roots caused concern about the possible genetic inheritance. Red roots were again selected and prepared for backcrossing to 'Nutri-red' sub-lines.
- Sept. 2004      Planted BC3 seed in California with the respective sub-lines.
- Feb. 2005      Harvested roots and found that 100% of all backcross populations had complete expression of lycopene. Selected best lines for hybrid production and possible increase, one set of lines being RF 71-4911A & B.
- Sept. 2005/6    Planted new hybrids and backcross lines for potential advancement and seed increase.
- Feb. 2006/7    Evaluated and selected best hybrid combinations.

In summary, individual roots of 'Nutri-red' were found which lacked the fertility restorer gene. Repeated backcrossing of an orange carrot with male-sterile cytoplasm to one of these 'Nutri-red' roots resulted in the development of RF 71-4911A in a stable, red pigmented phenotype.

From observations made during two generations of multiplication and seed increases (during 2005 and 2006), RF 71-4911A was found to be uniform and stable within commercially acceptable limits. As is true with other carrot varieties, a small percentage of off-types can occur within commercially acceptable limits for almost any characteristic during the course of repeated multiplications. No variants are known or expected to occur.

EXHIBIT B

RF714911A

Statement of Distinctness for Red Carrot, ~~RF 71-4911A~~

SMS  
12/22/09

RF 71-4911A is the result of work to develop a male sterile line derived from a population of 'Nutri-red', a red carrot release developed by Seminis Vegetable Seeds, Inc. Individual roots of 'Nutri-red' were selected and crossed with a known male sterile line of orange color. The progeny were evaluated for flower type to identify any 'Nutri-red' root selections that lacked the nuclear fertility restorer gene. One root in particular, identified as RF 71-4911B, was found to be lacking this gene. Continued backcrossing of the male sterile progeny to the male sterile maintainer resulted in the development of RF 71-4911A.

The RF 71-4911A population is a more slender and refined carrot type, somewhat similar to the original 'Nutri-red' population. Roots are medium to narrow in diameter with a gradual taper to the root tip. They have a very smooth skin texture.

To our knowledge, the most similar variety to RF 71-4911A is 'Nutri-red'. The comparative characteristics which best distinguish the two varieties include, but may not be limited to:

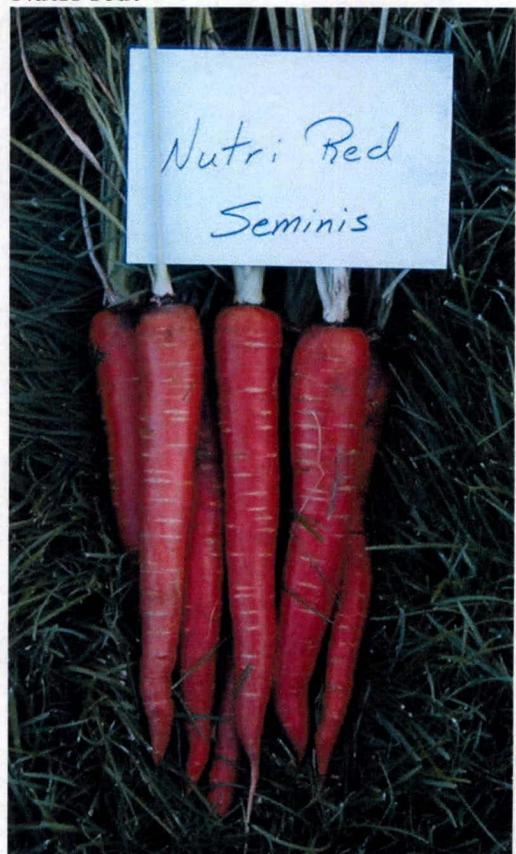
- Root Base: the roots of RF 71-4911A have a semi-blunt base, whereas the roots of 'Nutri-red' have a pointed base.
- Root Exterior Color: the exterior root color of RF 71-4911A is light red with an RHS color chart value of 184C, whereas 'Nutri-red' is dark red with an RHS color chart value of 59D.
- Flower Type: the flowers of RF 71-4911A are 100% male sterile, whereas the flowers of 'Nutri-red' are 100% male fertile.
- Flower Color: the flowers of RF 71-4911A are green with an RHS color chart value of 194C, whereas the flowers of 'Nutri-red' are white with an RHS color chart value of N155D.

The following photographs of RF 71-4911A and 'Nutri-red' depict the visual differences described above:

RF 71-4911A:



Nutri-red:



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U.S. DEPARTMENT OF AGRICULTURE  
 AGRICULTURAL MARKETING SERVICE  
 SCIENCE AND TECHNOLOGY  
 PLANT VARIETY PROTECTION OFFICE  
 BELTSVILLE, MD 20705

Exhibit C

OBJECTIVE DESCRIPTION OF VARIETY  
 Carrot (*Daucus carota*)

NAME OF APPLICANT (S) <u>Seminis Vegetable Seeds, Inc.</u>	TEMPORARY OR EXPERIMENTAL DESIGNATION <u>RF 71-4911A</u>	VARIETY NAME <u>RF714911A</u>
ADDRESS (Street and No. or RD No., City, State, Zip Code and Country) <u>2700 Camino del Sol Oxnard, CA 93030</u>		FOR OFFICIAL USE ONLY PVPO NUMBER <u>200800282</u>

PLEASE READ ALL INSTRUCTIONS CAREFULLY:

In the spaces on the left, enter the appropriate numbers that describe the characteristics of the application variety. On the right, enter the appropriate numbers that describe the characteristics of the most similar comparison variety. Right justify whole numbers by adding leading zeros if necessary. The variety that you choose for comparison should be the most similar one in terms of overall morphology, background and maturity. The comparison variety should be grown in field trials with the application variety for 2-3 location/years (environments) in the region and season of best adaptability. At least one year of trials should be conducted within the United States of America. In general, measurements of quantitative traits should be taken from one trial on 15-25 randomly selected plants or plant parts to obtain averages and statistics that describe a typical field of the variety. (Form technical content last updated Feb. 2003.)

Application Variety	Comparison Variety
<p>1. TYPE:</p> <p><u>6</u> 1 = Amsterdam 2 = Flakee 3 = Berlicum 4 = Chantenay 5 = Danvers                      6 = Imperator 7 = Nantes 8 = Other (Specify) _____</p>	<p>Comparison Variety Name <u>Nutri-red</u></p> <p><u>6</u> Type _____</p>
<p>2. REGION OF ADAPTATION IN THE U.S.A.:</p> <p><u>7</u> 1 = Northeast 2 = Northwest 3 = Southeast 4 = Southwest                      5 = North Central 6 = South Central 7 = Most Regions</p>	<p><u>7</u> Region of Adaptability</p>
<p>3. MARKET MATURITY:</p> <p><u>120</u> No Days from Seeding to Harvest</p>	<p><u>120</u> Days to Market Maturity</p>
<p>4. PLANT TOP: (At Harvest Stage)</p> <p><u>2</u> Habit: 1 = Erect 2 = Semi-erect 3 = Prostrate</p> <p><u>042</u> cm Plant Top Height (from Shoulder to Top of Crown)</p> <p><u>012</u> mm Plant Top Neck Diameter</p> <p><u>1</u> Top Attachment: 1 = Single 2 = Multiple</p>	<p><u>2</u> Habit</p> <p><u>050</u> cm Plant Top Height</p> <p><u>030</u> mm Plant Top Neck Diameter</p> <p><u>1</u> Top Attachment</p>
<p>5. LEAF: (At Harvest Stage)</p> <p><u>2</u> Name of Color Chart: 1 = Munsell Book of Color 2 = RHS Colour Chart                      3 = Other (Specify) _____</p> <p><u>3</u> Blade Color: 1 = Light Green 2 = Medium Green 3 = Dark Green                      4 = Other (Specify) _____</p> <p>Color Chart Value <u>132B</u></p>	<p><u>2</u> Name of Color Chart</p> <p><u>3</u> Blade Color:</p> <p>Color Chart Value <u>N134A</u></p>
Application Variety	Comparison Variety

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Application Variety	Comparison Variety
<p>5. LEAF: (continued)</p> <p><u>2</u> Blade Divisions: 1 = Fine 2 = Medium 3 = Coarse</p> <p><u>028</u> cm Blade Length (Without Petiole)</p> <p><u>018</u> cm Petiole Length from Crown to First Pinna</p> <p><u>1</u> Petiole Anthocyanin: 1 = Absent 2 = Present</p> <p><u>1</u> Petiole Pubescence: 1 = Absent 2 = Present</p>	<p><u>2</u> Blade Divisions</p> <p><u>030</u> cm Blade Length</p> <p><u>020</u> cm Petiole Length</p> <p><u>1</u> Petiole Anthocyanin</p> <p><u>1</u> Petiole Pubescence</p>
<p>6. ROOT: (At Market Maturity)</p> <p><u>18</u> mm Cortex (Phloem) Thickness (Midpoint X-Section)</p> <p><u>13</u> mm Core (Xylem) Thickness (Midpoint X-Section)</p> <p><u>24</u> cm Carrot Length (Minus Taproot)</p> <p><u>020</u> mm Length of Taproot</p> <p><u>036</u> mm Diameter at Shoulder</p> <p><u>031</u> mm Diameter at Midpoint</p> <p><u>1</u> Amount Exposed (Above Ground): 1 = None 2 = 1-10% 3 = 11-20% 4 = 21-30% 5 = 31-40% 6 = &gt; 40%</p> <p><u>2</u> Shape: 1 = Round 2 = Conic 3 = Cylindrical</p> <p><u>2</u> Collar: 1 = Sunken 2 = Level 3 = Square</p> <p><u>2</u> Shoulder: 1 = Rounded 2 = Sloping 3 = Square</p> <p><u>2</u> Base: 1 = Pointed 2 = Medium 3 = Blunt</p> <p><u>2</u> Surface Smoothness: 1 = Very Smooth 2 = Dimpled or Corrugated</p> <p><u>2</u> Number of Secondary Root Scars: 1 = None 2 = Few 3 = Many</p> <p><u>1</u> Appearance of Secondary Root Scars: 1 = Not Prominent 2 = Prominent</p> <p><u>2</u> Halo: 1 = None 2 = Faint 3 = Prominent</p> <p><u>2</u> Zoning: 1 = None 2 = Faint 3 = Prominent</p> <p><u>1</u> Flavor Harshness: 1 = Very Harsh 2 = Moderately Harsh 3 = Mildly Harsh</p> <p><u>1</u> Flavor Sweetness: 1 = Not Sweet 2 = Moderately Sweet 3 = Very Sweet</p>	<p><u>10</u> mm Cortex (Phloem) Thickness</p> <p><u>10</u> mm Core (Xylem) Thickness</p> <p><u>24</u> cm Carrot Length</p> <p><u>020</u> mm Length of Taproot</p> <p><u>032</u> mm Diameter at Shoulder</p> <p><u>022</u> mm Diameter at Midpoint</p> <p><u>1</u> Amount Exposed</p> <p><u>2</u> Shape</p> <p><u>2</u> Collar</p> <p><u>2</u> Shoulder</p> <p><u>1</u> Base</p> <p><u>2</u> Surface Smoothness</p> <p><u>2</u> Number of Secondary Root Scars</p> <p><u>2</u> Appearance of Secondary Root Scars</p> <p><u>2</u> Halo</p> <p><u>2</u> Zoning</p> <p><u>1</u> Flavor Harshness</p> <p><u>1</u> Flavor Sweetness</p>

Notes:

Halo: Cross-section showing color difference between xylem and phloem.

Zoning: Longitudinal cut showing color difference between xylem and phloem.

Application Variety	Comparison Variety
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Application Variety	Comparison Variety
<b>COLORS:</b>	
Color choices: 1 = White 2 = Yellow 3 = Orange 4 = Red 5 = Purple 6 = Green 7 = Salmon 8 = Light 9 = Dark 10 = Other (describe)	
Color Examples: <u>02</u> = Yellow; <u>34</u> = Orange-Red; <u>94</u> = Dark Red	
<u>2</u> Name of Color Chart: 1 = Munsell Book of Color 2 = RHS Colour Chart 3 = Other (Specify) _____	
Above Ground Exterior Color: <u>84</u> Shoulder (Color chart value <u>184C</u> )	<u>94</u> Shoulder (Color chart value <u>59D</u> )
Above Ground Exterior Color: <u>84</u> Skin (Color chart value <u>184C</u> )	<u>94</u> Skin (Color chart value <u>59D</u> )
Below Ground Exterior Color: <u>84</u> Shoulder (Color chart value <u>184C</u> )	<u>94</u> Shoulder (Color chart value <u>59D</u> )
Below Ground Exterior Color: <u>84</u> Skin (Color chart value <u>184C</u> )	<u>94</u> Skin (Color chart value <u>59D</u> )
X-Section Interior Color: <u>84</u> Xylem (Core) (Color chart value <u>184D</u> )	<u>04</u> Xylem (Color chart value <u>63B</u> )
X-Section Interior Color: <u>84</u> Phloem (Color chart value <u>184D</u> )	<u>04</u> Phloem (Color chart value <u>63A</u> )
<b>7. FLOWER:</b>	
<u>06</u> Flower Color (Color chart value <u>194C</u> )	<u>01</u> Flower Color (Color chart value <u>NISSD</u> )
<u>2</u> Male Fertility: 1 = Fertile 2 = Male-Sterile 3 = Other _____	<u>1</u> Male Fertility
<u>2</u> Anthers: 1=Normal 2=Petaloid 3= Other _____	<u>1</u> Anthers
<b>7. SEED:</b>	
<u>125</u> cm Height of Seed Stalk	<u>95</u> cm Height of Seed Stalk
<u>2</u> Stalk Pubescence: 1 = Absent 2 = Little 3 = Moderate 4 = Heavy	<u>2</u> Stalk Pubescence
<u>120</u> mm Diameter of First Order Umbel	<u>120</u> mm Diameter of First Order Umbel
<u>2</u> Seed Spines: 1 = Absent 2 = Present	<u>2</u> Seed Spines
<u>205</u> mg per 100 Seeds	<u>210</u> mg per 100 Seeds
<b>8. DISEASE REACTIONS: (1 = Susceptible; 2 = Resistant; give races if known)</b>	
<u>1</u> Alternaria Blight	<u>1</u> Alternaria Blight
<u>1</u> Aster Yellows	<u>1</u> Aster Yellows
___ Cavity Spot	<u>1</u> Cavity Spot
___ Cercospora Blight	___ Cercospora Blight
___ Motley Dwarf Virus	<u>1</u> Motley Dwarf Virus
___ Powdery Mildew	<u>1</u> Powdery Mildew
___ Pythium Root Dieback	<u>1</u> Pythium Root Dieback
<u>1</u> Schlerotinia Decay	<u>1</u> Schlerotinia Decay
___ Other (Specify) <u>N/A</u>	___ Other (Specify) <u>N/A</u>
<b>9. INSECT REACTIONS: (1 = Susceptible; 2 = Resistant; give races if known)</b>	
<u>1</u> Root Knot Nematode	<u>1</u> Root Knot Nematode
___ Other (Specify) <u>N/A</u>	___ Other (Specify) <u>N/A</u>
Application Variety	Comparison Variety

7

Application Variety	Comparison Variety
10. PHYSIOLOGICAL REACTIONS: (1 = Susceptible and 2 = Resistant) <u>2</u> Bolting <u>2</u> Root Splitting	<u>2</u> Bolting <u>2</u> Root Splitting

COMMENTS:

U.S. DEPARTMENT OF AGRICULTURE  
AGRICULTURAL MARKETING SERVICE

Application is required in order to determine if a plant variety protection certificate is to be issued (7 U.S.C. 2421). The information is held confidential until the certificate is issued (7 U.S.C. 2426).

**EXHIBIT E  
STATEMENT OF THE BASIS OF OWNERSHIP**

1. NAME OF APPLICANT(S)  Seminis Vegetable Seeds, Inc.	2. TEMPORARY DESIGNATION OR EXPERIMENTAL NUMBER  RF 71-4911A	3. VARIETY NAME  RF714911A
4. ADDRESS (Street and No., or R.F.D. No., City, State, and ZIP, and Country)  2700 Camino del Sol Oxnard, California 93030	5. TELEPHONE (Include area code)  (805) 647-1572	6. FAX (Include area code)  (805) 918-2545
7. PVPO NUMBER  #200800282		

SMS  
1/22/09

8. Does the applicant own all rights to the variety? Mark an "X" in the appropriate block. If no, please explain.  YES  NO

9. Is the applicant (individual or company) a U.S. national or a U.S. based company? If no, give name of country.  YES  NO

10. Is the applicant the original owner?  YES  NO If no, please answer one of the following:

a. If the original rights to variety were owned by individual(s), is (are) the original owner(s) a U.S. National(s)?  YES  NO If no, give name of country

b. If the original rights to variety were owned by a company(ies), is (are) the original owner(s) a U.S. based company?  YES  NO If no, give name of country

11. Additional explanation on ownership (Trace ownership from original breeder to current owner. Use the reverse for extra space if needed):

The variety named in this application was developed by the Seminis Vegetable Seeds, Inc., employee (breeder) identified below. By agreement between the employee and Seminis Vegetable Seeds, Inc., all rights to any invention, discovery, or development made by an employee are assigned to the Company. No rights to such an invention, discovery, or development are retained by the employee.

Employee (Breeder): Rob Maxwerll

Site Location: Payette, Idaho

**PLEASE NOTE:**

Plant variety protection can only be afforded to the owners (not licensees) who meet the following criteria:

1. If the rights to the variety are owned by the original breeder, that person must be a U.S. national, national of a UPOV member country, or national of a country which affords similar protection to nationals of the U.S. for the same genus and species.
2. If the rights to the variety are owned by the company which employed the original breeder(s), the company must be U.S. based, owned by nationals of a UPOV member country, or owned by nationals of a country which affords similar protection to nationals of the U.S. for the same genus and species.
3. If the applicant is an owner who is not the original owner, both the original owner and the applicant must meet one of the above criteria.

The original breeder/owner may be the individual or company who directed the final breeding. See Section 41(a)(2) of the Plant Variety Protection Act for definitions.

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0055. The time required to complete this information collection is estimated to average 0.1 hour per response, including the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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**U.S. DEPARTMENT OF AGRICULTURE  
AGRICULTURAL MARKETING SERVICE  
SCIENCE AND TECHNOLOGY  
PLANT VARIETY PROTECTION OFFICE  
BELTSVILLE, MD 20705**

**EXHIBIT F  
DECLARATION REGARDING DEPOSIT**

<b>NAME OF OWNER (S)</b> Seminis Vegetable Seeds, Inc.	<b>ADDRESS (Street and No. or RD No., City, State, and Zip Code and Country)</b> 2700 Camino del Sol Oxnard, CA 93030	TEMPORARY OR EXPERIMENTAL DESIGNATION RF 71-4911A
		VARIETY NAME <i>RF714911A</i>
<b>NAME OF OWNER REPRESENTATIVE (S)</b> Carol L. Miller	<b>ADDRESS (Street and No. or RD No., City, State, and Zip Code and Country)</b> 37437 State Highway 16 Woodland, CA 95695	FOR OFFICIAL USE ONLY
		PVPO NUMBER #200800282

*JMS 12/22/09*

I do hereby declare that during the life of the certificate a viable sample of propagating material of the subject variety will be deposited, and replenished as needed periodically, in a public repository in the United States in accordance with the regulations established by the Plant Variety Protection Office.

*Carol L. Miller*  
\_\_\_\_\_  
Signature

*4. Jun. 08*  
\_\_\_\_\_  
Date

**a Subject Matter****Plant Variety Protection Act****7 U.S.C § 2402*****Right to plant variety protection; plant varieties protectable***

As enacted in 1970, the PVPA exempted "okra, celery, peppers, tomatoes, carrots, and cucumbers" as a result of lobbying by the Campbell's Soup Company. The exemption was repealed in 1980. Tuber-propagated plants, such as potatoes, were added in 1994.

- (a) *In general.* – The breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety, or the successor in interest of the breeder, shall be entitled to plant variety protection for the variety, subject to the conditions and requirements of this chapter, if the variety is –

- (1) new ...
- (2) distinct ...
- (3) uniform, in the sense that any variations are describable, predictable, and commercially acceptable;
- (4) stable, in the sense that the variety, when reproduced, 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 § 2401(a)*****Definitions and rules of construction***

- (6) *Sexually reproduced.* – The term “sexually reproduced” includes any production of a variety by seed, but does not include the production of a variety by tuber propagation.
- (7) *Tuber propagated.* – The term “tuber propagated” means propagated by a tuber or a part of a tuber.
- (9) *Variety.* – The term “variety” means a plant grouping within a single botanical taxon of the lowest known rank, that, without regard to whether the conditions for plant variety protection are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one characteristic and considered as a unit with regard to the suitability of the plant grouping for being propagated unchanged. A variety may be represented by seed, transplants, plants, tubers, tissue culture plantlets, and other matter.

**b Procedures****Plant Variety Protection Act****7 U.S.C § 2422*****Content of application***

An application for a certificate recognizing plant variety rights shall contain:

- (1) The name of the variety except that a temporary designation will suffice until the certificate is to be issued. The variety shall be named in accordance with regulations issued by the Secretary.
- (2) A description of the variety setting forth its distinctiveness, uniformity, and stability and a description of the genealogy and breeding procedure, when known. The Secretary may require amplification, including the submission of adequate photographs or drawings or plant specimens, if the description is not adequate or as complete as is reasonably possible, and submission of records or proof of ownership or of allegations made in the application. An applicant may add to or correct the description at any time, before the certificate is issued, upon a showing acceptable to the Secretary that the revised description is retroactively accurate. Courts shall protect others from any injustice which would result. The Secretary may accept records of the breeder and of any official seed certifying agency in this country as evidence of stability where applicable.
- (3) A statement of the basis of the claim of the applicant that the variety is new.
- (4) A declaration that a viable sample of basic seed (including any propagating material) necessary for propagation of the variety will be deposited and replenished periodically in a public repository in accordance with regulations to be established hereunder.
- (5) A statement of the basis of applicant's ownership.

There is hereby established in the Department of Agriculture an office to be known as the Plant Variety Protection Office, which shall have the functions set forth in this chapter.

**7 U.S.C § 2321**  
*Establishment*

The Secretary [of Agriculture] shall maintain a register of descriptions of United States protected plant varieties.

**7 U.S.C § 2329**  
*Register of protected plant varieties*

The Secretary [of Agriculture] may publish, or cause to be published, in such format as the Secretary shall determine to be suitable, the descriptions of plant varieties protected including drawings and photographs.

**7 U.S.C § 2330(a)(1)**  
*Publications*

**Genecorp, Inc. v. Progeny Advanced Genetics, Inc.**

**50 U.S.P.Q.2d 1213 (N.D. Cal. 1998)**

Genecorp has filed a complaint against Progeny alleging infringement of Plant Variety Protection Certificate No. 8400060 which covers a variety of leaf lettuce known as Genecorp Green. The Genecorp

Green Certificate was issued on August 31, 1986 and will expire on August 31, 2004.

Genecorp's complaint alleges that Progeny infringed the Genecorp Green Certificate by producing, marketing and selling a variety of leaf lettuce known as Savannah Green. On May 28, 1996 Progeny filed Plant Variety Protection Certificate Application No. 9600262 for Savannah Green.

On February 10, 1997, Genecorp initiated a protest proceeding against Progeny's Savannah Green PVP Application by filing a Petition to Protest. According to plaintiff's counsel, the Plant Variety Protection Office has advised that "it generally takes two years to process an application for a Plant Variety Protection Certificate."

Defendant Progeny argues that Genecorp's infringement suit should be stayed because the doctrine of primary jurisdiction requires that the Savannah Green PVP Application be processed before the suit continues. The doctrine of primary jurisdiction comes into play whenever enforcement of a claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body. Primary jurisdiction would require a court to refer such issues to the administrative body and stay further proceedings so as to give the parties a reasonable opportunity to seek an administrative ruling. Two factors are used to determine whether the doctrine of primary jurisdiction applies: (1) the desirable uniformity that results when the administrative agency rules first and (2) the expert and specialized knowledge that the administrative agency could apply to an issue.

Here, primary jurisdiction does not apply on the basis of uniformity because the PVP Office will not resolve important questions regarding Genecorp's infringement claim when it decides whether to issue a PVP Certificate for Savannah Green. To obtain a PVP Certificate, the applicant need only show that the variety is new, distinct, uniform and stable. It does not appear that the PVP Office makes any findings or can provide any remedy with respect to infringement when it examines a PVP Application. Instead, the PVP Act provides that a civil action shall be the remedy for infringement available to the owner of PVP certificate.

At first it appears that if the PVP Office issues a PVP Certificate for Savannah Green and if a proceeding in this court results in a finding of infringement of Genecorp Green, then the two decisions will not produce desired uniformity. This seems to be a problem because the issuance of a PVP Certificate means implicitly that the PVP Office found Savannah Green to be "clearly distinct" from Genecorp Green. However, the issuance of a PVP Certificate for Savannah Green would not mean that Progeny did not commit any acts that constitute infringement of the Genecorp Green Certificate. To prove

its infringement claim, Genecorp must show either that Savannah Green is a variety to which the infringement provision of the PVP Act applies or that Progeny committed infringement of the Genecorp Green certificate in the process of creating Savannah Green. Therefore, the desire for uniformity does not justify primary jurisdiction in this case because the PVP Office will not make sufficient findings as to infringement, if at all, when it examines the Savannah Green application.

While the PVP Office does have expert and specialized knowledge, the PVP Act itself has not restricted determinations of “clearly distinguishable” exclusively to the PVP Office. Therefore, primary jurisdiction does not warrant a stay on this ground because the PVP Act allows courts to make determinations of what is “clearly distinguishable” and does not appear to mandate that the PVP Office be the primary forum for resolution of the issue.

Finally, defendant Progeny contends that a stay is warranted in this case because stays are routinely granted in patent reexamination cases. The court disagrees because the Savannah Green Application and the protest by Genecorp are significantly different from a patent reexamination proceeding. In particular, the fact that the patent in dispute in a reexamination proceeding has already been issued is significant because the existence of a patent creates certain intellectual property rights in the holder of the patent. In this case, no rights have been conferred on defendant Progeny by way of its Savannah Green Application. Therefore, the court finds that the Savannah Green PVP Application process is significantly different from a patent reexamination and that a stay is not required on this ground.

### Plant Variety Protection Act

(b) *Term.* –

- (1) *In general.* – Except as provided in paragraph (2), the term of plant variety protection shall expire 20 years from the date of issue of the certificate in the United States, except that ... (B) in the case of a tree or vine, the term of the plant variety protection shall expire 25 years from the date of issue of the certificate.
- (2) *Exceptions.* – If the certificate is not issued within three years from the effective filing date, the Secretary may shorten the term by the amount of delay in the prosecution of the application attributed by the Secretary to the applicant.

- (c) *Expiration upon failure to comply with regulations; notice.* – The term of plant variety protection shall also expire if the owner

PVPA § 83

7 U.S.C § 2483

*Contents and term of plant variety protection*

fails to comply with regulations, in force at the time of certifying, relating to replenishing seed in a public repository, or requiring the submission of a different name for the variety, except that this expiration shall not occur unless notice is mailed to the last owner recorded as provided in section 2531(d) of this title and the last owner fails, within the time allowed thereafter, not less than three months, to comply with said regulations, paying an additional fee to be prescribed by the Secretary.

### c Ownership

#### Plant Variety Protection Act

##### 7 U.S.C § 2402

##### *Right to plant variety protection; plant varieties protectable*

As enacted in 1970, the PVPA used a "date of determination" priority system that substantially resembled the pre-AIA "first to invent" priority system. The PVPA was amended in 1994 to switch to an AIA-like "date of filing" system to enable the U.S. to ratify the International Union for the Protection of New Varieties of Plants.

- (a) *In general.* – The breeder of any sexually reproduced or tuber propagated plant variety ... shall be entitled to plant variety protection for the variety ... if the variety is –
- (1) new, in the sense that, on the date of filing of the application for plant variety protection, propagating or harvested material of the variety has not been sold or otherwise disposed of to other persons, by or with the consent of the breeder, or the successor in interest of the breeder, for purposes of exploitation of the variety (A) in the United States, more than 1 year prior to the date of filing [or longer periods for activity outside of the United States]
  - (2) distinct, in the sense that the variety is clearly distinguishable from any other variety the existence of which is publicly known or a matter of common knowledge at the time of the filing of the application;
  - (3) uniform ...; and
  - (4) stable ...
- (b) *Multiple applicants.* –
- (1) *In general.* – If 2 or more applicants submit applications on the same effective filing date for varieties that cannot be clearly distinguished from one another, but that fulfill all other requirements of subsection (a), the applicant who first complies with all requirements of this chapter shall be entitled to a certificate of plant variety protection, to the exclusion of any other applicant.
  - (2) *Requirements completed on same date.* –
    - (A) *In general.* – Except as provided in subparagraph (B), if 2 or more applicants comply with all requirements for protection on the same date, a certificate shall be issued for each variety.

(B) *Varieties indistinguishable.* – If the varieties that are the subject of the applications cannot be distinguished in any manner, a single certificate shall be issued jointly to the applicants.

(a) *Definitions.* – As used in this chapter:

(2) *Breeder.* – The term “breeder” means the person who directs the final breeding creating a variety or who discovers and develops a variety. If the actions are conducted by an agent on behalf of a principal, the principal, rather than the agent, shall be considered the breeder. The term does not include a person who redevelops or rediscovers a variety the existence of which is publicly known or a matter of common knowledge.

7 U.S.C § 2401

*Definitions and rules of construction*

(b) *Rules of construction.* – For the purposes of this chapter:

(1) *Sale or disposition for nonreproductive purposes.* – The sale or disposition, for other than reproductive purposes, of harvested material produced as a result of experimentation or testing of a variety to ascertain the characteristics of the variety, or as a by-product of increasing a variety, shall not be considered to be a sale or disposition for purposes of exploitation of the variety.

(2) *Sale or disposition for reproductive purposes.* – The sale or disposition of a variety for reproductive purposes shall not be considered to be a sale or disposition for the purposes of exploitation of the variety if the sale or disposition is done as an integral part of a program of experimentation or testing to ascertain the characteristics of the variety, or to increase the variety on behalf of the breeder or the successor in interest of the breeder.

(3) *Sale or disposition of hybrid seed.* – The sale or disposition of hybrid seed shall be considered to be a sale or disposition of harvested material of the varieties from which the seed was produced.

(4) *Application for protection or entering into a register of varieties.* – The filing of an application for the protection or for the entering of a variety in an official register of varieties, in any country, shall be considered to render the variety a matter of common knowledge from the date of the application, if the application leads to the granting of protection or to the entering of the variety in the official register of varieties, as the case may be.

(5) *Distinctness.* – The distinctness of one variety from another

may be based on one or more identifiable morphological, physiological, or other characteristics (including any characteristics evidenced by processing or product characteristics, such as milling and baking characteristics in the case of wheat) with respect to which a difference in genealogy may contribute evidence.

- (6) *Publicly known varieties.* –
  - (A) *In general.* – A variety that is adequately described by a publication reasonably considered to be a part of the public technical knowledge in the United States shall be considered to be publicly known and a matter of common knowledge.
  - (B) *Description.* – A description that meets the requirements of subparagraph (A) shall include a disclosure of the principal characteristics by which a variety is distinguished.
  - (C) *Other means.* – A variety may become publicly known and a matter of common knowledge by other means.

#### d Defenses

Somewhat unusually, we need to talk about defenses before discussing what constitutes infringement under the PVPA. The reason is that one particular defense, the “brown-bagging” provision, has cast such a long shadow over the (relatively scant) PVPA caselaw that it drives many of the interpretive controversies. For now, take it for granted that obviously large-scale commercialization – like sales on the open market between strangers of PVPA-protected seeds to farmers who then plant the seeds and sell them on the open market to strangers, and so on – infringe. We will return to the details in the next subsection.

#### Plant Variety Protection Act

The Secretary may declare a protected variety open to use on a basis of equitable remuneration to the owner, not less than a reasonable royalty, when the Secretary determines that such declaration is necessary in order to insure an adequate supply of fiber, food, or feed in this country and that the owner is unwilling or unable to supply the public needs for the variety at a price which may reasonably be deemed fair. Such declaration shall remain in effect not more than two years. In the event litigation is required to collect such remuneration, a higher rate may be allowed by the court.

PVPA § 44  
7 U.S.C § 2404  
*Public interest in wide usage*

PVPA § 112  
7 U.S.C § 2542  
*Grandfather clause*

Nothing in this chapter shall abridge the right of any person, or the successor in interest of the person, to reproduce or sell a variety developed and produced by such person more than one year prior to the effective filing date of an adverse application for a certificate of plant variety protection.

Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 2541 [1] of this title, it shall not infringe any right hereunder for a person to save seed produced by the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on the farm of the person, or for sale as provided in this section. A bona fide sale for other than reproductive purposes, made in channels usual for such other purposes, of seed produced on a farm either from seed obtained by authority of the owner for seeding purposes or from seed produced by descent on such farm from seed obtained by authority of the owner for seeding purposes shall not constitute an infringement. A purchaser who diverts seed from such channels to seeding purposes shall be deemed to have notice under section 2567 of this title that the actions of the purchaser constitute an infringement.

PVPA § 113  
7 U.S.C § 2543  
*Right to save seed; crop exemption*

The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this chapter.

PVPA § 114  
7 U.S.C. § 2544  
*Research exemption*

Transportation or delivery by a carrier in the ordinary course of its business as a carrier, or advertising by a person in the advertising business in the ordinary course of that business, shall not constitute an infringement of the protection provided under this chapter.

PVPA § 115  
7 U.S.C § 2545  
*Intermediary exemption*

**Jim Chen, *The Parable of the Seeds***  
81 Notre Dame L. Rev. 105 (2005)

*A. The PVPA in Overview*

The PVPA contains an intriguing limitation designed to preserve the "public interest in wide usage" in an otherwise protected variety." The Secretary of Agriculture may "declare a protected variety open to use on a basis of equitable remuneration to the owner," but only if the Secretary determines that compulsory licensing of a protected variety "is necessary in order to insure an adequate supply of fiber, food, or feed in this country and that the owner is unwilling or unable to supply the public needs for the variety at a price which may reasonably be deemed fair." Compulsory licensing under this provision "shall remain in effect not more than two years."

To my knowledge, however, the PVPA's "public interest" provision has never been invoked. Evidently, at no time since 1970 has the United States approached so precarious a state of food security that the Secretary of Agriculture has felt compelled to compromise proprietary interests conferred under the PVPA.

The PVPA contains two further limitations of arguably greater interest to breeders and policy-makers. The PVPA's extravagantly complicated and controversial "crop exemption" in principle permits a farmer "to save seed" from protected varieties and to "use such saved seed in the production of a crop." The other exemption, known as the PVPA's "research exemption," declares simply that "the use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute infringement."

These exemptions represent the most significant distinctions between the PVPA and the Patent Act. But for its crop and research exemptions, the PVPA might be the legal tool of choice for commercial plant breeders seeking to protect their investment in new plant varieties. Whereas patents are relatively expensive to obtain and set a higher threshold for protection," plant variety protection is easier and cheaper to obtain. In contrast with the PVPA's relatively modest request for "a description of the variety setting forth its distinctiveness, uniformity and stability and a description of the genealogy and breeding procedure, when known," the Patent Act demands far more extensive obligations of description and disclosure. Nothing in the PVPA imposes the equivalent of the Patent Act's requirements of nonobviousness and enablement. In particular, the absence of a nonobviousness requirement is a significant difference if one accepts that the nonobviousness criterion performs the principal work of discriminating between patent-worthy and patent-unworthy inventions. In short, whereas the Patent Act offers robust protection in exchange for a comprehensive disclosure of the technology underlying a new plant variety, the PVPA grants much weaker protection upon delivery of a lower-quality disclosure.

Given the historic difficulty that plant breeders have encountered in attempting to satisfy the Patent Act's description requirement, the PVPA provides an alternative, more accessible legal system in which the plant genome essentially speaks for itself. The PVPA's exemptions, however, have effectively diverted many plant breeders toward the Patent Act. In exchange for fulfilling the Patent Act's more rigorous process, plant breeders can evade the PVPA's research and crop exemptions. Quite significantly, the right to save seed of plants registered under the PVPA does not impart the right to save seed of plants patented under the Patent Act. Patent-holders are also immune, unlike their counterparts whose varieties are protected only under the PVPA, from the use of a certified plant variety to develop a new in-

bred line. The PVPA defines the "use" of a protected "variety in producing a hybrid or different variety" as infringement, but excludes from that definition the use of a protected variety in "developing" such a variety.

### *B. The Crop Exemption*

Section 113 has always allowed farmers who plant seed protected by a PVPA certificate to engage in a "bona fide sale for other than reproductive purposes, made in channels usual for such other purposes." This uncontroversial aspect of the crop exemption protects farmer-to-market sales of a crop grown from protected seeds as food or feed or for other nonreproductive purposes. Indeed, if the PVPA lacked this exemption, the statute would bar farmers from selling any protected crop whose seed is sold for food or fiber. Throughout the history of the PVPA, section 113 has also permitted farmers "to save seed produced by [them] from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and to use such saved seed in the production of a crop" for on-farm use. This facet of the crop exemption protects the traditional agricultural practice known as "bin run," or the use of seed from one crop to produce subsequent crops. At least with respect to self-pollinated crops such as wheat, soybeans, and cotton, all of which reproduce true-to-type, legal protection of bin run effectively restricts a breeder to a single sale of each variety to each individual grower of a particular crop. (Cross-pollinated hybrid crops such as corn, sorghum, and sunflowers are a different matter; because they lose hybrid vigor after a single planting, farmers must buy new seed each planting season.) The bin run exemption is a robust version of copyright law's "first sale" doctrine: the plant breeder gets exactly one chance to sell the information "encoded" in PVPA-certified seed to any individual farmer.

As enacted in 1970, however, section 113 also allowed "a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell such saved seed to other persons so engaged, for reproductive purposes." This version of the statute prevailed for nearly a quarter century. Its effect was plain: the old crop exemption enabled farmers to go directly into the business of selling PVPA-protected seeds alongside the plant breeders. In one of the earliest cases interpreting section 113, a federal court of appeals recognized the incompatibility between brown-bag sales under the crop exemption and the PVPA's overarching purpose of spurring the development of new plant varieties:

In purpose and operation, the farmer exemption appears to be at odds with the primary purpose of the Act. While

the main body of the Act assures developers of novel varieties the exclusive right to sell and reproduce that variety, the crop exemption dilutes that exclusivity by allowing individual farmers to sell the protected variety without liability. The broader the construction given the exemption, the smaller the incentive for breeders to invest the substantial time and effort necessary to develop new strains. The less time and effort that is invested, the smaller the chance of discovering superior agricultural products. If less time and effort is invested, long-term benefits to the farmer in the form of superior crops and higher yields will be lost.

The legal firestorm over brown-bagging would not go wholly unchecked. The judicial and legislative branches of the United States government eventually intervened. In the 1995 decision of *Asgrow*, the Supreme Court limited brown-bag sales to "only such seed as [a farmer] has saved for the purpose of replanting his own acreage." While the *Asgrow* case awaited the Supreme Court's decision on the merits, Congress in 1994 repealed the brown-bagging provisions of the PVPA's crop exemption. In conformity with the Supreme Court's presumptive refusal to grant retroactive effect to statutes, *Asgrow* governed only cases filed under the PVPA as that statute read before its 1994 amendments; all post-1994 sales of seed protected under the PVPA have conveyed no brown-bagging privileges on farmers.

By eliminating farmers as a significant source of competition for commercially developed seed, the legislative rejection of brown-bagging restored much of the PVPA's value to commercial plant breeders. The 1994 amendment also represented a significant setback for the recognition of farmers' rights in American law.

### *C. The Research Exemption*

The PVPA generally withholds liability from "any act done privately and for noncommercial purposes." The statute's more focused research exemption provides that "[t]he use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute infringement." The presence of a research exemption separate from the noncommercial acts exemption may suggest that a competing plant breeder can lawfully appropriate a protected variety without authority and use it in a breeding program to develop new commercial varieties, at least as long as such new varieties are different enough not to be "essentially derived" from the original protected variety. The interpretation of the research exemption is vital to the proper functioning of the PVPA, because its coverage, if misconstrued, could overlap entirely with the statute's definition of infringement. Congress expected that PVPA infringement would "al-

most never” arise through “independent work, but by willful reproduction starting from the protected variety itself.”

PVPA infringement almost invariably begins with a supply of protected seed. Coupled with sufficient knowledge of agronomy and a penchant for experimentation, access to PVPA-protected reproductive matter may enable other parties to propagate specimens of a protected plant for purposes other than feed, fiber, or food. This is true even of hybrids, which over the course of the twentieth century became the predominant form of cultivar in many crops. Traditionally associated with allogamous, or cross-pollinating, crops such as maize, sunflower, brassicas, cucurbits, carrots, beets, and onions, the use of hybrid cultivars has become common even in certain autogamous (i.e., self-pollinating) crops, including sorghum, tomato, and peppers and in the production of allogamous crops in nonindustrialized countries. Hybrid corn, perhaps the most commercially valuable crop produced by this technique, begins with the development of two inbred lines by self-pollination and selection until each line is relatively homozygous. The use of pollen from the male inbred line to fertilize silks on the female inbred line then yields hybrid seed.

Despite all precautions, each bag of hybrid seeds contains a small amount of inbred seeds. These “chasing selfs,” if planted, reproduce the parent lines true-to-type. With sufficient patience and land, a competing plant breeder, a farmer, or an academic researcher can use chasing selfs to unlock the inbred parent lines of a hybrid variety of corn, sorghum, or sunflower. Planting all the seeds from a bag of hybrid seed in a configuration that puts adequate space between plants facilitates ready identification of any inadvertently included inbred plants. Lacking heterosis, or hybrid vigor, inbred plants look different from the taller hybrids. In the past decade, major commercial seed breeders have resolved several lawsuits alleging breach of intellectual property rights through use of the “chasing selfs” technique.

The crucial issue presented by the research exemption is the definition of “plant breeding or other bona fide research.” This verbal formulation defines the extent of research activities shielded from PVPA liability. The plain language of the research exemption shields only genuine, bona fide research activities. Surreptitious acts, such as efforts to isolate chasing selfs in a bag of hybrid seed, cannot constitute “plant breeding or other bona fide research.” Whatever else it might be, it is hard to imagine how surreptitious exploitation of another party’s proprietary seed for the purpose of duplicating that variety could be viewed as a “good faith” activity. There is nothing “bona fide” about converting another company’s proprietary plant variety. Competitors do not enjoy some sort of open-ended “breeder’s exemption” entitling them to unauthorized exploitation of proprietary

Does chasing selfs violate the trade secret rights of the first breeder? Does the answer depend on how the competing breeder obtained the hybrid seeds? See *Pioneer Hi-Bred Intern. v. Holden Foundation Seeds, Inc.*, 35 F. 3d 1226 (8th Cir. 1994).

seed.

### e Infringement

#### Plant Variety Protection Act

##### 7 U.S.C § 2541

##### *Infringement of plant variety protection*

"Owners may give notice to the public by physically associating with or affixing to the container of seed of a variety or by fixing to the variety, a label containing either the words 'Unauthorized Propagation Prohibited' or the words 'Unauthorized Seed Multiplication Prohibited' and after the certificate issues, such additional words as 'U.S. Protected Variety.'" 7 U.S.C. § 2567

- (a) *Acts constituting infringement.* – Except as otherwise provided in this subchapter, it shall be an infringement of the rights of the owner of a protected variety to perform without authority, any of the following acts in the United States, or in commerce which can be regulated by Congress or affecting such commerce, prior to expiration of the right to plant variety protection but after either the issue of the certificate or the distribution of a protected plant variety with the notice under section 2567 of this title:
- (1) sell or market the protected variety, or offer it or expose it for sale, deliver it, ship it, consign it, exchange it, or solicit an offer to buy it, or any other transfer of title or possession of it;
  - (2) import the variety into, or export it from, the United States;
  - (3) sexually multiply, or propagate by a tuber or a part of a tuber, the variety as a step in marketing (for growing purposes) the variety;
  - (4) use the variety in producing (as distinguished from developing) a hybrid or different variety therefrom;
  - (5) use seed which had been marked "Unauthorized Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited" or progeny thereof to propagate the variety;
  - (6) dispense the variety to another, in a form which can be propagated, without notice as to being a protected variety under which it was received;
  - (7) condition the variety for the purpose of propagation, except to the extent that the conditioning is related to the activities permitted under section 2543 of this title;
  - (8) stock the variety for any of the purposes referred to in paragraphs (1) through (7);
  - (9) perform any of the foregoing acts even in instances in which the variety is multiplied other than sexually, except in pursuance of a valid United States plant patent; or
  - (10) instigate or actively induce performance of any of the foregoing acts.
- (c) *Applicability to certain plant varieties.* – This section shall apply equally to –

- (1) any variety that is essentially derived from a protected variety, unless the protected variety is an essentially derived variety;
  - (2) any variety that is not clearly distinguishable from a protected variety;
  - (3) any variety whose production requires the repeated use of a protected variety; and
  - (4) harvested material (including entire plants and parts of plants) obtained through the unauthorized use of propagating material of a protected variety, unless the owner of the variety has had a reasonable opportunity to exercise the rights provided under this chapter with respect to the propagating material.
- (d) *Acts not considered infringing.* – It shall not be an infringement of the rights of the owner of a variety to perform any act concerning propagating material of any kind, or harvested material, including entire plants and parts of plants, of a protected variety that is sold or otherwise marketed with the consent of the owner in the United States, unless the act involves further propagation of the variety or involves an export of material of the variety, that enables the propagation of the variety, into a country that does not protect varieties of the plant genus or species to which the variety belongs, unless the exported material is for final consumption purposes.
- (e) *Private noncommercial uses.* – It shall not be an infringement of the rights of the owner of a variety to perform any act done privately and for noncommercial purposes.
- (3) *Essentially derived variety.* –
- (A) *In general.* – The term “essentially derived variety” means a variety that—
- (i) is predominantly derived from another variety (referred to in this paragraph as the “initial variety”) or from a variety that is predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety;
  - (ii) is clearly distinguishable from the initial variety; and
  - (iii) except for differences that result from the act of derivation, conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

PVPA § 41(a)

7 U.S.C § 2401(a)

*Definitions and rules of construction*

- (B) *Methods.* – An essentially derived variety may be obtained by the selection of a natural or induced mutant or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, transformation by genetic engineering, or other method.

### Delta and Pine Land Co. v. Sinkers Corp.

177 F.3d 1343 (1999)

The court described the delinting process as follows: "To process cottonseed, such as a farmer might purchase from Delta, the seed is first taken to a gin where most of the fiber or lint is separated from the seed. The seed can then be taken to a delinter, such as Sinkers. The delinting process removes the remaining lint. Undelinted, but ginned, cottonseed arrives at Sinkers's Kennett facility in a truck. In some cases, individual farmers bring cottonseed to the facility in pickup trucks. In other cases, however, large quantities of cottonseed, from many different distributors, farmers and farming cooperatives, arrive in tractor-trailer rigs. Upon its arrival at Sinkers's facility, undelinted cottonseed is placed in a "run bin". The seed is then fed into an auger, where it is wetted with a sulfuric acid solution. From there, the seed passes through a centrifuge where the solution is spun off. The seed emerges in a damp-dry condition and is passed through two dryers and two buffers. In the drying and buffing process, all remaining lint is separated from the seed. After culls, sticks and debris are removed from the bulk seed, the seed is treated with chemicals (if the client so requests—this is the "conditioning" stage of the process, the seed having by now been delinted), and then placed in fifty-pound bags. After the seed has been bagged, it is loaded onto trucks and transported to its next destination, which may or may not be the place from which the seed was sent, depending on the instructions given to the delinter."

Delta Pine and Land is a developer and breeder of cotton planting seed. It holds numerous PVP Certificates protecting its novel seed varieties. DPL sells these protected cottonseed varieties through approved distributors. The authorized distributors sell seed to growers who plant the seed, harvest the cotton, and then dispose of all excess protected cottonseed.

Sinkers's principal business activity consists of delinting and conditioning cottonseed for use as planting seed. Cotton growers bring undelinted cottonseed to Sinkers, Sinkers delints the cottonseed per their request, and then turns the cottonseed over to whomever the grower specifies. The delinting process is an essential step in preparing cottonseed for planting. Virtually all cotton farmers in the United States utilize delinted cottonseed in planting their crops.

The PVPA gives the holder of a PVP Certificate rather broad exclusive rights. However, at the time this case was brought in the district court, there was one express, broad exemption to these exclusive rights.<sup>3</sup> The PVPA allowed a farmer to save seed and to use such "saved seed" to produce crops on his own farm, and furthermore allowed certain "farmer-to-farmer" sales of excess saved seed. This exemption was contained in 7 U.S.C. § 2543, which provided as follows:

Except to the extent that such action may constitute an infringement under [§§ 2541(3) and (4)], it shall not infringe any right hereunder for a person to save seed produced by him from seed obtained . . . by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section: Provided, that without regard to [§ 2541(3)] it shall not infringe any right hereunder for a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell such saved seed to other persons so engaged, for

<sup>3</sup>his exemption is no longer part of the PVPA. The pertinent language was deleted from the statute in 1994 greatly narrowing this sole express exemption. The amendments deleting certain language, however, apply only to PVP Certificates issued after April 4, 1995, that were not pending on or before that date.

reproductive purposes.

The Supreme Court later interpreted this exemption to mean that, for a farmer to meet the requirements of the above proviso, the farmer may sell for reproductive purposes only so much seed as he has saved for the purpose of replanting his own acreage. *Asgrow Seed Co. v. Winterboer* Presumably, such sales occur only when the farmer reduces or eliminates his cotton acreage, and, thus, has "saved seed" for which he or she has no farming use. Otherwise, there has been little case law interpreting the PVPA. But the language of the statute is clear: the only express exemption to a PVP Certificate holder's rights is that included in section 2543 for farmer-to-farmer transfers of protected seed. In the instant case, however, the district court implied an additional exemption to the rights of a PVP Certificate holder. We must decide if the court was correct in its discernment and its definition of this exemption.

*Asgrow*: 513 U.S. 179, (1995)

I. TRANSFER OF POSSESSION WITHOUT AUTHORITY: 7 U.S.C. § 2541(1)

Delta alleges that Sinkers infringed their rights under 7 U.S.C. § 2541(1) "merely by virtue of its transfer of possession of seed without the benefit of an exemption from PVPA liability." Sinkers's defense rested on an extension of the express exemption for the farmer-to-farmer sales that it viewed as implied in the PVPA, as previously interpreted. Sinkers argued that it was a mere passive third-party to the lawful transfers of possession incident to sales arranged between farmers under the express exemption and therefore could not itself be liable. Until *Asgrow*, the leading case on the farmer-to-farmer exemption was *Delta and Pine Land Co. v. Peoples Gin Co.*. It remains the only other significant precedent on implied exemptions under the PVPA.

*People's Gin Co*: 694 F.2d 1012 (5th Cir. 1983)

In *People's Gin Co*, the sole issue was whether the involvement of a third party broker rendered otherwise exempt sales between farmers ineligible for the exemption. The Fifth Circuit held that 7 U.S.C. § 2543 "only exempts sales of the protected variety from one farmer directly to another farmer accomplished without the active intervention of a third party." That case concerned the infringement liability of a farmer's co-operative which was brokering exchanges of seed between its members. The fact that the farmer's cooperative, Peoples Gin Company, also ran a gin was not an issue in that case, as the whole focus was on the cooperative's brokering activities. In the instant case, however, the district court made a fact-finding that Sinkers did not broker or actively intervene to arrange the sales that led to the transfers of possession challenged by Delta. We must agree with that fact-finding because on this record it cannot be seen as clearly erroneous. Indeed, it is essentially undisputed. Therefore, we see this case as entirely distinguishable on its facts from *People's Gin Co*. The issue raised in this case, then, is one of first impression. It is whether

a passive third-party to a sales transaction, such as a ginner or a delin-ter, can be held liable for infringement under 7 U.S.C. § 2541(1), as a participant in unauthorized possession transfers, if they fall outside the farmer-to-farmer exemption.

The district court, in resolving this issue, relied on *People's Gin Co* and in particular the language "active intervention" used by the Fifth Circuit to distinguish between exempt and non-exempt farmer-to-farmer sales. *People's Gin Co* focused solely on sales – selling the protected seed, offering it for sale or soliciting an offer to buy it, and did not reach the transfer of possession clause at issue in the instant case. The district court acknowledged this distinction, but still decided that as this was a subsection (1) case, if the Fifth Circuit had drawn a distinction with regards to selling and buying seed, then that distinction could be drawn with regards to the transfer of possession clause. Accordingly, the district court applied an active/passive (or broker/non-broker) distinction to the subsection (1) transfer of possession claim in the instant case, even though Sinkers was obviously not a broker, holding that:

the passive conduct of [Sinkers] on the facts here [does] not ... constitute a delivery, shipment or transfer of possession of seed by [Sinkers] within the meaning of § 2541(1), regardless of whether the seed involved is protected or the underlying sale or transfer involving [Sinkers's] customer is within the § 2543 exemption.

Today we hold that the district court's interpretation of 7 U.S.C. § 2541(1) is erroneous. Because the plain language of subsection (1) itself does not require the transfer act to be an "active" one, i.e., by a broker, the subsection necessarily appears to comprehend a situation where infringement by transfer of possession could occur without the delin-ter or a third party brokering a sale, or deciding to whom to transfer possession, but rather was nonetheless transferring possession without authorization from the PVP Certificate holder. Applying the exemption more broadly to grant blanket immunity to a delin-ter conflicts with the provision providing for liability for any transfer of possession of protected seed.

There is, to be sure, a statement in *People's Gin Co* that:

A sale is exempt if the seller instructs his cooperative to forward his seed to a particular named buyer. In that situation, the cooperative has not arranged the sale. Nor has it played an active role in the transaction. It has merely served as the vehicle for the transfer of possession.

We agree with the district court that such a factual scenario was not present and hence not at issue in *People's Gin Co* and consequently

this statement is dictum.

More importantly, we do not believe the adaptation of Peoples to this case by the district court was consistent with the structure and purpose of the prohibition on unauthorized and non-exempt transfers of possession in subsection (1). The district court is, in effect, adding limiting language ("actively") to subsection (1) that was left out by Congress in subsection (1) and used by Congress only in subsection (8). The district court found that Sinkers did not induce anyone to take possession of or sell the seed. The district court also found that Sinkers did not transfer title to the seed. However, Sinkers undeniably transferred possession<sup>[5]</sup> of the seed, when it delivered the seed to whomever its customer requested delivery be made. Sinkers was given control over the undelinted seed by the farmer or cooperative that delivered the seed to Sinkers, and then Sinkers transferred control of the delinted seed to the farmer or cooperative identified as the recipient by Sinkers's customer. For these reasons, we hold there is no requirement associated with subsection (1) of active intervention or brokering, as there is with subsection (8).

On the other hand, the broadest possible reading of subsection (1) does not make much sense to us, either. We cannot imagine that Congress would have meant to make a completely innocent third-party liable for infringement because it transferred possession of seed to a farmer at the request of another farmer, its customer. An example of when Congress could not have meant to impose liability might be where a single farmer, Joan, brings in one truckload of seed to be delinted, and Farmer Bob picks the seed up in a transfer of possession that is illegal, because, unbeknownst to the delinter, Joan does not actually farm cotton. Thus, while the transaction appears to fall within the exemption for farmer-to-farmer transfer, actually it does not. The delinter, we think, should be liable for all illegal transfers of possession, when not brokered by them, only if it has scienter. That is, when transferring possession of protected seed under instructions from its customer, the delinter is liable only if it knows the transfer is not within the exemption for farmer-to-farmer transfers. Absent scienter, however, involvement in farmer-to-farmer transfers outside the express exemption, should not subject delinters and ginners to liability for infringement.

The dissent disagrees with this test, arguing, in effect, that delinters and ginners should not be liable for infringement, even with scienter, as long as they did not broker the transfer of possession of the seed. We do not believe that Congress meant for delinters and ginners to be exempt from infringement of the PVPA, even when they are following the instructions of their customers, if they know they are participating in an illegal activity. An example of a scenario highlighting this difference between the dissent's view and our own

might be one in which Farmer Joan brings in her seed to be delinted, and signs a contract for two points of delivery. Farmer Joan has had a bumper harvest of protected cottonseed this year, in our example, and Farmer Bob has had a terrible year. Farmer Joan agrees to sell her excess protected seed to Farmer Bob, so that he doesn't have to pay the higher prices charged by the PVP Certificate holder for the protected seed. Farmer Joan tells the delinter that she would like half of her seed delinted and returned to her so that she can replant the same acreage that she had the year before (e.g., the "saved seed" allowed under Asgrow). Farmer Joan then tells the delinter that she would like the other half of her protected seed delinted and delivered to Farmer Bob to use for reproductive purposes on his farm. The delinter at this point clearly has scienter, and knows that Farmer Joan, at least, is participating in an unlawful activity. We cannot believe that Congress did not mean for the delinter to be found liable for infringing the PVPA in this scenario, but that is the result the dissent's test would cause. According to their "brokerage test", the delinter has done nothing wrong here. We feel that if Congress meant the delinters and ginners to be able to follow unquestioningly their customer's orders and still avoid liability, surely they would have written an express per se exemption into the PVPA, just as they did for common carriers.

The common carrier exception is in PVPA § 115, 7 U.S.C. §2545, excerpted above.

We therefore hold that the correct reading of subsection (1) requires that a delinter, ginner, or other third-party transferor facilitating a farmer-to-farmer sale know (knowledge is presumed in a scenario where the third party brokers the transaction) or should reasonably know that its unauthorized transfer of possession is an infringing transaction, i.e., that the sale is not exempt under section 2543. Liability for infringement under subsection (1) thus turns on knowledge. If Sinkers knew, or should have known, that the transfer of possession was not within the farmer-to-farmer exemption, then it can be held liable for infringing subsection (1), but only then.

We note that the district court also erred in stating that "the passive conduct of Sinkers on the facts here does not constitute infringement regardless of whether the seed involved is within the § 2543 exemption." Under *Asgrow* a farmer is allowed to save seed to replant his or her own acreage the next year. In order to plant the seed it must be delinted. Therefore, *Asgrow* must also carve an exemption out for the transfer of possession of protected seed to a delinter if it is only the seed the farmer is saving for his or her own acreage. Whether the seed involved is within the section 2543 exemption thus becomes a crucial and important question.

We note that the scenario where the seed is returned to the farmer or cooperative from which the seed was received potentially complicates application of the "should have known" standard, as a farmer

is entitled to save seed for reproductive use on his own farm, and may in fact save seed for several years of future plantings. However, there are still "red flags" which a delinter such as Sinkers can spot. If a farmer returns year after year with more seed than he or she could possibly use, based either on Sinkers's knowledge of the actual size of the farmer's acreage or, imply an absurdly large amount of seed, then clearly this seed is not being saved for reproductive purposes just for the farmer's own acreage, and Sinkers would have scienter.

We note that the dissent expresses concern over the "paper trail" that it speculates this test will create. First of all, the certificate holder is required to prove that the ginners and/or delinters knew or should have known they were processing "hot seed." Thus, there is no burden on the ginner or delinter to disprove anything. Accordingly, in many situations no record keeping would be needed.

Presumably the ginners and delinters process seed full-time. This would suggest that they work with the same farmers from year to year, and have some idea of how much seed is a reasonable amount of saved seed for a particular farmer, or farming cooperative lawfully to bring in for processing. It should be obvious, for example, that enough seed to replant forty square miles of cotton fields is not a reasonable amount for a cooperative to bring in as saved seed for processing. In such a case, but only then, the ginner or delinter may indeed want to ask for written reassurance that it will not be breaking the law by processing this huge quantity of seed, because processing inevitably requires transferring possession of the seed, once delinted or ginned, to someone. However, this written assurance does not impart immunity. If the certificate holder can prove actual knowledge, or show that the delinter or ginner should have known it was handling hot seed, the delinter or ginner is still liable for infringement of the PVPA. We note, furthermore, that while, of course, on this record we could not describe the contents of a standard contract between a farmer or cooperative and a delinter or ginner, it is reasonable to assume that it would address: the price per pound for the processing; the delivery terms; and the condition the farmer can expect the seed to be in when it is returned or re-delivered by the ginner and/or delinter. This contract may also specify the chemical conditioning treatments the farmer or cooperative wants the seed exposed to ("So ... they tell you ... whether they want [the seed] double treated or triple treated"); the amount of cleaning the seed should be given ("we have ... some farmers that like to have the seed ... cleaned a little heavy [t]ake a little more waste out to give you a better seed"); it may give the farmer a warranty that his seed will not be mixed with colored cottonseed, that his seed will not be mixed with non-USDA approved seed, and that he will receive the same variety of seed back that he dropped off to be processed. We do not believe, with this

many other specifications which may be present in a contract for cottonseed processing, that it is placing a significant burden on the delinters or ginners to place one more paragraph in the contract, thus providing some limited protection against liability. Accordingly, our test hardly "creates" a complex record-keeping regime. One apparently already exists.

#### II. ACTIVE INDUCEMENT BY BROKERAGE: 7 U.S.C. § 2541(8)

Delta next alleged that by willfully ignoring the large quantities of apparently protected seed that Sinkers was processing without its authority, Sinkers actively induced unlawful transfers of possession by others, and thus infringed Delta's rights under 7 U.S.C. § 2541(8). The district court found, as stated above, that Sinkers did not intervene as a third-party in the transfers of possession of the protected seed. We agree, for it was not clear error for the district court to find that Sinkers did not broker protected seed transfers and did not actively induce anyone to transfer possession of the seed to other parties in any way violative of the statute. Sinkers merely turned delinted seed over to whomever its customers, such as Nodena, identified. In subsection (8) of section 2541, the critical words "instigate or actively induce", clearly evince congressional intent to limit liability under this subsection to those such as brokers, who perform such functions when they arrange transfers of seed, in the instant case via the delinter, between independent sellers and buyers. The district court correctly found, however, that Sinkers did not perform either of these functions. Certainly, its findings are not clearly erroneous. Indeed, the facts seem undisputed. Delta argues here only that Sinkers recklessly or with willful indifference transferred possession of large quantities of protected seed in violation of the PVPA. This might be true, but we make no decision on that issue here, because, even if the allegation is true, it is insufficient to trigger 7 U.S.C. § 2541(8). Sinkers did not broker the sale or transfer of possession of any protected seed, or otherwise instigate or actively induce others to infringe.

#### III. THE NOTICE REQUIREMENT: 7 U.S.C. § 2541(6)

Finally, we address the issue of the notice required under subsection (6) of 7 U.S.C. § 2541. The district court only summarily addressed this issue, holding that "the Court would read the 'under which it was received' clause of § 2541(6) to limit the notice requirement to instances in which the seed was received with a label stating that it was a protected variety." We vacate the judgment based on this holding by the district court. The proper test is not whether a physical label is somehow attached to the seed when the seed is received, but rather whether through that or other means the one in receipt, here Sinkers, knew, or should have known that the seed is a protected va-

riety. Subsection (6) provides that it is infringement to “dispense the novel variety to another ... without notice as to being a protected variety under which it was received.” The notice that must be received is not restricted to actual notice, or to notice in the form of labels on the seed, as the district court concluded, or else Congress would surely have included language indicating such restrictions.

By comparison, a patentee seeking to give notice to the public that an item is patented is required by Congress to mark it according to a specific list of acceptable methods as detailed in 35 U.S.C. § 287. The language here is much broader, and merely reads that dispensing of the novel variety without notice that it is a novel variety infringes the rights of the holder of the PVP Certificate covering the novel variety. Because Congress gave specific notice requirements in 35 U.S.C. § 287, and omitted these requirements in subsection (6), we read the latter statute not to require express notice, or labels on receipt, in order for a failure to give notice to infringe.

In the Nodena example, the district court found that references in Sinkers’s own germination logs to this seed as “Lot 5” seed reflected Nodena’s own designation of the seed in that manner to indicate that the seed was DPL-50 seed. Under the test applied by the district court, because this seed arrived with no physical tag on it to indicate that it was protected DPL-50 seed, Sinkers had no responsibility to notify its transferee that the transferred seed was protected seed. However, Sinkers was informed by Nodena that it was Lot 5 seed, according to the notations in its own logs. If on remand the district court finds that Sinkers had notice, i.e., that it knew the term “Lot 5” was Nodena’s way of designating protected DPL-50 seed, then Sinkers infringed Delta’s PVPA rights when it did not label the bags containing Nodena’s delinted seed as protected seed. We further understand that in order to protect the vigor and germination ability of the cottonseed, the delinter and ginner need to know the type of seed they are processing so that they know how to process it, e.g., the proper storage method, the amount of moisture to expose it to, and the temperature least likely to cause it to germinate early. Early maturation seed that has undergone no chemical treatments by the manufacturer, is processed differently from late maturation seed that may have been genetically altered to not be affected by herbicides. It is, therefore, likely that they are accurately informed by the cooperative and farmers of the varieties of seed being delivered for processing and that they may want to take affirmative steps, e.g., germination tests, to assure themselves of the exact varieties accepted for processing, lest they become liable for harming the seed. Once a ginner or delinter has determined the variety of cottonseed undergoing processing, it has an affirmative duty to label the cottonseed with the variety upon

returning or re-delivering the cotton-seed.

Clevenger, Circuit Judge, dissenting:

I agree that some limit must be placed on the transfer of possession statute to avoid absurd results. Even the Supreme Court has noted that this statute is virtually impossible to parse satisfactorily. *See Asgrow*

Some 17 years ago, the Fifth Circuit (which incidentally knows more about cotton growing, ginning and delinting than we) grappled with the Act and found another way of placing some sensible limits on the transfer and labeling provisions of the Act. In *People's Gin Co*, that court held that a party who is but a passive participant in a farmer-to-farmer transfer cannot be held liable under the Act. In that case, the defendants were found to have arranged sales transactions among the farmers; not being merely passive, they were held liable under the Act. From 1983 until today, *People's Gin Co* has been the law of the Cotton Belt. Indeed, when this case was brought, the plaintiffs were under the impression that Sinkers had been actively participating in arranging the farmer-to-farmer transfers, and that this presumably would be an easy case for them to win under the law of *People's Gin Co*. As is so often the case, however, discovery proved the plaintiffs wrong: the evidence proves, as a matter of fact, that Sinkers has been a mere passive conduit in the farmer-to-farmer sales. For that reason, the district court simply applied the law of the Cotton Belt and relieved Sinkers from liability under the Act. The court quite reasonably noted that a delinter who is merely passively carrying out the instruction of its customers in delivering or releasing delinted seed is not substantively different from a delinter who merely returns the delinted seed to the person who asked it to be delinted. The court opined, and I agree, that a mere return of delinted seed to the sender should not violate the transfer of possession provision.

The majority prefers not to follow the lead of the Fifth Circuit. I think it is a mistake to read a scienter requirement into the transfer of possession provision. It seems clear that Congress put the scienter element where it belongs, in section 2541(8).

Under the law as stated in *People's Gin Co*, ginners and delinters were saved the need to create a "paper trail" to protect completely passive conduct from liability under the Act. Under the rule devised by the majority in this case, ginners and delinters will become paper-keeping traffic cops. Ginners and delinters will have to keep up-to-date records on the membership of cotton cooperatives, including the acreage planted in cotton each season by each member of the cooperative. Under the majority's rule, a forty member cooperative (forty farms of roughly a square mile each) will be a prima facie suspect of delivering excess seed to the ginner or delinter. Ginners and delinters

will also have to keep current with any increase in acreage purchased by farmers during the course of a year, so they can satisfy themselves that a farmer is not delivering too much seed for ginning or delinting. Presumably ginners and delinters will want to ask those who deliver seed to them to provide them with certificates that say something like "the seed we are delivering is within the current section 2543 exemption." Those who deliver the seed to those who deliver it to ginners and delinters will also want some kind of certificate, to the same effect. The paper trail presumably will lead right back to the section 2543 farmer who is trying to save seed for his own use, or for sale as now permitted under section 2543. I can see mountains of paper piling up throughout the Cotton Belt. I can also see lots of work for lawyers trying and defending this kind of case. And many headaches for judges, who will have to decide if a case is lost, or won, when there are (as there inevitably will be) glitches here and there in the paper trail that, in a perfect, Federal Circuit world, will lead from farmer Joan on her south 40 to her neighbor with the truck who brings her seed to a coop, which gives the seed to another to take it first to the ginner, then to the delinter and finally either back to Joan or to the person who buys her seed. Now all of this seems like a whole lot of trouble being visited on a settled law that went unchallenged for a very long time, and only got challenged in this case when the proofs under the settled law ran against the plaintiff.

The majority responds to my concern by guessing what goes into a cottonseed delinting contract, assuming farmer Joan signs such a contract, and then postulating that all a ginner or delinter needs to do to avoid liability is to stick a clause in the contract saying something like "you promise me that the amount of seed you are delivering does not exceed the amount you can lawfully save for replanting." That it will be so easy to satisfy the scienter requirement seems to me all the more reason why we should leave settled law alone.

The majority opinion notes that Congress amended the Act in 1994. That amendment preserves the right of a farmer to save seed from the crop he produces from protected seed he has purchased. The farmer must either use such saved seed "in the production of a crop for use on the farm of the person," or sell such amount of the saved seed in a "bona fide sale for other than reproductive purposes."

This case, of course, arises under the statute before its amendment, and therefore neither the majority nor I can say with authority how the holding of the majority will apply to the future. We can predict, however, that a farmer who has purchased protected seed, and who wishes to use or sell the seed propagated by his plantings of protected seed—as the amended Act permits—will need the services of a delinter. It thus seems that, in order to avoid the absurd results that follow from an unrestrained reading of the Act, either a "passive" or

a “knowing” exception to the statute, or some other escape valve, is required.

I of course recognize that I, like the majority, read an exception into an otherwise broad statute. Whether either of us is correct in so doing is a matter for others to determine. Perhaps the Supreme Court will wish to grapple with the Act, again.

### 3 The Punchline

#### **JEM Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.** 534 U.S. 124 (2001)

This case presents the question whether utility patents may be issued for plants under, or whether the Plant Variety Protection Act and the Plant Patent Act of 1930 are the exclusive means of obtaining a federal statutory right to exclude others from reproducing, selling, or using plants or plant varieties. We hold that utility patents may be issued for plants.

The United States Patent and Trademark Office (PTO) has issued some 1,800 utility patents for plants, plant parts, and seeds. Seventeen of these patents are held by Pioneer Hi-Bred International. Pioneer’s patents cover the manufacture, use, sale, and offer for sale of the company’s inbred and hybrid corn seed products. A patent for an inbred corn line protects both the seeds and plants of the inbred line and the hybrids produced by crossing the protected inbred line with another corn line. *See, e.g.*, U.S. Pat. No. 5,506,367. A hybrid plant patent protects the plant, its seeds, variants, mutants, and trivial modifications of the hybrid. *See* U.S. Pat No. 5,491,295.

As this Court recognized over 20 years ago in *Chakrabarty*, the language of § 101 is extremely broad. Several years after *Chakrabarty*, the PTO Board of Patent Appeals and Interferences held that plants were within the understood meaning of “manufacture” or “composition of matter” and therefore were within the subject matter of § 101. *In re Hibberd*. It has been the unbroken practice of the PTO since that time to confer utility patents for plants. To obtain utility patent protection, a plant breeder must show that the plant he has developed is new, useful, and nonobvious. In addition, the plant must meet the specifications of § 112, which require a written description of the plant and a deposit of seed that is publicly accessible.

The 1930 PPA conferred patent protection to asexually reproduced plants. Significantly, nothing within either the original 1930 text of the statute or its recodified version in 1952 indicates that the PPA’s protection for asexually reproduced plants was intended to be exclusive. Importantly, chapter 15 nowhere states that plant patents are the exclusive means of granting intellectual property protection

*Hibberd*: 227 U.S.P.Q. 443 (BPAI 1985)

to plants. Although unable to point to any language that requires, or even suggests, that Congress intended the PPA's protections to be exclusive, petitioners advance three reasons why the PPA should preclude assigning utility patents for plants. We find none of these arguments to be persuasive.

First, petitioners argue that plants were not covered by the general utility patent statute prior to 1930. Prior to 1930, two factors were thought to remove plants from patent protection. The first was the belief that plants, even those artificially bred, were products of nature for purposes of the patent law. The second obstacle to patent protection for plants was the fact that plants were thought not amenable to the written description requirement of the patent law. The PPA thus gave patent protection to breeders who were previously unable to overcome these obstacles.

This does not mean, however, that prior to 1930 plants could not have fallen within the subject matter of § 101. Rather, it illustrates only that in 1930 Congress *believed* that plants were not patentable under § 101, both because they were living things and because in practice they could not meet the stringent description requirement. Yet these premises were disproved over time. As this Court held in *Chakrabarty*, "the relevant distinction" for purposes of § 101 is not "between living and inanimate things, but between products of nature, whether living or not, and humanmade inventions." In addition, advances in biological knowledge and breeding expertise have allowed plant breeders to satisfy § 101's demanding description requirement.

Second, petitioners maintain that the PPA's limitation to asexually reproduced plants would make no sense if Congress intended § 101 to authorize patents on plant varieties that were sexually reproduced. But this limitation once again merely reflects the reality of plant breeding in 1930. At that time, the primary means of reproducing bred plants true-to-type was through asexual reproduction. Congress thought that sexual reproduction through seeds was not a stable way to maintain desirable bred characteristics. Thus, it is hardly surprising that plant patents would protect only asexual reproduction, since this was the most reliable type of reproduction for preserving the desirable characteristics of breeding.

Third, petitioners argue that in 1952 Congress would not have moved plants out of the utility patent provision and into § 161 if it had intended § 101 to allow for protection of plants. Petitioners again rely on 138\*138 negative inference because they cannot point to any express indication that Congress intended § 161 to be the exclusive means of patenting plants. But this negative inference simply does not support carving out subject matter that otherwise fits comfortably within the expansive language of § 101, especially when § 101 can protect different attributes and has more stringent requirements

than does § 161.

By passing the PVPA in 1970, Congress specifically authorized limited patent-like protection for certain sexually reproduced plants. Petitioners therefore argue that this legislation evidences Congress' intent to deny broader § 101 utility patent protection for such plants. Petitioners' argument, however, is unavailing for two reasons. First, nowhere does the PVPA purport to provide the exclusive statutory means of protecting sexually reproduced plants. Second, the PVPA and § 101 can easily be reconciled. Because it is harder to qualify for a utility patent than for a Plant Variety Protection (PVP) certificate, it only makes sense that utility patents would confer a greater scope of protection.

At the time the PVPA was enacted, the PTO had already issued numerous utility patents for hybrid plant processes. Many of these patents, especially since the 1950's, included claims on the products of the patented process, i. e., the hybrid plant itself. Such plants were protected as part of a hybrid process and not on their own. Nonetheless, these hybrids still enjoyed protection under § 101, which reaffirms that such material was within the scope of § 101.

Justice Breyer, with whom Justice Stevens joins, dissenting:

I believe that the words "manufacture" or "composition of matter" do *not* cover these plants. That is because Congress intended the two more specific statutes to exclude patent protection under the Utility Patent Statute for the plants to which the more specific Acts directly refer.

## C Drug Approval

The Food and Drug Administration oversees one of the most intensive regulatory regimes in the whole of the U.S. Code. A "new drug," for example, cannot be shipped in interstate commerce unless it has gone through the FDA approval process. Why does this matter to an IP course? First, because the structure of regulatory approval changes the IP strategies of actors affected by it. Second, because Congress has rewritten the patent laws to take account of the realities of regulatory approval for certain products. (*Medtronic* summarizes.) Third, because the regulatory approval gateway is itself a source of IP-like rights, which can give one company the effectively exclusive right to use the information embedded in its drug product. And fourth, because Congress has created entirely new forms of informational exclusivity to deal with the wrinkles of the system.

*Cf. Anna B. Laakmann, A Property Theory of Medical Innovation, 56 Jurimetrics J. 117 (2016); Robin Feldman, Regulatory Property: The New IP, Colum. J.L. & Arts (forthcoming)*

There are similar but different regulatory regimes for the approval of animal drugs; of medical devices like syringes, pacemakers, and diagnostic tests; and of "biological products" like vaccines, blood plasma, and genetic therapies. We focus on drugs in this section because they illustrate all of the essential issues. There's a quick hit on biologics a little further down.

## 1 Patent Issues

The modern drug regulatory regime is, in one sense, oriented towards patent as its preferred form of intellectual property. But its demands have also compelled patent law to adapt to better fit.

**Kara B. Swanson, *Food and Drug Law as Intellectual Property Law*  
2011 Wisc. L. Rev. 331**

Within the nineteenth-century food and drug markets, the predominant use of intellectual property was to protect medicines. Patents were not, however, the preferred means of protecting commercial interests in medicines. Despite the use of the term "patent medicines" to describe nineteenth-century nostrums, only a small percentage of medicines were patent-protected in the nineteenth century. What were widely referred to as "patent medicines" during the nineteenth and early twentieth centuries were usually not patented. "Patent medicines" referred to proprietary medicines, medicines sold by only one manufacturer, containing a secret combination of ingredients. A historian of the entrepreneurs who sold such nostrums in the nineteenth and twentieth centuries has argued that only the least savvy sought patent protection for their recipes.

No one but the manufacturer knew what was in the pills, liquids, or ointments sold. When patients bought such medicines as self-treatment, or, as often happened, when physicians prescribed them, neither prescribing doctor nor patient knew what was being ingested. Instead, both relied upon advertising copy about the powers of the medicine and the recommended dosage.

Secrecy allowed the manufacturer to hide, for example, the fact that the medicine contained mostly water, or common household ingredients, or significant amounts of alcohol, the revelation of which, it was argued, would drive away consumers. Doctors and pharmacists further alleged that manufacturers had no compunction about changing the ingredients of a medicine to respond to fluctuations in prices of ingredients, while continuing to sell it under the same packaging, using the secrecy of their formulas to disguise shifting compositions. Businessmen bought and sold trade names rather than secret formulas, patents, or manufacturing know-how as they sought to maximize profits.

Elite regular physicians contrasted proprietary medicines based on secrecy against what they called "ethical" medicines. These medicines were the formulary medicines, known parts of the *materia medica*. These medicines were listed in the *United States Pharmacopeia* or the *National Formulary*, and, if mixtures, could be compounded by any druggist based on published formulae. They, too, were sold under brand names that could be protected as trademarks, but the brand

name identified the manufacturer, not the particular product. These so-called ethical manufacturers who built businesses on supplying doctors and pharmacists with consistent, good quality supplies of formulary drugs were a small part of the drug market." By the turn of the twentieth century, as the campaign of regular physicians against proprietary medicines gained strength, the ethical medicines were also defined by their advertisement to physicians, rather than directly to the public.

Regular physicians had long criticized the sale and use of proprietary medicines, even as medical journals accepted advertisements from their manufacturers and many doctors wrote prescriptions for such medicines. The critiques generally fell into three categories: (1) such nostrums were sold for far more than the value of their ingredients, and therefore were a fraud on the public's pocketbook; (2) such nostrums actively harmed their users by containing powerful drugs such as morphine; and (3) such nostrums in no way fulfilled the promises made on their labels and in their elaborate advertisements, like claims to cure cancer, tuberculosis, and syphilis. At best, consumers were being hoodwinked, and at worst, they were poisoning themselves and their children.

A campaign for comprehensive federal regulation began in earnest in 1879, when the first federal food and drug bill was introduced into Congress. From that year until 1906, such a bill was unsuccessfully introduced into every Congress. The 1906 Act as finally passed outlawed the interstate shipment of "adulterated" or "misbranded" food or drugs and their manufacture within the District of Columbia and the territories.

The proprietary medicine manufacturers quickly reduced the Act's regulatory power to inhibit their business model by winning the case *United States v. Johnson*. In his opinion, Justice Oliver Wendell Holmes declared that Congress had not intended to consider any claims about therapeutic value made on product labels as false or misleading, for such were merely matters of opinion, not susceptible to examination by the Bureau of Chemistry. Thus, manufacturers could continue to fill their labels with broad claims of cure. Congress attempted to strengthen the regulation of false claims of therapeutic value by passing the Sherley Amendment in 1912. This fix, however, failed to fully correct the problem, as the courts interpreted the language of the amendment prohibiting "false and fraudulent" claims to require a showing of intentional falsehood. While the FDA did pursue egregious claims of cure, with so many testimonials as to the value of their products, manufacturers could easily avoid a jury finding of intentional falsehood.

After two decades of agitation and five years of effort within the FDR administration, the new bill, the Federal Food, Drug, and Cos-

metic Act, passed in 1938. The new Act was much longer and more detailed, as its drafters had sought to close perceived loopholes in the first regulatory scheme. All drugs had to bear a label with "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count" as well as the name and address of the manufacturer or distributor. Most significantly, for any non-formulary drug, the "common or usual name" of each active ingredient had to be listed on the label. Finally, many ingredients of proprietary medicines would be revealed to the public, even if the exact formulae were not.

From a contemporary perspective, we might assume that the purity campaign, as a campaign against trade secrets, would embrace patents as a better intellectual property regime. Patents are often understood as a complementary choice to trade secrets, offering a strong limited-term monopoly in exchange for public disclosure. Today, we are very familiar with the arguments for the use of patents to protect pharmaceuticals—patents allow a period of exclusive sales during which time the originator of a new medicine reaps monopoly pricing as a just reward for a large investment in research and development, providing the necessary reward to incentivize the risky and expensive process of drug development. Once the drug comes off patent, other manufacturers can make and sell the same drug, causing the price paid by consumers to drop.

In 1938, as the world of laboratory-created drugs was just emerging, this argument was not yet dominant. Instead, Americans, and particularly American doctors and pharmacists, were familiar with another argument regarding patents and medicines, an argument that had persisted over the previous century. This older argument described "medical patents" – a term which lumped together any patents to medicines, methods of treatment, and medical devices – as unethical.

Yet, the new scientific ways of knowing had changed the landscape of both trade secrets and patents within the drug market. Chemistry made keeping secrets from competitors much more difficult. The proprietary medicines could be analyzed and their contents publicized. Manufacturers did not even necessarily need to do this work themselves; the AMA did some of this analysis and publication as part of its campaign against secrecy.

The remarkable aspect of the late 1930s in retrospect is not that medical patents became commonplace, unopposed by both the ethical manufacturers and organized medicine, but that for a brief window of time, the medical profession envisioned medical patents allowing a medically controlled drug marketplace. Rather than seeing patents as an unmitigated evil, allowing the privatization of what should be used for the public benefit, the medical profession saw

them as a way of increasing its own authority, a counterweight to the profit-oriented firms and the useful, but medically uninformed, federal bureaucrats in the FDA and the patent office. Instead of patents making medical professionals unethical, the control of patents by ethical professionals would make patents, now perceived as necessary aspects of a new, more complicated pharmacopeia, ethical.

Instead, through the federal food and drug regulation and the new science, doctors traded a drug marketplace dominated by secret proprietaries that offered little therapeutic value for a drug marketplace dominated by new corporatized proprietaries that offered medical miracles. Organized medicine had to be content with the control it would increasingly gain as prescription drugs became a legal category. As self-dosing became less common, doctors became the key gatekeepers on the demand side of the burgeoning market in pharmaceuticals. During the course of the twentieth century, doctors gained the ability to control their patient's access to medications, but lost any hope that doctors or medically controlled organizations would exercise control over the supply side. What medications were available for doctors to prescribe would be determined by the drug companies and the FDA.

### **Merck KGaA v. Integra Lifesciences I, Ltd.**

545 U.S. 193 (2005)

As amended at 21 U.S.C § 301 *eq seq.*

The Federal Food, Drug, and Cosmetic Act (FDCA) regulates the manufacture, use, or sale of drugs. Under the FDCA, a drugmaker must submit research data to the FDA at two general stages of new-drug development. First, a drugmaker must gain authorization to conduct clinical trials (tests on humans) by submitting an investigational new drug application (IND). The IND must describe "preclinical tests (including tests on animals) of the drug adequate to justify the proposed clinical testing." Second, to obtain authorization to market a new drug, a drugmaker must submit a new drug application (NDA), containing "full reports of investigations which have been made to show whether or not the drug is safe for use and whether the drug is effective in use." Pursuant to FDA regulations, the NDA must include all clinical studies, as well as preclinical studies related to a drug's efficacy, toxicity, and pharmacological properties.

21 U.S.C. § 355(i)(1)(A);

21 U.S.C. § 355(b)(1)

### **Eli Lilly & Co. v. Medtronic, Inc.**

496 U.S. 661 (1990)

Now twenty years.

35 U.S.C. § 154.

Under federal law, a patent "grant[s] to the patentee, his heirs or assigns, for the term of seventeen years, . . . the right to exclude others from making, using, or selling the invention throughout the United States." Except as otherwise provided, "whoever without authority makes, uses or sells any patented invention, within the United States

during the term of the patent therefor, infringes the patent.”. The parties agree that the 1984 Act was designed to respond to two unintended distortions of the 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval. First, the holder of a patent relating to such products would as a practical matter not be able to reap any financial rewards during the early years of the term. When an inventor makes a potentially useful discovery, he ordinarily protects it by applying for a patent at once. Thus, if the discovery relates to a product that cannot be marketed without substantial testing and regulatory approval, the “clock” on his patent term will be running even though he is not yet able to derive any profit from the invention.

The second distortion occurred at the other end of the patent term. In 1984, the Court of Appeals for the Federal Circuit decided that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement, see § 271(a), even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval. *See Roche Products, Inc. v. Bolar Pharmaceutical Co.* Since that activity could not be commenced by those who planned to compete with the patentee until expiration of the entire patent term, the patentee’s *de facto* monopoly would continue for an often substantial period until regulatory approval was obtained. In other words, the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term.

The Drug Price Competition and Patent Term Restoration Act of 1984 sought to eliminate this distortion from both ends of the patent period. Section 201 of the Act established a patent-term extension for patents relating to certain products that were subject to lengthy regulatory delays and could not be marketed prior to regulatory approval. The eligible products were described as follows:

- (1) The term ‘product’ means:
  - (A) A human drug product.
  - (B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.
- (2) The term ‘human drug product’ means the active ingredient of
  - (A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or
  - (B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cos-

35 U.S.C. § 271(a)

*Roche v. Bolar*: 733 F. 2d 858 (Fed. Cir. 1984)

Informally known as Hatch-Waxman, after its Congressional champions

35 U.S.C. § 156(f) (2016). NB: the language has been amended since *Medtronic*; this is the current version.

metic Act and the Virus-Serum-Toxin Act) ...

Section 201 provides that patents relating to these products can be extended up to five years if, *inter alia*, the product was "subject to a regulatory review period before its commercial marketing or use," and "the permission for the commercial marketing or use of the product after such regulatory review period [was] the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred."

35 U.S.C. § 271(e)(1)

The distortion at the other end of the patent period was addressed by § 202 of the Act. That added to the provision prohibiting patent infringement, the paragraph at issue here, establishing that "it shall not be an act of infringement to make, use, or sell a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." This allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval.

The core of the present controversy is that petitioner interprets the statutory phrase, "a Federal law which regulates the manufacture, use, or sale of drugs," to refer only to those individual provisions of federal law that regulate drugs, whereas respondent interprets it to refer to the entirety of any Act (including, of course, the FDCA) at least some of whose provisions regulate drugs. If petitioner is correct, only such provisions of the FDCA as § 505, governing premarket approval of new drugs, are covered by § 271(e)(1), and respondent's submission of information under FDCA § 515, governing premarket approval of medical devices, would not be a noninfringing use.

*Merck v. Integra* is to similar effect: § 271(e) protects "uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the FDA."

It seems most implausible to us that Congress, being demonstrably aware of the *dual* distorting effects of regulatory approval requirements in this entire area – dual distorting effects that were roughly offsetting, the disadvantage at the beginning of the term producing a more or less corresponding advantage at the end of the term – should choose to address both those distortions only for drug products; and for other products named in § 201 should enact provisions which not only leave in place an anticompetitive restriction at the end of the monopoly term but simultaneously expand the monopoly term itself, thereby not only failing to eliminate but positively aggravating distortion of the 17-year patent protection. It would take strong evidence to persuade us that this is what Congress wrought, and there is no such evidence here.

## 2 Hatch-Waxman

A firm that develops a new (or "pioneer") drug has a regulatory advantage: following approval of its NDA, no other firm is legally al-

lowed to market the drug. A generic firm could of course submit its own NDA. This would probably be faster and cheaper than the pioneer firm's NDA: after all, it would know what drug to test and write up. But it would still be slow and expensive, because it would require a full course of clinical testing and regulatory filing. So some firms tried to argue that generic drugs required no new approval from the FDA. They failed, and (*Generix*) explains why. So the baseline remained that a generic drug requires a full NDA of its own.

In 1984, Congress enacted a grand bargain between pioneer and generic firms, commonly known as Hatch-Waxman for the names of its sponsors, that alters this baseline in several important ways:

1. It gives generic firms the option of filing an "abbreviated" NDA, or ANDA, in place of a full NDA based on new clinical trials (*Actavis*).
2. It then prohibits the FDA from approving ANDAs during certain statutory exclusivity periods. *Actavis Elizabeth* illustrates, and Erika Lietzan discusses.
3. It creates specialized procedures to sort out conflicting claims over patents potentially reading on generic drugs (*Caraco*).
4. Finally, it gives a limited form of exclusivity to generic drug firms who successfully challenge patents: 180 days during which no other ANDA can be approved for the same product. *FTC v. Actavis* illustrates the economic significance of this exclusivity.

### **United States v. Generix Drug Corp.**

460 U.S. 453 (1983)

The active ingredients in most prescription drugs constitute less than 10% of the product; inactive "excipients" (such as coatings, binders, and capsules) constitute the rest. The term "generic drug" is used to describe a product that contains the same active ingredients but not necessarily the same excipients as a so-called "pioneer drug" that is marketed under a brand name.<sup>1</sup> Respondent Generix is a distributor of generic drugs manufactured by other firms.

The Government initiated this action to enjoin Generix from distributing in interstate commerce a number of generic drug products that contain eight specified active ingredients. It alleged that the FDA had never approved new drug applications with respect to any of those products.

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<sup>1</sup> Generic drugs, also called "copycat" or "me-too" drugs, are usually marketed at relatively low prices because their manufacturers do not incur the research, development, and promotional costs normally associated with the creation and marketing of an original product.

The Court of Appeals for the Fifth Circuit, now the Eleventh Circuit held that the statutory prohibition against the sale of a “new drug” without prior approval does not apply to a drug product having the same active ingredients as a previously approved drug product, regardless of any differences in excipients. It based that conclusion on its view that the statutory requirement of evaluating the safety and effectiveness of new drugs must normally relate to active ingredients, because the precise technique of formulating the finished drug is not part of the information generally known to the medical or scientific community. Moreover, it believed that the legislative history suggested that Congress had not intended to create a product-by-product licensing system.

The Court of Appeals misread the statutory text. Generic drug products are quite plainly drugs within the meaning of the FDCA.

**FTC v. Actavis, Inc.**

133 S. Ct. 2223 (2013)

A drug manufacturer, wishing to market a new prescription drug, must submit a New Drug Application to the federal Food and Drug Administration and undergo a long, comprehensive, and costly testing process, after which, if successful, the manufacturer will receive marketing approval from the FDA. *See* 21 U.S.C. § 355(b)(1) (requiring, among other things, “full reports of investigations” into safety and effectiveness; “a full list of the articles used as components”; and a “full description” of how the drug is manufactured, processed, and packed).

Once the FDA has approved a brand-name drug for marketing, a manufacturer of a generic drug can obtain similar marketing approval through use of abbreviated procedures. The Hatch-Waxman Act permits a generic manufacturer to file an Abbreviated New Drug Application specifying that the generic has the same active ingredients as and is biologically equivalent to, the already-approved brand-name drug. In this way the generic manufacturer can obtain approval while avoiding the costly and time-consuming studies needed to obtain approval for a pioneer drug. The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer’s approval efforts, speeds the introduction of low-cost generic drugs to market, thereby furthering drug competition.

**Actavis Elizabeth LLC v. U.S. Food and Drug Admin.**

625 F.3d 760 (D.C. Cir. 2010)

The Hatch–Waxman Amendments allowed generic versions of previously approved drugs to gain approval through the submission of an ANDA. These abbreviated applications reduce the effort required to gain marketing approval by, among other things, allowing the appli-

cant to rely on clinical studies submitted as part of a previous new drug application.

The Hatch–Waxman Amendments also grant various periods of marketing exclusivity to certain pioneer drugs. The exclusivity provisions protect these drugs from generic competition for the specified terms by preventing the submission of abbreviated applications that refer to them.

If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval ...

In addition to this five-year period, the Amendments grant three-year exclusivity to drugs that include previously approved active ingredients if the application for the drug “contains. reports of new clinical investigations ... essential to the approval of the application and conducted or sponsored by the applicant.”

The FDA has implemented these exclusivity provisions through regulations. The regulations give five years of exclusivity for each “drug product that contains a new chemical entity.”. A “new chemical entity” is “a drug that contains no active moiety that has been approved by FDA in any other” new drug application. “Active moiety” is defined as “the molecule or ion ... responsible for the physiological or pharmacological action of the drug substance.” [Various related forms of molecules or ions, including esters, salts, and other forms that differ only in their noncovalent bonds, are considered to be the same “active moiety.”]

In 2007, the Food and Drug Administration approved Vyvanse, a name-brand drug for the treatment of attention deficit hyperactivity disorder. Two years later, Actavis submitted an application for lisdexamfetamine dimesylate, a generic version of the same drug. The FDA returned Actavis’ application. It did so because it had previously determined that Vyvanse was entitled to five years of marketing exclusivity under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act. Actavis brought this action claiming that Vyvanse was not entitled to five years of exclusivity.

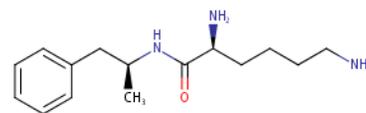
Lisdexamfetamine dimesylate is a salt of lisdexamfetamine. Since, under the agency’s regulations, salts are not considered active moieties, the agency’s analysis centered on the lisdexamfetamine molecule alone. Lisdexamfetamine consists of a portion of lysine, a

21 U.S.C. § 355(j)(5)(f)(ii)

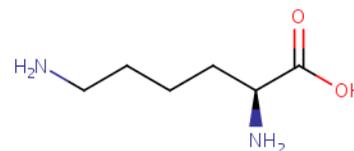
21 U.S.C. § 355(j)(5)(F)(iii)

The Best Pharmaceuticals for Children Act gives six months of additional exclusivity if the applicant conducts certain require forms of pediatric testing. See 21 U.S.C. § 355a.

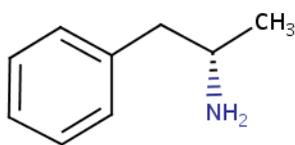
21 C.F.R. § 314.108(a) & (b)(2))



Lisdexamfetamine



Lysine



Dextroamphetamine

common amino acid, connected to dextroamphetamine. These two parts are linked by [a covalent bond]. Once it enters the body, lisdexamfetamine undergoes a chemical conversion to produce dextroamphetamine.

Actavis thinks this language [quoted above] prevents the FDA from granting five-year exclusivity to any drug containing a drug molecule (such as lisdexamfetamine) that eventually produces a previously approved drug molecule in the body.

Actavis relies mainly on the term “active ingredient,” which it says obligates the FDA to identify the particular drug molecule that reaches the “site” of the drug’s action. This molecule, Actavis argues, is necessarily the “active ingredient” of the drug in question, regardless of the form of the molecule before it enters the body. But there is nothing to indicate that Congress used the term in the sense Actavis urges. The Hatch–Waxman Amendments do not define active ingredient. The legislative history establishes only that Congress was concerned with providing incentives for innovation by granting five-year exclusivity to “new chemical entities” and is silent on what determines novelty.

Actavis argues that by using the term “active,” Congress was requiring the FDA to determine the particular molecule that provides the drug’s “activity,” which it claims is limited to the drug’s specific therapeutic effect. If this molecule has been previously approved, then five-year exclusivity is not warranted. But the FDA is right—or at least we have been given no reason to doubt—that the activity of a drug cannot be reduced to such a simple formulation. The agency has concluded that the entire pre-ingestion drug molecule should be deemed responsible for the drug’s activity, which can include its “distribution within the body, its metabolism, its excretion, or its toxicity.” There is no reason to believe Congress thought differently—or thought about it at all.

In the FDA’s view, drug derivatives such as lisdexamfetamine *are* “major innovations” deserving five-year exclusivity. The FDA’s regulations leave many types of drug derivatives eligible only for three-year exclusivity. The FDA’s policy is based on its view that drug derivatives containing covalent bonds are, on the whole, distinct from other types of derivative drugs such that the former are uniquely deserving of “new chemical entity” status and the resulting five-year exclusivity. We are hard pressed to second-guess the FDA’s view, especially since it rests on the agency’s evaluations of scientific data within its area of expertise. At best, Actavis has offered evidence that some covalent structural changes do not alter the basic properties of the drug in question and that some noncovalent structural changes do. But agencies may employ bright-line rules for reasons of administrative convenience, so long as those rules fall within a zone of rea-

Note that Hatch-Waxman NCE active-ingredient exclusivity applies only to ANDAs. Actavis remained free to submit a full NDA in support of its proposal to market lisdexamfetamine dimesylate.

sonableness and are reasonably explained. The FDA has explained that its policy is based in part on the “difficulty in determining precisely which molecule, or portion of a molecule, is responsible for a drug’s effects.” Nothing in the record establishes that the FDA’s approach is unreasonable. Given the complexity of the statutory regime, we defer to the agency’s interpretation.

**Erika Lietzan, *The Myths of Data Exclusivity***  
20 Lewis & Clark L. Rev. 91 (2016)

The conventional narrative indicates that data exclusivity is *affirmatively* provided by the state—the subtext being that the natural state of affairs is one *without* data exclusivity. Many legal scholars and policy writers describe data exclusivity as comparable to intellectual property, as patent-like, or even as a sub-type of intellectual property. The innovative industry also tends to characterize it as a type of intellectual property. Both economic and legal scholars analogize to monopoly when describing market conditions during data exclusivity – the subtext again being that natural competition has been affirmatively blocked by the State. The key to the conventional narrative is that exclusivity is artificial and provided, as a benefit, to pioneers.

But there is another way to understand what is going on. The government requires a license to market new drugs, which it will issue after reviewing the results of research to support the marketability of the drug. Anyone may apply for a license, and indeed – subject to any relevant patent protection one or another of the companies might enjoy as well as their business judgment about the value of the investment – multiple companies may file for licenses to market the same drug or drugs that are similar. That is to say, the drug approval statutes – the regulatory apparatuses – do not preclude two, or three or more applicants from seeking approval of the same thing on the same terms. From a regulatory perspective, all face the same scientific burden – preclinical and clinical research in a full application, showing the finished product is safe and effective. The second and third applicant will have a reduced burden as a practical matter simply because approval of the first product – and the large volume of information released about the contents of the application – will eliminate much of the trial and error that the first applicant experienced. They will know what to study and what not to study, they will know how to design their trials, they will know what results to expect, and they can reverse engineer the first entrant’s product to determine a suitable formulation, route of administration, dosage form, and strength. All of this will save these applicants *some* time and money, but the bulk of their expenses remain, deriving from the clinical trials that must still be performed to obtain a license.

After a period of time, federal law permits other companies to

Lietzan defines data exclusivity as "prohibitions on submission or approval of *abbreviated* applications, which implicitly or explicitly rely on previously submitted data."

What does the FDA's new drug approval process look like from a trade-secret point of view? Does this help explain the term "data exclusivity?"

Drug approval isn't the only case of data exclusivity in federal law. For example, the Federal Insecticide, Fungicide, and Rodenticide Act, which is understandably concerned with the safety of chemicals being used for their toxic qualities, has its own data exclusivity regime administered by the EPA.

Lietzan defines market exclusivity as "prohibitions on submission or approval of any competing application, even if supported by a full complement of original data."

obtain licenses for identical or highly similar medicines *without* the same amount of supporting research. The drug approval statutes remove the high evidentiary hurdle and substitute a different one, with a significantly lower investment requirement. A license to market is now available for the price of comparative analytical testing and perhaps modest comparative clinical testing. As a scientific matter, these follow-on applicants are able to obtain licenses because they rely on the research performed by the earlier applicant. That these are reliance-based applications should not be controversial. FDA has conceded that as a regulatory matter a follow-on applicant uses the first entrant's research, even if sometimes couching it as using the "fact" of the first entrant's approval. Many courts characterizing generic drug approval use the same language. In brief, then, once data exclusivity expires, any applicant may justify market entry using the research paid for and submitted by the pioneer to justify its own entry to the market. This reframes data exclusivity as a period before the law gives the pioneer's competitors something not previously available to them – a faster and cheaper license, resulting from permission to rely on the pioneer's research.

When the narrative is recast, the central myth of exclusivity is exposed; it is not a grant of anything to anyone. Data exclusivity is the *absence* of an abbreviated pathway. It does not prevent subsequent entrants from doing exactly what the first entrant did – developing the product, testing it, submitting a full application, and launching the drug, subject to relevant patent and business considerations. Contrasting *data* exclusivity with *market* exclusivity should make this clear.

Orphan-drug exclusivity is the main example in current U.S. law of market exclusivity. An orphan drug is intended to treat a rare disease or condition; the sponsor makes this showing by demonstrating that the disease affects fewer than 200,000 persons in this country or that the company does not expect to recover its costs of research and development when marketing the product. If a drug has been designated as an orphan drug, then – upon approval – it is entitled to seven years of market exclusivity. This means the FDA may not approve the same drug for the same condition for seven years, even if proposed in a full application supported by original research. Orphan-drug exclusivity is an affirmatively granted right, in the sense that it prevents subsequent entrants from doing what they would ordinarily and otherwise be permitted to do – study the molecule themselves and reach the market on the same terms as the first entrant.

**Caraco Pharmaceutical Labs v. Novo Nordisk**  
132 S. Ct. 1670 (2012)

Because the FDA cannot authorize a generic drug that would infringe a patent, the timing of an ANDA's approval depends on the scope and duration of the patents covering the brand-name drug. Those patents come in different varieties. One type protects the drug compound itself. Another kind – the one at issue here – gives the brand manufacturer exclusive rights over a particular method of using the drug. In some circumstances, a brand manufacturer may hold such a method-of-use patent even after its patent on the drug compound has expired.

To facilitate the approval of generic drugs as soon as patents allow, the Hatch-Waxman Amendments and FDA regulations direct brand manufacturers to file information about their patents. The statute mandates that a brand submit in its NDA "the patent number and the expiration date of any patent which claims the drug for which the [brand] submitted the [NDA] or which claims a method of using such drug." And the regulations issued under that statute require that, once an NDA is approved, the brand provide a description of any method-of-use patent it holds. That description is known as a use code, and the brand submits it on FDA Form 3542. As later discussed, the FDA does not attempt to verify the accuracy of the use codes that brand manufacturers supply. It simply publishes the codes, along with the corresponding patent numbers and expiration dates, in a fat, brightly hued volume called the Orange Book (less colorfully but more officially denominated Approved Drug Products with Therapeutic Equivalence Evaluations).

21 U.S.C. S S 355(b)(1)

After consulting the Orange Book, a company filing an ANDA must assure the FDA that its proposed generic drug will not infringe the brand's patents. When no patents are listed in the Orange Book or all listed patents have expired (or will expire prior to the ANDA's approval), the generic manufacturer simply certifies to that effect. Otherwise, the applicant has two possible ways to obtain approval.

One option is to submit a so-called section viii statement, which asserts that the generic manufacturer will market the drug for one or more methods of use not covered by the brand's patents. A section viii statement is typically used when the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug. If the ANDA applicant follows this route, it will propose labeling for the generic drug that "carves out" from the brand's approved label the still-patented methods of use. The FDA may approve such a modified label as an exception to the usual rule that a generic drug must bear the same label as the brand-name product. FDA acceptance of the carve-out label allows the generic company to place its drug on the market (assuming the ANDA meets other requirements), but only for a subset of approved uses – i.e., those not covered by the brand's patents.

Of particular relevance here, the FDA will not approve such an ANDA if the generic's proposed carve-out label overlaps at all with the brand's use code. The FDA takes that code as a given: It does not independently assess the patent's scope or otherwise look behind the description authored by the brand. According to the agency, it lacks "both the expertise and the authority" to review patent claims; although it will forward questions about the accuracy of a use code to the brand, its own "role with respect to patent listing is ministerial." Thus, whether section viii is available to a generic manufacturer depends on how the brand describes its patent. Only if the use code provides sufficient space for the generic's proposed label will the FDA approve an ANDA with a section viii statement.

21 U.S.C. S 355(j)(2)(A)(vii)(IV)

The generic manufacturer's second option is to file a so-called paragraph IV certification, which states that a listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." A generic manufacturer will typically take this path in either of two situations: if it wants to market the drug for all uses, rather than carving out those still allegedly under patent; or if it discovers, as described above, that any carve-out label it is willing to adopt cannot avoid the brand's use code. Filing a paragraph IV certification means provoking litigation. The patent statute treats such a filing as itself an act of infringement, which gives the brand an immediate right to sue. Assuming the brand does so, the FDA generally may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed. Accordingly, the paragraph IV process is likely to keep the generic drug off the market for a lengthy period, but may eventually enable the generic company to market its drug for all approved uses.

35 U.S.C. S 271(e)(2)(A)

In the late 1990's, evidence mounted that some brands were exploiting this statutory scheme to prevent or delay the marketing of generic drugs, and the Federal Trade Commission (FTC) soon issued a study detailing these anticompetitive practices. That report focused attention on brands' submission of inaccurate patent information to the FDA. In one case cited by the FTC, *Mylan Pharmaceuticals, Inc. v. Thompson*, a brand whose original patent on a drug was set to expire listed a new patent ostensibly extending its rights over the drug, but in fact covering neither the compound nor any method of using it. The FDA, as was (and is) its wont, accepted the listing at its word and accordingly declined to approve a generic product. The generic manufacturer sued to delete the improper listing from the Orange Book, but the Federal Circuit held that the Hatch-Waxman Amendments did not allow such a right of action. As the FTC noted, that ruling meant that the only option for generic manufacturers in Mylan's situation was to file a paragraph IV certification (triggering an infringement suit) and then wait out the usual 30-month period be-

*Mylan v. Thompson*: 268 F.3d 1323 (Fed. Cir. 2001)

fore the FDA could approve an ANDA.

Congress responded to these abuses by creating a mechanism, in the form of a legal counterclaim, for generic manufacturers to challenge patent information a brand has submitted to the FDA. The provision authorizes an ANDA applicant sued for patent infringement to “assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information submitted by the [brand] under subsection (b) or (c) [of S 355] on the ground that the patent does not claim either (aa) the drug for which the [brand’s NDA] was approved; or (bb) an approved method of using the drug.”

The counterclaim thus enables a generic competitor to obtain a judgment directing a brand to “correct or delete” certain patent information that is blocking the FDA’s approval of a generic product. This case raises the question whether the counterclaim is available to fix a brand’s use code.

The text and context of the provision demonstrate that a generic company can employ the counterclaim to challenge a brand’s overbroad use code. The Hatch-Waxman Amendments authorize the FDA to approve the marketing of a generic drug for particular unpatented uses; and section viii provides the mechanism for a generic company to identify those uses, so that a product with a label matching them can quickly come to market. The statutory scheme, in other words, contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones. Within that framework, the counterclaim naturally functions to challenge the brand’s assertion of rights over whichever discrete use (or uses) the generic company wishes to pursue. That assertion, after all, is the thing blocking the generic drug’s entry on the market. The availability of the counterclaim thus matches the availability of FDA approval under the statute: A company may bring a counterclaim to show that a method of use is unpatented because establishing that fact allows the FDA to authorize a generic drug via section viii.

Consider the point as applied to this case. Caraco wishes to market a generic version of repaglinide for two (and only two) uses. Under the statute, the FDA could approve Caraco’s application so long as no patent covers those uses, regardless whether a patent protects yet a third method of using the drug. Novo agrees that Caraco could bring a counterclaim if Novo’s assertion of patent protection for repaglinide lacked any basis – for example, if Novo held no patent, yet claimed rights to the pair of uses for which Caraco seeks to market its drug. But because Novo has a valid patent on a *different* use, Novo argues that Caraco’s counterclaim evaporates. And that is so even though, once again, Caraco has no wish to market its product for that patented use and the FDA stands ready, pursuant to the statute, to approve Caraco’s product for the other two. To put the matter sim-

21 U.S.C. S 355(j)(5)(C)(ii)(I)

Justice Kagan’s statutory construction discussion makes for entertaining reading but would take us too far afield. Here’s a sample: “‘Not an’ sometimes means ‘not any,’ in the way Novo claims. If your spouse tells you he is late because he ‘did not take a cab,’ you will infer that he took no cab at all (but took the bus instead). But now stop a moment. Suppose your spouse tells you that he got lost because he ‘did not make a turn.’ You would understand that he failed to make a particular turn, not that he drove from the outset in a straight line.”

ply, Novo thinks the counterclaim disappears because it has a patent for a method of use in which neither Caraco nor the FDA is interested at all.

Another aspect of the counterclaim provision – its description of available remedies—dispatches whatever remains of Novo’s arguments. According to the statute, a successful claimant may obtain an order requiring the brand to “correct or delete” its patent information. Our interpretation of the statute gives content to both those remedies: It deletes a listing from the Orange Book when the brand holds no relevant patent and corrects the listing when the brand has misdescribed the patent’s scope. By contrast, Novo’s two arguments would all but read the term “correct” out of the statute.

**FTC v. Actavis, Inc.**  
133 S.Ct. 2223 (2013)

Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent’s term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a “reverse payment” settlement agreement. And the basic question here is whether such an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws.

Apparently most if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation, and specifically in the context of suits brought under statutory provisions allowing a generic drug manufacturer (seeking speedy marketing approval [under an ANDA]) to challenge the validity of a patent owned by an already-approved brand-name drug owner.

The Hatch-Waxman Act requires the generic manufacturer in its Abbreviated New Drug Application to “assure the FDA” that the generic “will not infringe” the brand-name’s patents. The generic can provide this assurance in one of several ways. It can certify that the brand-name manufacturer has not listed any relevant patents. It can certify that any relevant patents have expired. It can request approval to market beginning when any still-in-force patents expire. Or, it can certify that any listed, relevant patent “is invalid or will not be infringed by the manufacture, use, or sale” of the drug described in the Abbreviated New Drug Application. Taking this last-mentioned route (called the “paragraph IV” route), automatically counts as patent infringement, and often means provoking litigation. If the brand-name patentee brings an infringement suit within 45 days, the FDA then must withhold approving the generic, usually

21 U.S.C. § 355(j)(2)(A)(vii)

35 U.S.C. § 271(e)(2)(A)

for a 30-month period, while the parties litigate patent validity (or infringement) in court. If the courts decide the matter within that period, the FDA follows that determination; if they do not, the FDA may go forward and give approval to market the generic product.

Hatch-Waxman provides a special incentive for a generic to be the first to file an ANDA taking the paragraph IV route. That applicant will enjoy a period of 180 days of exclusivity (from the first commercial marketing of its drug). During that period of exclusivity no other generic can compete with the brand-name drug. If the first-to-file generic manufacturer can overcome any patent obstacle and bring the generic to market, this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars. Indeed, the Generic Pharmaceutical Association said in 2006 that the "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." The 180-day exclusivity period, however, can belong only to the first generic to file. Should that first-to-file generic forfeit the exclusivity right in one of the ways specified by statute, no other generic can obtain it.

21 U.S.C § 355(j)(5)(B)(iv)

In 1999, Solvay Pharmaceuticals, a respondent here, filed a New Drug Application for a brand-name drug called AndroGel. The FDA approved the application in 2000. In 2003, Solvay obtained a relevant patent and disclosed that fact to the FDA, as Hatch-Waxman requires.

Later the same year another respondent, Actavis, Inc. (then known as Watson Pharmaceuticals), filed an Abbreviated New Drug Application for a generic drug modeled after AndroGel. [Other parties omitted.] Solvay initiated paragraph IV patent litigation against Actavis and Paddock. Thirty months later the FDA approved Actavis' first-to-file generic product, but, in 2006, the patent-litigation parties all settled. Under the terms of the settlement Actavis agreed that it would not bring its generic to market until August 31, 2015, 65 months before Solvay's patent expired (unless someone else marketed a generic sooner). Actavis also agreed to promote AndroGel to urologists. Solvay agreed to pay an estimated \$19-\$30 million annually, for nine years, to Actavis. The companies described these payments as compensation for other services Actavis promised to perform, but the FTC contends the other services had little value. According to the FTC the true point of the payments was to compensate Actavis for agreeing not to compete against AndroGel until 2015.

On January 29, 2009, the FTC filed this lawsuit against all the settling parties. The FTC's complaint alleged that respondents violated § 5 of the Federal Trade Commission Act by unlawfully agreeing "to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years."

15 U.S.C. § 45

Solvay's patent, if valid and infringed, might have permitted it

to charge drug prices sufficient to recoup the reverse settlement payments it agreed to make to its potential generic competitors. And we are willing to take this fact as evidence that the agreement's anticompetitive effects fall within the scope of the exclusionary potential of the patent. But we do not agree that that fact, or characterization, can immunize the agreement from antitrust attack.

This Court's precedents make clear that patent-related settlement agreements can sometimes violate the antitrust laws. For one thing, to refer simply to what the holder of a valid patent could do does not by itself answer the antitrust question. The patent here may or may not be valid, and may or may not be infringed. And that exclusion may permit the patent owner to charge a higher-than-competitive price for the patented product. But an *invalidated* patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe. The paragraph IV litigation in this case put the patent's validity at issue, as well as its actual preclusive scope. The parties' settlement ended that litigation. The FTC alleges that in substance, the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages. That form of settlement is unusual. There is reason for concern that settlements taking this form tend to have significant adverse effects on competition.

Given these factors, it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well. Rather, the general procompetitive thrust of the Hatch-Waxman Act, its specific provisions facilitating challenges to a patent's validity, and its later-added provisions requiring parties to a patent dispute triggered by a paragraph IV filing to report settlement terms to the FTC and the Antitrust Division of the Department of Justice, all suggest the contrary.

But, one might ask, as a practical matter would the parties be able to enter into such an anticompetitive agreement? Would not a high reverse payment signal to other potential challengers that the patentee lacks confidence in its patent, thereby provoking additional challenges, perhaps too many for the patentee to "buy off?" Two special features of Hatch-Waxman mean that the answer to this question is "not necessarily so." First, under Hatch-Waxman only the first challenger gains the special advantage of 180 days of an exclusive right to sell a generic version of the brand-name product. And as noted, that right has proved valuable – indeed, it can be worth several hundred million dollars. Subsequent challengers cannot secure that exclusivity period, and thus stand to win significantly less than the first if they bring a successful paragraph IV challenge. That is, if subse-

quent litigation results in invalidation of the patent, or a ruling that the patent is not infringed, that litigation victory will free not just the challenger to compete, but all other potential competitors too (once they obtain FDA approval). The potential reward available to a subsequent challenger being significantly less, the patentee's payment to the initial challenger (in return for not pressing the patent challenge) will not necessarily provoke subsequent challenges. Second, a generic that files a paragraph IV after learning that the first filer has settled will (if sued by the brand-name) have to wait out a stay period of (roughly) 30 months before the FDA may approve its application, just as the first filer did. These features together mean that a reverse payment settlement with the first filer removes from consideration the most motivated challenger, and the one closest to introducing competition. It may well be that Hatch-Waxman's unique regulatory framework, including the special advantage that the 180-day exclusivity period gives to first filers, does much to explain why in this context, but not others, the patentee's ordinary incentives to resist paying off challengers (i.e., the fear of provoking myriad other challengers) appear to be more frequently overcome.

The FTC urges us to hold that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a "quick look" approach, rather than applying a "rule of reason." We decline to do so. That is because the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.

To say this is not to insist that the Commission need litigate the patent's validity, empirically demonstrate the virtues or vices of the patent system, present every possible supporting fact or refute every possible pro-defense theory. We leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.

### 3 Orphan Drugs

Lietzan contrasts the "data exclusivity" granted to pioneer drugs to the "market exclusivity" granted to orphan drugs. This section considers the orphan-drug exclusivity in more detail. Because it prohibits any subsequent NDA, it is in effect a true IP regime that gives patent-like protection for the only economically significant use of a

product.

**Genentech, Inc. v. Bowen**  
676 F. Supp. 301 (D.D.C. 1987)

As food and drug regulatory statutes go, the Orphan Drug Act is relatively straightforward and politically uncontroversial. A pharmaceutical company often must spend \$80 million or more to develop a single new drug. When the potential market for a drug is small – because the number of persons afflicted with the particular disease or condition which the drug treats is relatively small – it may be impossible for the manufacturer to recover its sizable research and development investment, much less realize an acceptable return on that investment. The Act is designed to combat the general unwillingness of pharmaceutical manufacturers to invest in the development of commercial drugs for the treatment of diseases which, although devastating to their victims, afflict too small a proportion of the population to make them commercially viable.

The Act seeks to encourage the development of “orphan drugs” by reducing the overall financial cost of development, while enhancing the developer’s ability to recover that cost through sale of the drug. Specifically, the Act attempts to reduce development costs by streamlining the FDA’s approval process for orphan drugs, by providing tax breaks for expenses related to orphan drug development,[by authorizing the FDA to assist in funding the clinical testing necessary for approval of an orphan drug, and by creating an Orphan Products Board to coordinate public and private development efforts. The Act seeks to enhance the orphan drug manufacturer’s ability to recover his investment by granting the manufacturer seven years of exclusive marketing rights “for such drug for such [rare] disease or condition.” A “rare disease or condition” is one which “affects less than 200,000 persons in the United States,” or one which “affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug.”

21 U.S.C. § 360bb

Qualification for orphan drug benefits occurs in a two-step process. At any phase of the research and development process, a manufacturer who believes its drug will treat a “rare disease or condition” may apply to the FDA for designation as “a drug for a rare disease or condition.” Although the Act does not limit the number of drugs that may be designated for treatment of a particular rare disease the FDA’s present policy is to not consider requests for orphan drug designation made after that drug has received full FDA marketing approval for that particular disease.

While any number of drugs may receive the development-phase

benefits of the Act, only one manufacturer may receive exclusive marketing rights. This post-development benefit is reserved for the first manufacturer to receive full FDA approval of its drug as safe and effective for commercial sale.

If the FDA ... approves an application ... for a drug designated under section 360bb of this title for a rare disease or condition, the FDA may not approve another application ... for such drug for such disease or condition for a person who is not the holder of such approved application ... until the expiration of seven years from the date of approval of the approved application. ...

21 U.S.C. § 360cc(a)

The FDA may authorize another manufacturer to produce "such drug for such disease or condition" only if the exclusive marketer consents in writing or is incapable of providing sufficient quantities of the drug.

As originally enacted, the Act limited the availability of exclusive marketing rights to drugs "for which a United States Letter of Patent may not be issued..." In considering the proposed legislation, the House Committee on Energy and Commerce found that many potential orphan drugs are not patentable, and stated: "In order to provide some incentive for the development of these particular orphan drugs, the Committee's bill includes an exclusive marketing right for the sponsor of such a drug." Thus, the exclusivity provision of the Act was designed to complement the patent laws, filling gaps which might leave orphan drug manufacturers unprotected.

In 1985, Congress amended the Act to delete the non-patentability criterion in the exclusivity provision. The Committee's expectation when it drafted the original provision in 1983 had been that exclusivity would be used primarily by orphan drugs that could not get product patents. However, experience under the Act demonstrated that reliance on the incentives of patent protection for all patentable orphan drugs would be insufficient. First, many patents expire before completion of the clinical testing necessary for FDA marketing approval. Second, in many cases the product patent on a drug is held by an individual or company other than the one that intends to test the drug for use against a rare disease, and prior academic publication in the area precludes issuance of a use patent. Accordingly, the fact that a product patent has been issued does not always ensure that a manufacturer will have a sufficient incentive to apply for permission to market the drug as an orphan drug.

In expanding the exclusivity provision to cover both patented and unpatented orphan drugs, the Committee noted that the provision would only benefit the sponsors of drugs with less than seven years of product patent protection available, and explained the dif-

ference between exclusivity under the Act and traditional patent protection. First, traditional patents generally offer much broader protection than orphan drug exclusivity, which is limited to treatment of a particular disease. Second, while the inviolability of a patent is limited only by the holder's ability to enforce his rights in court, orphan drug exclusivity exists only so long as the sponsor adequately supplies the market.

The Committee expressed its desire that elimination of the patentability distinction, while probably still not making orphan drugs profitable business ventures, would strengthen development by providing greater certainty to potential orphan drug sponsors.

### **Sigma-Tau Pharmaceuticals, Inc. v. Schwetz**

288 F.3d 141 (4th Cir. 2002)

Sigma-Tau Pharmaceuticals developed a drug to treat a rare condition known as carnitine deficiency in people with inborn metabolic disorders.<sup>1</sup> The FDA designated Sigma-Tau's levocarnitine drug an "orphan drug" and approved Sigma-Tau's application to market it. Its exclusivity for inborn metabolic disorders expired in 1999.

Sigma-Tau later received FDA approval for use of its levocarnitine drug for the prevention and treatment of a second rare condition – carnitine deficiency in patients with end-stage renal disease who are undergoing dialysis. Sigma-Tau's exclusivity for treating carnitine deficiency in ESRD patients expires in 2006.

The FDA recently approved the applications of two drug manufacturers, private intervenor Gensia Sicor Pharmaceuticals, Inc. and Bedford Laboratories, to market and sell generic forms of Sigma-Tau's levocarnitine drug. The agency approved the generics for the treatment of patients with inborn metabolic disorders, the unprotected indication. The generics compete with Carnitor.

As a result of these generic drug approvals, Sigma-Tau brought suit against the FDA on May 10, 2001. Sigma-Tau sought to have the approvals rescinded, or, in the alternative, to have the FDA change the generics' labeling to protect Sigma-Tau's orphan exclusivity. Sigma-Tau submits that the generics were in fact intended for use in patients with ESRD who are undergoing dialysis, and that they thereby infringed on the seven-year period of orphan exclusivity that Carnitor currently enjoys under the ODA.

The plain language of the ODA is unambiguous, and the FDA's approvals of the generics in this case comported with the clear wording of the statute. It is apparent that the FDA did not "approve an-

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<sup>1</sup>Carnitine deficiency can manifest itself in many ways, including the failure to thrive in infants, cardiomyopathy, recurrent infections, muscle weakness, and liver dysfunction.

other application ... for such drug for such disease or condition" here, but rather approved "another application ... for such drug" for a different disease or condition, one that was no longer subject to exclusivity. That is, the agency approved generic versions of Sigma-Tau's levocarnitine drug for people with inborn metabolic disorders, for which the period of orphan exclusivity had expired. The FDA did not approve the generics for the treatment of ESRD patients.

By using the words "such drug for such disease or condition," Congress made clear its intention that § 360cc(a) was to be disease-specific, not drug-specific. In other words, the statute as written protects uses, not drugs for any and all uses.

Sigma-Tau contends that the FDA was obligated to look beyond the labeling to what Sigma-Tau maintains is the reality of the situation, which is that most of the need for the generics – and thus most of the money to be made – lies in treating patients with ESRD. But this point is unavailing.

The evidentiary basis for the agency's approvals must be the use for which the approvals are sought – that is, the use for which the generics are labeled. The FDA necessarily approves the generics before their manufacturers engage in any actual marketing. If we were to ignore the deference due the FDA and impose exacting evidentiary standards upon its generic drug approval process, the agency would be faced with formidable problems. This is because many of the sources of evidence and market data to which Sigma-Tau points cannot be effectively analyzed in the pre-approval context. Thus, the intended-use inquiry Sigma-Tau urges upon us might evolve into a foreseeable-use test. Then, once the FDA approved an orphan drug for a protected indication, generic competitors might be prohibited from entering the market for almost any use.

As the district court noted, not only might this course of events result in extensions of exclusivity periods that Congress never intended, but it also might frustrate the longstanding practice of Congress, the FDA, and the courts not to interfere with physicians' judgments and their prescription of drugs for off-label uses. In light of the ensuing effects on the delivery of health care and drug prices in this country, such interference with off-label use is not something we would be wise to welcome, let alone help to bring about. Even Sigma-Tau appears to agree that the medical community's foreseeable off-label use of drugs does not violate the ODA.

## 4 Biologics

Biological products, or "biologics," are regulated somewhat differently than conventional drugs, and they raise subtly different patent issues. We're not going to get into the details of the regulatory regime.

Instead, consider how the greater complexity of biological products poses its own distinctive problems, particularly around assessing similarity for ownership and infringement purposes.

**Janet Freilich, *Patent Infringement in the Context of Follow-On Biologics***  
16 Stan. Tech. L. Rev. 9 (2012)

A biologic, or "biological product" is defined to mean "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product ... applicable to the prevention, treatment, or cure of a disease or condition of human beings." Biologics are complex proteins which are bigger, more intricate, and more poorly-understood than small molecule drugs. Biologics can be extracted from animal cells or tissue that naturally produce the protein or scientists can genetically modify cells or tissue to create a system that produces larger quantities of the protein. Because of the potential to scale up production, most biologic proteins are produced using the latter technique.

It is much more difficult to create (and to regulate) a "generic" biological product than a generic small molecule drug. Small molecule generics usually include an identical active ingredient which is chemically identical to the brand name drug's active ingredient, and which can be synthesized in a predictable and replicable process. Small molecule drugs are also generally easy to characterize. Biologics, in contrast, cannot be synthesized chemically and are instead usually produced through a recombinant cell line. Compounding these challenges, the details of the production process used by the pioneer company are protected by various intellectual property methods. The production process is thus not fully controlled (or understood), and small differences in production process – or even production by the same process but in a different facility – can result in differences in the product, which can have adverse clinical consequences. Moreover, it may not even be possible, given the current state of scientific knowledge, to determine whether two biologics are, in fact, identical.

Because of the challenges in reproducing biologics and the lack of sensitive assays for differences, the data requirements for comparing follow-on biologics to a reference product are likely to be considerably higher than the data requirements for generic companies comparing their small molecule drug to a reference product. Small molecule drug manufacturers are usually required to conduct approximately 40 to 50 clinical tests, whereas follow-on biologic manufacturers in Europe (which has had follow-on biologic legislation since 2003) are required to conduct over 200 tests.

Because no follow-on biologics have been approved, courts have not yet addressed the question of infringement. However, the first bi-

ologics are starting to come off patent, meaning that they will go forward protected only by the weaker drug product, method, or product patents seen in the section on small-molecule drugs. This will spawn opportunities for follow-on biologic work-arounds which will, like their generic predecessors, struggle with maintaining sufficient similarity to the reference drug to satisfy the FDA while maintaining sufficient differences from the reference drug to avoid infringing by equivalents.

In general, courts have been reluctant to hold that a change in a biotechnology product infringes under the doctrine of equivalents. This may be because courts struggle to understand the technology, or because scientists themselves struggle to understand how the mechanics of small changes affect the function, way, and result of biotechnologies to the same extent that they understand the function, way and result of small molecule drugs.

## D Drug Marketing

Even after approval, the regulatory regime for drugs creates interesting intellectual property issues because the *marketing* of drugs is heavily restricted. We focus on issues relating to drugs' names, physical design, and advertising.

### 1 Names

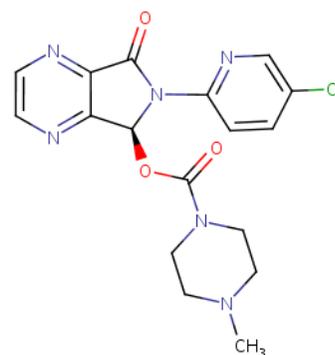
Trademark law regulates drug names to prevent confusion. But it is not the only body of law that does so: the FDA also limits what drug makers can and cannot call their drugs.

#### Note on Drug Naming

Drug names are trademarks, right? So trademark law applies? Yes, but.

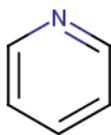
Any given drug typically has numerous names. (To illustrate, we'll focus on drugs with a single active ingredient.) Consider as an example the chemical with the following molecular structure shown in the margin. It has the molecular formula  $C_{17}H_{17}ClN_6O_3$ , but the molecular formula is a poor name, because it is far from unique. Many other organic compounds also have seventeen carbon atoms, seventeen hydrogens, a chlorine, a nitrogen, and six oxygens. Instead, here are some of the names this molecule goes by:

- *IUPAC Name*: According to the *Nomenclature of Organic Chemistry*, a 1600-page guide published and regularly revised by the International Union of Pure and Applied Chemists, the preferred IUPAC name of this molecule



A chemical

is [(7S)-6-(5-chloropyridin-2-yl)-5-oxo-7H-pyrrolo[3,4-b]pyrazin-7-yl] 4-methylpiperazine-1-carboxylate. This name is derived by systematically listing each component of the molecule, one at a time. Here, for example, 5-chloropyridin-2-yl describes the ring at the right of the molecule, with the 5 specifying where the chlorine atom is attached to it and the 2 specifying where it is attached to the rest of the molecule. The *Nomenclature* describes in exacting detail the components, their names, the order to list them in, and the various numbers, hyphens, and other connectives that explain the components' relationship in the molecule. In trademark terms, the IUPAC name describes the molecule's structure and is intended to serve as a generic term for it.



Pyridine

- InChI*: The IUPAC name contains components like chloropyridin that reflect the history of the common names people gave to molecules and their parts: pyridine is the nitrogen ring by itself. These common names don't directly reflect the underlying structure, so translating them back into the structure requires a great deal of knowledge about the different components and their names. The IUPAC has also promulgated a system, called InChI (short for "International Chemical Identifier") for converting molecular structures into more completely explicit descriptions that can be more straightforwardly converted back. The InChI for this molecule is InChI=1S/C17H17ClN6O3/c1-22-6-8-23(9-7-22)17(26)27-16-14-13(19-4-5-20-14)15(25)24(16)12-3-2-11(18)10-21-12/h2-5,10,16H,6-9H2,1H3/t16-/m0/s1. The InChI individually names each atom in the molecule, so it is longer, but also a little more transparent – which makes it easier for computers to reason about molecular structure. (A similar but somewhat less rigorous description system called SMILES would describe the molecule as CN1CCN(CC1)C(=O)OC2C3=NC=CN=C3C(=O)N2C4=NC=C(C=C4)Cl.) The InChI also describes the molecule's structure and is intended to serve as a generic term for it.
- CAS Registry Number*: IUPAC names and InChIs are long and can be unwieldy – imagine transcribing an InChI trying to make sure you had each digit right, or glancing at two IUPAC names to see whether they were the same. The Chemical Abstracts Service, operated by the American Chemical Society (the leading professional organization for chemists in the United States) maintains an index of molecules that operates on very different principles. Each molecule in the index has a systematic name given according to the system *Naming and Indexing of Chemical*

*Substances for Chemical Abstracts* published by the CAS – very much like the IUPAC system but only 156 pages and different in some respects – but also an index number, which has no chemical significance, i.e. bears no relationship to the molecule's structure. Nonetheless, it is still intended to serve as a generic term for the molecule: anyone who looks up 138729-47-2 in the CAS Registry will find the molecular diagram and its systematic name, along with much more information about it. Because they are short, CAS Registry numbers are easier to read aloud and recognize at a glance; they are also commonly used in computer databases of chemicals. CAS Registry Numbers are assigned by the CAS; one must submit an application and pay a fee to obtain one. But as just noted, they are not "owned" by the applicant; the point is to make information about the chemical available to all (useful, for example, if one would like to advertise and sell a new compound one has just formulated).

- *InChIKey*: An interesting hybrid of the InChI and CAS Registry Number is the InChIKey. Take an InChI, and then run it through a hashing algorithm (specified by IUPAC) to yield a unique string of letters and numbers with a fixed length and format. This string has no chemical meaning, just like a CAS Registry Number. But it is decentralized like an InChI: anyone can come up with one. This molecule's InChIKey is GBBSUAFBMRNDJC-INIZCTEOSA-N.
- *Adopted Name*: All of these chemical names aren't particularly meaningful to humans. So humans have given the molecule an adopted name (also called a "nonproprietary name"): *eszopiclone*. Adopted names for drugs are assigned by the United States Adopted Names Council, which is sponsored by the American Medical Association, the United States Pharmacopeial, and the American Pharmacists Association, and collaborates with the FDA. It works with applicants – typically companies considering manufacturing drugs – to devise appropriate adopted names according to a detailed **list of criteria**. Here are a few of the principles:
  1. A nonproprietary name should be useful primarily to health care practitioners, especially physicians, pharmacists, nurses, educators, dentists and veterinarians.
  - 2.a The name for the active moiety of a drug should be a single word, preferably with no more than four syllables.
  - 3.a A common, simple word element (a "stem") should be incorporated in the names of all members of a group of related drugs when pertinent, common characteristics can

For example, the stem *-clone* indicates a hypnotic tranquilizer, the stem *-cog* is used for blood coagulation factors, and the stem *-conazole* describes an antifungal agent.

be identified, such as similarity of pharmacological action.

4. A name should be free from conflict with other nonproprietary names and with established trademarks and should be neither confusing nor misleading. ...
  1. Prefixes that imply "better," "newer" or "more effective;" prefixes that evoke the name of the sponsor, dosage form, duration of action or rate of drug release should not be used. Examples include "dura," "forte," or "efex."

New adopted names are subject to a long list of specific requirements, such as that "the letter 'f' should be used instead of 'ph'." The USAN Council publishes a list of adopted names, and it also works with the applicant to forward proposed adopted names to the World Health Organization for inclusion in its own International Nonproprietary Names index. As the names of this type of name suggest, it too is meant to be generic in the sense that anyone is free to use the name to refer to the chemical – but notice how trademark considerations are starting to creep into the choice of names. Adopted names chosen this way are partly descriptive (look at those stems) and partly coined (look at the list of things the names may not describe). (Here is the USAN Council's [statement on eszopiclone](#).)

See 21 C.F.R. § 299.4

Are the following the names of drugs or of elves?

- Frova
- Erestor
- Isentress
- Qvar
- Celeborn
- Oropher

See *Which Is It: Prescription Drug or Tolkien Elf?* at *How Stuff Works: Entertainment*

- *Established Name:* The FDA considers some names to be "established names" for drugs – or, informally, the "generic name," because it generally functions as a generic name in the trademark law sense. The distinction between an adopted name and an established name is simply that the latter has the FDA's sanction as "the" generic name, not just "a" generic name. (As we will see in a moment, the FDA requires drugmakers to list the established name of their products, even when they also use a trademark). Where the USAN Council has selected an assigned name, the FDA will treat it as the established name, so the established name of this drug is also eszopiclone. But not all established names come through the USAN Council. Some drugs have "common names": i.e., the names that have come to be used generically by the public to refer to the drug. aspirin is an example.
- *Proprietary Name:* And now back to trademarks. When a drugmaker submits an application to the FDA, it must also list the proprietary name it proposes to market the drug under. The FDA will then engage in an extensive substantive examination of the name designed to minimize errors by medical professionals and patients. Under its [Contents of a Complete Submission for the Evaluation of Proprietary Names](#) (2016) and [Best Practices in De-](#)

veloping **Proprietary Names for Drugs** (draft 2014), the FDA will, for example:

- Require that the proprietary name be different from the established name. Indeed, the proprietary name may *not* incorporate USAN stems at all.
- Reject proposed proprietary names that are confusingly similar to other proprietary names, established names, or ingredient names. This is a much more searching inquiry than the trademark likelihood of confusion analysis. The FDA will compare the proposed name against its Phonetic and Orthographic Computer Analysis system for look-alike and sound-alike combinations, and also conduct or require “simulation studies”:

Name simulation tests should reflect the full range and variety of tasks involved in the prescribing, transcribing, dispensing, and administration of drugs, as well as tasks involved in consumer selection of OTC drugs. Simulations should include common and easily simulated characteristics of real use, such as using ruled or unruled paper, prescription pads, computer order entry, and telephone orders to approximate written, oral, and electronic prescribing in the setting of care for the proposed product (e.g., inpatient and outpatient settings, long-term care). Simulations also should approximate the diversity of real-world prescribing conditions by varying factors such as background noise, handwriting samples, different ink colors, directions for use, and different voices/accents. In addition, the simulation study should present the proprietary name with the corresponding product characteristics (e.g., strength, route, dosage, and frequency) that are likely to be used to communicate prescriptions and orders for the proposed product.

- Prevent the use of the same proprietary name on products with different active ingredients.
- Reject a proposed proprietary name that could “result in ... misbranding if it is false or misleading, such as by making misrepresentations with respect to safety or efficacy.” The FDA elaborates:

For example, a fanciful proprietary name may misbrand a product by suggesting that it has some

unique effectiveness or composition when it does not. For example, FDA likely would object to a proposed proprietary name that contained the prefix *best* or that sounds like *best* because it implies superiority over other currently available therapies. In the absence of appropriate scientific evidence to support claims that the product is superior to other competing products currently on the market to treat the condition, such a proposed name would be misleading.

Note that this review is separate and apart from the USPTO's review of a trademark application. This is true on the back end as well as the front end: someone proposing to sell a competing branded version of the same drug will need to get its name through the FDA's approval process, not just past the trademark standard. The result – as you can probably guess by now – is that the FDA's rigorous standards for proprietary names in effect create a special and distinctive trademark system for branded drugs. Here, our molecule is sold under the proprietary name Lunesta for the treatment of insomnia. The brand name doesn't directly say that it works as a sleep aid, but it certainly suggests certain appealing characteristics of one.

**Senate Report No. 448, 87th Congress, 1st Session (1961)  
Administered Prices--Drugs**

In addition to patent controls and the vast amounts spent on advertising and promotion, the control of the market by the large drug companies stems from a third source of power; this is their remarkable success in persuading physicians to prescribe by trade names rather than generic names. Where this is done the small manufacturer is automatically excluded from the market, regardless of whether the drugs are patented or non-patented, and the opportunity for price competition disappears. This state of affairs is furthered by anything which causes the physician to be apprehensive of, or have difficulty in, prescribing by generic names.

The multiplicity of names' for products in the drug industry virtually exceeds the bounds of human imagination. First, there is the chemical name which attempts to spell out the structural makeup of the drug; and here a variety of forms of expression is possible. Next comes the generic name which may or may not represent an abbreviation of the more complex chemical name; this is the name commonly used to identify the drug in formularies, the teaching of medicine, etc. Ordinarily a drug has one generic name, but there are cases where two or three are employed. Finally a drug usually has a host of in-

dividual trade names used by the various companies engaged in the promotion of the product. In consequence, a single drug product is represented in the market by such complex body of nomenclature as to intimidate even the initiates in the field. And if one can visualize this situation for a single drug multiplied by the thousands of drugs currently marketed, he can get some impression of the chaos existing in the area of drug nomenclature.

The new so-called synthetic penicillin illustrates the problem. The chemical name for this product is alpha-phenoxyethyl penicillin potassium. This set of syllables is also used as a generic name. In addition, there are two other generic names – potassium penicillin 152 and phenethicillin potassium. Since the product is protected by patent, there are only six sellers, each of whom markets under his own trade name. Thus the prescribing physician is bombarded with promotional material for Syncillin, Darcil, Alpen, Chemipen, Dramcillin-S, and Maxipen. All of these are, of course, the same chemical compound.

Speaking of them, Dr. Walter Modell, professor of pharmacology and therapeutics at Cornell University Medical College, stated:

They are colored differently (pink, peach, green, and two shades of yellow) and are advertised as distinctive materials but no effort is made in promotional material to inform the physician who is urged to use them that they are otherwise identical.

In this example the busy practitioner is confronted with three generic names, six brand names used as the name of the drug itself, and at least five different colors. Thus, there are 14 different identification symbols for the identical drug. In terms of nomenclature, each product stands isolated; indeed, there is an attempt to conceal the identical nature of the drug.

### Code of Federal Regulations

- (1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation shall accompany such proprietary name or designation ...
- (2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, lay-

**Drugs; statement of ingredients**  
**21 C.F.R. § 201.10(g)**

out, contrast, and other printing features.

**Kos Pharmaceuticals, Inc. v. Andrx Corp.**

369 F.3d 700 (3d Cir. 2004)

On October 3, 2000, Kos filed an application with the PTO to register ADVICOR as the mark for a new medication designed to improve cholesterol levels. This new drug combines 20 milligrams of lovastatin (which lowers LDL, or "bad" cholesterol) with varying strengths (500, 750, or 1000 milligrams) of an extended-release formulation of niacin (which increases HDL, or "good" cholesterol). Kos has been selling its proprietary extended-release form of niacin under the trade name Niaspan since 1997. In July 2001 Kos began advertising, and in December 2001 began selling, its new combination drug, Advicor.

Shortly after Kos began marketing Advicor, it learned that Andrx planned to use the mark ALTOCOR for its own new anticholesterol medication, which would contain only a single active ingredient, an extended-release form of lovastatin, in varying strengths (10, 20, 40 or 60 milligrams). Andrx announced on January 31, 2002 that it had received preliminary marketing approval for Altocor from the FDA. On February 5, 2002, the PTO published for opposition the ALTOCOR mark, which Andrx had applied to register in December 2000.

Kos tried to dissuade or otherwise prevent Andrx from using the ALTOCOR mark several times, both before and after Andrx began selling its new drug. Kos also expressed its concerns about potential confusion to the FDA division responsible for reviewing proposed new drug names from a public health perspective, the Office of Drug Safety's Division of Medication Errors and Technical Support. The Division of Medication Errors had preliminarily approved the name Altocor in November 2001. At that time, the Division stated that the "name Advicor looks and sounds similar to Altocor," but concluded that the "difference in the written strengths" of the drugs reduced the risk of "error ... between the two products."

The parties submitted competing medical affidavits to support their respective views as to the nature and severity of potential consequences of mis-filled prescriptions. Per Kos, niacin – and thus Advicor, but not Altocor – may cause serious injury, or even death, to patients with various conditions or sensitivities to the drug. Other, less serious, side effects of niacin may worry patients who have not been warned of those effects, and who may thus discontinue needed treatment. Patients who mistakenly receive Altocor rather than Advicor are also at risk, says Kos, since the conditions the niacin is meant to address will remain untreated. Andrx, on the other hand, claims that the "safety profile of both products is similar" and that there need not be "any unusual concern" about "harm to the public if the Andrx

product is substituted for the KOS product.”

[The District Court denied a preliminary injunction. The Court of Appeals reversed. The excerpts that follow focus on the relationship between the FDA’s consideration of the proposed name and the likelihood of confusion inquiry under the Lanham Act.]

The District Court used an overly narrow definition of confusion, in effect evaluating the likelihood of *misdispensing* rather than *confusion*. Andrx also claims that “the FDA and the USPTO have determined that the marks are not confusingly similar.” But neither of those proceedings can supplant the required Lanham Act analysis. First, the FDA applies a standard different from the Lanham Act “likelihood of confusion” test at issue here. The FDA reviews proposed drug names to predict potential confusion that may arise in the actual prescription process. Misdispensing is not the only type of confusion actionable under the Lanham Act. Indeed, to the extent that the FDA’s proprietary name review is relevant here, the reviewing division’s statement that the “name Advicor looks and sounds similar to Altocor” actually supports Kos’s claim.

The facial similarity of the marks is apparent on their face. Both are seven-letter, three-syllable words that begin and end with the same letters and the same sounds. The marks are also similar in that both are coined words, not found even in approximation in the English or any other familiar language. Two names that look and sound similar will naturally seem even more similar where there are no differences in meaning to distinguish them. Nor can the similarity of coined marks be explained by, or ameliorated by virtue of, any relationship between the marks and the products identified.

The district court and the parties treated medical professionals, such as doctors, nurses and pharmacists, as the relevant consumers.<sup>12</sup> These trained professionals may be expected to be knowledgeable about, and to exercise care in distinguishing between, medicines. We have emphasized a countervailing concern that weighs against allowing the expertise of physicians and pharmacists to trump other factors in assessing the likelihood of confusion in drug cases. Prevention of confusion and mistakes in medicines is too vital to be trifled with since confusion in such products can have serious consequences for the patient.

Andrx argues that confusion is even less likely here than in other cases involving medical professionals since prescriptions must reflect

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<sup>12</sup>We note that neither the parties nor the court below addressed the possible confusion of ultimate consumers. While doctors and pharmacists play a gate-keeping role between patients and prescription drugs, they are not the ultimate consumers. Patients are. Courts have noted that drugs are increasingly marketed directly to potential patients through, for example, “ask-your-doctor-about-Brand-X” style advertising.

the different chemical composition of the drugs, with Advicor prescriptions specifying strengths of two active ingredients, and Altocor only one. Of course, this difference in prescribing is not relevant to the common practice of providing samples or to any type of confusion other than misdispensing. There is no reason to believe that medical expertise as to products will obviate confusion as to source or affiliation or other factors affecting goodwill.

Advicor and Altocor are both prescription drugs used to improve cholesterol levels. The products are of the same type and serve the same function in slightly different (but overlapping) ways that may be appropriate for slightly different (but overlapping) sets of patients. That doctors will need to decide which drug to prescribe does not mean they won't see the drugs as related or otherwise associate them. Indeed, it could be argued that the opposite is true, that is, that they will associate the products because they must consider both to decide which to prescribe.

The parties submitted competing medical affidavits to support their respective views as to the nature and severity of the potential consequences of a mis-filled prescription. Andrx also disputed Kos's allegations as to the risks of misdispensing by arguing it is extremely unlikely that a pharmacist would improperly fill a prescription. The district court resolved this dispute in Andrx's favor, holding that Kos had not proven that the public would face a serious health risk absent an injunction. The colloquy at the hearing shows that the court was impressed by the FDA's statement that the "possibility of confusion was minimal," and was persuaded that "it would be difficult to imagine a situation" where the drugs would be confused "when a pharmacist is filling a prescription." We note that, although the FDA's inquiry is not equivalent to the Lanham Act "likelihood of confusion" test, its review of proprietary drug names is relevant in assessing the health risks of mis-filled prescriptions. Indeed, the purpose of FDA review is to predict potential confusion that may arise in the actual prescription process. We defer to the district court's resolution of this factual dispute because its finding is supported by the record and is thus not clearly erroneous.

We must, however, distinguish between the court's finding that Kos did not establish a "serious health risk" and its conclusion that "therefore, the public interest does not favor" injunctive relief. While we defer to the former, the court's ultimate assessment of the public interest is clearly erroneous because it does not take into account the right of the public not to be deceived or confused.

### 666 Problem

In *United States v. 70 1/2 Dozen Bottles, and 76 1/2 Dozen Bottles of "666"*, 1938-1964 FDLI Jud. Rec. 89 (M.D. Ga. 1944), the Monticello Drug



Bottle of 666, date unknown.

Company had sold a product containing quinine under the name "666". During World War II, the supply of quinine was restricted and Monticello stopped putting it in 666. It was seized and destroyed as a "misbranded drug" under the theory that keeping the same name and trade dress would mislead consumers into "accepting the new product under the impression that they were obtaining the old product." Is this theory sound? Is it consistent with what you know of trademark law?

## 2 Design

One might expect the law of drug trade dress to track the law of drug names closely. One would be wrong.

### **Shire US Inc. v. Barr Laboratories, Inc.** 329 F.3d 348 (3d Cir. 2003)

Adderall is a central nervous system stimulant used in treating attention deficit hyperactivity disorder (ADHD) available only by prescription and dispensed to patients in pharmacy vials labeled "prescription-only" as required by law. Adderall is composed of the mixed salts of a single-entity amphetamine and is a controlled substance. Shire first placed Adderall on the market in 1996 and since that time it has enjoyed substantial success so that by 2001 it had a 32% market share in the United States ADHD prescription market.

Adderall originally came in two dosage strengths and colors, 10 mg. (blue, round) and 20 mg. (orange, round). The tablets are currently either blue or pale orange/peach and either round or oval. Color and size vary with the tablet's strength, seven of which currently are prescribed: 5 mg. (blue, round), 7.5 mg. (blue, oval), 10 mg. (blue, round), 12.5 mg. (orange/peach, round), 15 mg. (orange/peach, oval), 20 mg. (orange/peach, round), and 30 mg. (orange/peach, round). Adderall tablets are scored and stamped with the mark "AD" on one side and the dosage size, e.g., "10" on the other.

Shire's product literature, promotional materials, and mailings, which its sales staff distributed to physicians, feature color pictures of the Adderall tablets and sometimes direct patients to examine the tablets to ensure that they have received exactly the drug prescribed. Shire does not advertise its products in general consumer publications, but pictures of Adderall tablets appear in the Physician's Desk Reference and in certain consumer books. While Shire continues to sell Adderall, it altered its marketing strategy for 2002 and discontinued promoting Adderall, promoting instead a patented, sustained-release version of the drug, Adderall XR.

Barr, a public company that develops and manufactures generic and proprietary pharmaceuticals, was the first manufacturer of a



Shire 20mg Adderall mixed amphetamine salts

generic equivalent to Adderall. It began developing a generic amphetamine salt alternative in 1998 and started marketing it in February 2002 after submitting an ANDA<sup>4</sup> to the FDA and obtaining its approval. The FDA has approved Barr's generic amphetamine salts as safe and effective, and has classified Barr's product, which it manufactures in accordance with FDA regulations, as therapeutically equivalent to Adderall. Barr's product is the bioequivalent of Adderall, for which it thus may be interchanged freely. According to Shire, however, the products contain different inactive ingredients, and, in particular, Barr's tablets contain saccharin, a once controversial ingredient the FDA only recently removed from its list of banned substances.

Barr manufactures its generic amphetamine salts in 5 mg. (blue, oval), 10 mg. (blue, oval), 20 mg. (orange/peach, oval), and 30 mg. (orange/peach, oval) tablets.<sup>4</sup> Barr's generic amphetamine salts are oval and convex in shape. Both the size and the color of Barr's tablets are linked to dosage. The face of the tablets has a "b" mark or the trade name Barr, and contains a numerical product code. The district court, on the basis of its physical examination of the tablets and the record before it, determined that while Barr's tablets, like Shire's, are blue and peach/light orange and those colors are keyed to dosage amounts, their shape and markings are different and "[j]uxtaposed against one another, the products are similar though not identical."



Barr 20mg mixed amphetamine salts

On April 30, 2002, Shire filed this action against Barr, alleging that Barr's sale of generic amphetamine salts copying Adderall's appearance constituted unfair competition and diluted Shire's rights under federal and state law. The district court found that Shire "has not credibly rebutted Barr's theory that the similar color-coding and shape of the products are particularly meaningful for ADHD patients and enhance efficacy" [and thus are functional].

Dr. Lawson F. Bernstein's declaration explains that because ADHD patients overuse visual cues, (1) when therapeutically equivalent ADHD products have similar visual recognition properties, adult ADHD patients will experience less confusion in correctly identifying the agent and/or its dosage strength; (2) given that almost all patients require some initial dosage titration and a subsequent substantial majority require intermittent dosage adjustment, the color coding of a particular preparation of mixed amphetamine salts tablets confers a substantial degree of clinical functionality for the patient

<sup>4</sup>For Barr's product to be approved as a generic equivalent for Adderall, it was required to produce the same dosage strengths available for Adderall. Shire, however, launched its mid-range dosages (7.5 mg., 12.5 mg. and 15 mg.) after Barr filed its ANDA with the FDA. In an internal memorandum, Shire indicated that its motivation for introducing these new strengths was to "buy time" to protect market share because generic substitutes would not be available for all strengths, thereby minimizing competition from substitutes.

in the titration/adjustment process; (3) many adult patients may take multiple daily dosages of different strength amphetamine salts tablets, also inferring the usefulness of similar color-coding.

Dr. Blume's affidavit explains that a generic drug's similar appearance to the branded product "enhances patient safety and compliance with the medically prescribed dosing regimen" and that safety and compliance "would be particularly important for ADHD drugs when non-medical intermediaries (such as school secretaries) dispense mid-day doses to children [treated for ADHD]." Blume's affidavit explains, "Dosage form similarities enhance patient acceptance" and points to generic formulations of other central nervous system drugs that are identical or mirror the brand drug in color."

Gregory Drew, a registered pharmacist and Vice President of Pharmacy Health Services for Rite Aid Corporation, explains that Rite Aid prefers that "the generic tablet look as similar to the branded tablet as possible" so as to "increase patient acceptance and comfort," as well as compliance and that "all other things being equal, Rite Aid will choose to stock the generic product that most closely resembles the branded product."

Most of the opinions on which Shire relies were district court opinions from the early 1980s<sup>14</sup> which the court here was not bound to follow. In addition, the cases on which Shire relies are distinguishable on their facts.

Most significantly, though the cases involved prescription drugs, none involved controlled substances and in all of the cases there was evidence of the passing off of the defendant's product by pharmacists, or of an intent to induce illegal substitution on the defendant's part.

It is true that in several of the cases on which Shire relies, the defendant offered affidavits and declarations of pharmacists and physicians making claims relating to functionality that the courts in those cases did not credit the evidence. For example, in *SK&F, Co. v. Premo Pharmaceutical Lab.*, Dr. Shafer, a physician, submitted an affidavit in which he supported the sale of similarly configured generic tablets as he believed this configuration would enable the patient to feel confident that there was no change in the chemistry of the medication and that patients might become uneasy, confused or react adversely if the generic medication looked different from the market innovator. But we explained that the district court nevertheless "apparently chose not to credit the assertion of the Shafer affidavit, crediting instead

*SK&F*: 625 F.2d 1055 (3d Cir. 1980)

<sup>14</sup>Those cases were decided prior to: (1) the enactment in 1984 of the Hatch-Waxman amendment, which established a federal policy favoring the marketing of therapeutic equivalents of generic drugs, (2) the 1999 amendment to 15 U.S.C. § 1125(a)(3) which places the burden of proving non-functionality of unregistered trade dress on the plaintiff, and (3) the Supreme Court's decisions in *Wal-Mart* and *TrafFix*.

the affidavits of Drs. Meyerson and Tannenbaum that in their experience the appearance of a drug bears no established relationship to its therapeutic efficacy." Just as in *SK&F* we deferred to the district court's findings of fact it is appropriate for us to do so in this case as well.

*Ives*: 488 F. Supp. 394 (E.D.N.Y. 1980)

While district courts in this circuit have rejected functionality arguments similar to those the court credited in this case, other district courts, such as that in *Ives Laboratories, Inc. v. Darby Drug Co.*<sup>19</sup>, have credited similar testimony bearing on functionality. In *Ives* the manufacturer of the prescription drug cyclandelate sought an injunction against manufacturers of generic cyclandelate claiming that the defendants' use of the same capsule colors was "a false designation of origin" or a "false description or representation" of defendants' product. But the district court in *Ives* found that capsule colors were functional in several respects. "First, many elderly patients associate the appearance of their medication with its therapeutic effect. Second, some patients co-mingle their drugs in a single container and then rely on the appearance of the drug to follow their doctors' instructions. Third, to some limited extent color is also useful to doctors and hospital emergency rooms in identifying overdoses of drugs."

**Jeremy A. Greene & Aaron S. Kesselheim, *Why Do the Same Drugs Look Different? Pills, Trade Dress, and Public Health***

365 *New Eng. J. Med.* 83 (2011)

Protection of intellectual property covering the physical attributes of pills therefore served two primary purposes. One purpose of trade-dress protection was to reduce the practice of palming off. Premo Pharmaceuticals was sued for trade-dress infringement when it marketed its generic version of the diuretic hydrochlorothiazide/triamterene with a maroon-and-white capsule identical to that of brand-name drug Dyazide, produced by Smith, Kline and French. In *SK&F*, the Third Circuit Court of Appeals upheld trade-dress protection because near-identical pills would facilitate the practice of "unscrupulous pharmacists" in "substituting less expensive generic drugs for the brand name drugs prescribed without informing their customers and without passing along the benefit of the lower price." The court also found that the color scheme was nonfunctional because it did not help patients identify the drug, pointing to other maroon-and-white capsules that were not diuretics.

A second purpose, the courts rationalized, was to allow trade-dress protection to serve a public health function by preventing the

<sup>19</sup>The court of appeals reversed in *Ives*, but the Supreme Court in turn reversed the court of appeals in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*

substitution of a drug that was similar but not identical to another. In *SK&F*, the two diuretic products were chemically equivalent, but their rate of absorption into the bloodstream (bioavailability) differed. In another case, a federal district court in Michigan enjoined a competitor from producing a version of the diet pill phentermine that was similar in appearance to a brand-name version because the efficacy of the hydrochloride salt of phentermine in the generic manufacturer's version did not necessarily match the efficacy of the brand-name manufacturer's phentermine resin complex, so the two drugs were not interchangeable. *Pennwalt v. Zenith Laboratories*. Notably, both these arguments upholding pharmaceutical trade-dress rights were meant to protect consumers from deception by the producers of look-alike drugs.

AstraZeneca's omeprazole (Prilosec) was widely promoted as "the purple pill" after its launch in 1989. As Prilosec's market exclusivity was ending, AstraZeneca launched the prescription-only follow-on product esomeprazole (Nexium) as "the new purple pill" in 2001 to encourage patients accustomed to taking Prilosec to switch to Nexium. Notably, when AstraZeneca began to sell omeprazole without a prescription as Prilosec OTC, the company changed the color of its product to salmon pink. Conversely, as Lilly's green-and-cream capsule fluoxetine (Prozac, 20 mg) faced generic-drug competition in 2001, the company repackaged fluoxetine in pink-and-purple capsules and marketed it as a new drug, Sarafem (20 mg), which was approved by the FDA in 2000 for the treatment of a new indication – perimenstrual dysphoric disorder. In this case, the change in color was designed to discourage physicians from prescribing the less expensive generic fluoxetine in place of Sarafem.

The 1997 FDA guidelines for expanding direct-to-consumer (DTC) advertising of prescription drugs further enhanced the power of pharmaceutical trade dress as broadcast campaigns began to include images of the pills themselves. One of the first drugs to be promoted heavily to consumers after its approval in 1998 was Viagra (sildenafil), Pfizer's drug for treating erectile dysfunction. The company included a picture of the drug in nearly all the advertisements for it, which served to identify the brand of Viagra with both the color (pale blue) and the shape (diamond) of the tablets.

[Despite *Shire*,] claims of trade dress remain vital in the pharmaceutical market. With increasing generic competition, trade-dress strategies are described in industry publications as ways for innovator firms to retain market share for their products after their patents and market exclusivity expire. During at least the past 5 years, brand-name pharmaceutical companies have begun to license their trade dress to manufacturers of so-called authorized generics, which advertise the characteristic of similar appearance as a reason for consumers

*Pennwalt*: 472 F.Supp. 413 (E.D. Mich. 1979)



Image from AstraZeneca website at [purplepill.com](http://purplepill.com)



Nexium capsules



Viagra tablet

to use these products.

If brand-name pharmaceutical manufacturers are no longer able to rely on trade dress to protect the attributes of their products, federal policies affecting this field need to be sharply reconsidered. A first step toward reform would be to include FDA certification of pharmaceutical size, shape, and color in the drug-approval process. For example, a pill's attributes could be proposed by the manufacturer during the original New Drug Application. Currently, such a process occurs for the brand name of the medication; extending it to pill appearance should not require additional legislation. This would create a clear path for generic manufacturers to declare during the ANDA process that their products have similar appearances. Where these drugs do differ (e.g., as in dyes, fillers, or excipients), physicians or pharmacists could still locate manufacturer data from unique identifier codes embossed on pills. Further public health benefits could emerge if the reduction in trade dress helps to combat the physician's persistent use of, and the patient's preference for, costly brands when generic equivalents are available.

The obvious limitation of this approach is that it would apply only to newly introduced pharmaceutical products, leaving most of the existing therapeutic armamentarium unaffected. Therefore, we suggest that a rational scheme be created for pharmaceuticals that have already been approved whereby each distinct agent could be identified by a combination of its size, shape, and color. An example of such a scheme is the successful introduction in the United Kingdom of color-coding for metered-dose inhalers. Patients with asthma had frequently confused bronchodilators with steroid inhalers, leading the National Health Service to systematize inhaler appearance: all short-acting inhalers (bronchodilators) became blue and all preventive agents (steroids) became brown, orange, or burgundy. A similar color-coding scheme was piloted in the United States for ophthalmologic products, in which the caps on generic preparations of atropine, pilocarpine, and other drug products having multiple strengths were color-coded to match those of the innovator-drug products.

### 3 Labeling and Advertising

The FDA strictly controls what drug makers must, may, and may not say when marketing their drugs. (In particular, all approved drugs must have a "label" that gives detailed information on how to use them and on potential health risks from using them.) These rules depart – in several fairly significant ways – from the usual general rules for false advertising. Hatch-Waxman requires that generic versions of a drug have a label that is "the same as the labeling approved for" the drug they copy. Is it any surprise that legally mandated copying

raises intellectual property issues?

### **Consumer-Directed Broadcast Advertisements: Guidance for Industry** (1999) (last updated 2002)

This guidance is intended to assist sponsors who are interested in advertising their prescription human and animal drugs, including biological products for humans, directly to consumers through broadcast media, such as television, radio, or telephone communications systems.

The Federal Food, Drug, and Cosmetic Act (the Act) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. For prescription drugs and biologics, the Act requires advertisements to contain "information in brief summary relating to side effects, contraindications, and effectiveness". The resulting information disclosure is commonly called the *brief summary*.

21 U.S.C. § 352(n)

The prescription drug advertising regulations distinguish between print and broadcast advertisements. Print advertisements must include the brief summary, which generally contains each of the risk concepts from the product's approved package labeling. Advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks in either the audio or audio and visual parts of the presentation; this is sometimes called the *major statement*.

21 CFR § 202.1

Sponsors of broadcast advertisements are also required to present a brief summary or, alternatively, may make "adequate provision ... for dissemination of the approved or permitted package labeling in connection with the broadcast presentation". This is referred to as the *adequate provision* requirement. The regulations thus specify that the major statement, together with adequate provision for dissemination of the product's approved labeling, can provide the information disclosure required for broadcast advertisements.

21 CFR § 202.1(e)(1)

The purpose of this guidance is to describe an approach that FDA believes can fulfill the requirement for adequate provision in connection with consumer-directed broadcast advertisements for prescription drug and biological products. The approach presumes that such advertisements:

- Are not false or misleading in any respect. For a prescription drug, this would include communicating that the advertised product is available only by prescription and that only a prescribing healthcare professional can decide whether the product is appropriate for a patient.

- Present a fair balance between information about effectiveness and information about risk.
- Include a thorough major statement conveying all of the product's most important risk information in consumer-friendly language.
- Communicate all information relevant to the product's indication (including limitations to use) in consumer-friendly language.

A sponsor wishing to use consumer-directed broadcast advertisements may meet the adequate provision requirement through an approach that will allow most of a potentially diverse audience to have reasonably convenient access to the advertised product's approved labeling. One acceptable approach to disseminating the product's approved labeling is described below. This approach includes the following components.

- Disclosure in the advertisement of an operating toll-free telephone number for consumers to call for the approved package labeling.
- Reference in the advertisement to a mechanism to provide package labeling to consumers with restricted access to sophisticated technology, such as the Internet, and those who are uncomfortable actively requesting additional product information or are concerned about being personally identified in their search for product information. [The FDA recommended print advertisements or "the availability of sufficient numbers of brochures containing package labeling in a variety of publicly accessible sites (e.g., pharmacies, doctors' offices, grocery stores, public libraries)."]
- Disclosure in the advertisement of an Internet web page (URL) address that provides access to the package labeling.
- Disclosure in the advertisement that pharmacists, physicians (or other healthcare providers), or veterinarians (in the case of animal drugs) may provide additional product information to consumers.

**Letter from Robert Dean, Division Director, OPDP, FDA, to Eric Gervais**

**Aug. 7, 2015**

Dear Mr. Gervais:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the Kim Kardashian Social Media Post for DICLEGIS (doxylamine succinate and pyridoxine hydrochloride) delayed-release tablets, for oral use (DICLEGIS) submitted by Duchesnay, Inc. (Duchesnay) under cover

of Form FDA 2253. The social media post was also submitted as a complaint to the OPDP Bad Ad Program. The social media post is false or misleading in that it presents efficacy claims for DICLEGIS, but fails to communicate any risk information associated with its use and it omits material facts. Thus, the social media post misbrands DICLEGIS within the meaning of the FDCA and makes its distribution violative. These violations are concerning from a public health perspective because they suggest that DICLEGIS is safer than has been demonstrated.

According to its FDA-approved product labeling (PI) (emphasis in original):

DICLEGIS is indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

#### **Limitations of Use**

DICLEGIS has not been studied in women with hyperemesis gravidarum.

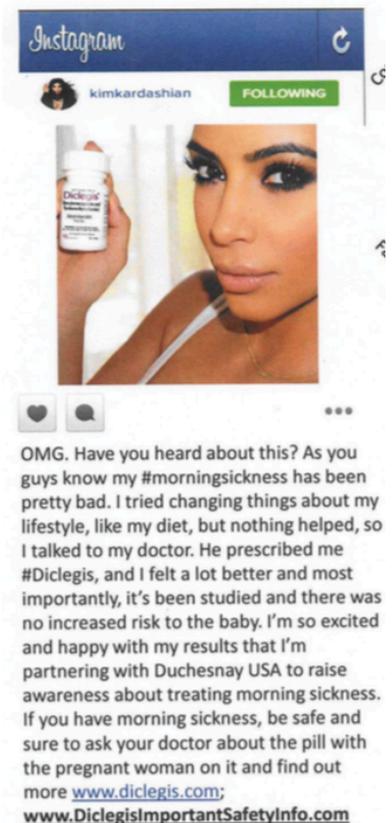
DICLEGIS is contraindicated in women with known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation, as well as in women who are taking monoamine oxidase inhibitors (MAOIs). The PI for DICLEGIS includes Warnings and Precautions regarding activities requiring mental alertness and concomitant medical conditions. In addition, the most common adverse reaction reported with DICLEGIS was somnolence.

The social media post is misleading because it presents various efficacy claims for DICLEGIS, but fails to communicate any risk information. For example, the social media post includes the following claims:

OMG. Have you heard about this? As you guys know my #morningsickness has been pretty bad. I tried changing things about my lifestyle, like my diet, but nothing helped, so I talked to my doctor. He prescribed me #Diclegis, and I felt a lot better and most importantly, it's been studied and there was no increased risk to the baby. I'm so excited and happy with my results that I'm partnering with Duchesnay USA to raise awareness about treating morning sickness. If you have morning sickness, be safe and sure to ask your doctor about the pill with the pregnant woman on it and find out more [www.diclegis.com](http://www.diclegis.com); [www.DiclegisImportantSafetyInfo.com](http://www.DiclegisImportantSafetyInfo.com).

The social media post, however, entirely omits **all** risk information. We note the statement, “[F]ind out more [www.diclegis.com](http://www.diclegis.com);

21 U.S.C. §§ 352(a), (n); 321(n); 331(a).  
See 21 CFR § 202.1(e)(5)



The challenged Kim Kardashian Social Media Post

www.DiclegisImportantSafetyInfo.com[,]” appears at the end of the social media post; however, this does not mitigate the misleading omission of risk information. By omitting the risks associated with DICLEGIS, the social media post misleadingly fails to provide material information about the consequences that may result from the use of the drug and suggests that it is safer than has been demonstrated.

In addition, the social media post is misleading because it fails to provide material information regarding DICLEGIS’ full approved indication, including important limitations of use. Specifically, it fails to convey that DICLEGIS has not been studied in women with hyperemesis gravidarum.

OPDP requests that Duchesnay immediately cease misbranding DICLEGIS and/or cease introducing the misbranded drug into interstate commerce.

### **United States v. Caronia**

703 F.3d 149 (2d Cir. 2012)

Under the Federal Food, Drug and Cosmetic Act, before drugs are distributed into interstate commerce, they must be approved by the FDA for specific uses. To obtain FDA approval, drug manufacturers are required to demonstrate, through clinical trials, the safety and efficacy of a new drug for each intended use or indication.

Once FDA-approved, prescription drugs can be prescribed by doctors for both FDA-approved and -unapproved uses; the FDA generally does not regulate how physicians use approved drugs. Indeed, courts and the FDA have recognized the propriety and potential public value of unapproved or off-label drug use. Off-label use is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine. FDA-approved indications were not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient. The FDA itself has observed:

Once a drug has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such “unapproved” or, more precisely, “unlabeled” uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.

The FDCA prohibits “misbranding.” A drug is misbranded if, *inter alia*, its labeling fails to bear “adequate directions for use,” which FDA regulations define as “directions under which the lay[person]

can use a drug safely and for the purposes for which it is intended.”<sup>3</sup> FDA regulations define intended use by reference to “the objective intent of the persons legally responsible for the labeling of drugs,” which may be demonstrated by, among other evidence, “oral or written statements by such persons or their representatives” and “the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.”

21 C.F.R. § 201.5

21 C.F.R. § 201.128.

The consequences for misbranding are criminal. Pharmaceutical manufacturers and their representatives can face misdemeanor charges for misbranding or felony charges for fraudulent misbranding. The government has repeatedly prosecuted – and obtained convictions against – pharmaceutical companies and their representatives for misbranding based on their off-label promotion. The FDCA and its accompanying regulations do not expressly prohibit the “promotion” or “marketing” of drugs for off-label use. The regulations do recognize that promotional statements by a pharmaceutical company or its representatives can serve as proof of a drug’s intended use. Off-label promotional statements could thus presumably constitute evidence of an intended use of a drug that the FDA has not approved. The FDA, however, has concluded that “an approved drug that is marketed for an unapproved use (whether in labeling or not) is misbranded because the labeling of such drug does not include ‘adequate directions for use.’” Thus, the government has treated promotional speech as more than merely evidence of a drug’s intended use – it has construed the FDCA to prohibit promotional speech as misbranding itself.

Orphan Medical manufactured the drug Xyrem, a powerful central nervous system depressant. Xyrem can cause serious side effects, including difficulty breathing while asleep, confusion, abnormal thinking, depression, nausea, vomiting, dizziness, headache, bedwetting, and sleepwalking. If abused, Xyrem can cause additional medical problems, including seizures, dependence, severe withdrawal, coma, and death. Xyrem’s active ingredient is gamma-hydroxybutyrate (“GHB”). GHB has been federally classified as the “date rape drug” for its use in the commission of sexual assaults.

Despite the risks associated with Xyrem and GHB, the FDA approved Xyrem for two medical indications. In July 2002, the FDA approved Xyrem to treat narcolepsy patients who experience cataplexy, a condition associated with weak or paralyzed muscles. In November 2005, the FDA approved Xyrem to treat narcolepsy patients with

<sup>3</sup>A drug is also misbranded if, *inter alia*: its label is false or misleading; the label fails to display required information prominently; its container is misleading; or it is dangerous to health when used in the dosage, manner, frequency, or duration prescribed, recommended, or suggested on the label.

excessive daytime sleepiness (“EDS”), a neurological disorder caused by the brain’s inability to regulate sleep-wake cycles.

Caronia was audio-recorded on two occasions as [he] promoted Xyrem for unapproved uses, including unapproved indications [including chronic fatigue chronic pain, and restless leg] and unapproved subpopulations [patients under 16]. He was found guilty of conspiracy to introduce a misbranded drug into interstate commerce.

On appeal, Caronia principally argues that the misbranding provisions of the FDCA prohibit off-label promotion, and therefore, unconstitutionally restrict speech. Caronia argues that the First Amendment does not permit the government to prohibit and criminalize a pharmaceutical manufacturer’s truthful and non-misleading promotion of an FDA-approved drug to physicians for off-label use where such use is not itself illegal and others are permitted to engage in such speech.

As off-label drug use itself is not prohibited, it does not follow that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers would directly further the government’s goals of preserving the efficacy and integrity of the FDA’s drug approval process and reducing patient exposure to unsafe and ineffective drugs. Prohibiting off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use “paternalistically” interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public’s detriment, informed and intelligent treatment decisions. In fact, in granting safe harbor to manufacturers by permitting the dissemination of off-label information through scientific journals, the FDA itself recognizes that public health can be served when health care professionals receive truthful and non-misleading scientific and medical information on unapproved uses of approved drugs.

If the government is concerned that off-label promotion may mislead physicians, it could guide physicians and patients in differentiating between misleading and false promotion, exaggerations and embellishments, and truthful or non-misleading information. The government could develop its warning or disclaimer systems, or develop safety tiers within the off-label market, to distinguish between drugs. The government could require pharmaceutical manufacturers to list all applicable or intended indications when they first apply for FDA approval, enabling physicians, the government, and patients to track a drug’s development. To minimize off-label use, or manufacturer evasion of the approval process for such use, the government could create other limits, including ceilings or caps on off-label prescriptions. The FDA could further remind physicians and manufacturers of, and even perhaps further regulate, the legal liability surround-

ing off-label promotion and treatment decisions.[11] Finally, where off-label drug use is exceptionally concerning, the government could prohibit the off-label use altogether.

Accordingly, even if speech can be used as evidence of a drug's intended use, we decline to adopt the government's construction of the FDCA's misbranding provisions to prohibit manufacturer promotion alone as it would unconstitutionally restrict free speech. We construe the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs.

**Wyeth v. Levine**  
129 S. Ct. 1187 (2009)

Phenergan is Wyeth's brand name for promethazine hydrochloride, an antihistamine used to treat nausea. The injectable form of Phenergan can be administered intravenously through either the "IV-push" method, whereby the drug is injected directly into a patient's vein, or the "IV-drip" method, whereby the drug is introduced into a saline solution in a hanging intravenous bag and slowly descends through a catheter inserted in a patient's vein. The drug is corrosive and causes irreversible gangrene if it enters a patient's artery.

Diana Levine's injury resulted from an IV-push injection of Phenergan. Phenergan entered Levine's artery, either because the needle penetrated an artery directly or because the drug escaped from the vein into surrounding tissue (a phenomenon called "perivascular extravasation") where it came in contact with arterial blood. As a result, Levine developed gangrene, and doctors amputated first her right hand and then her entire forearm. In addition to her pain and suffering, Levine incurred substantial medical expenses and the loss of her livelihood as a professional musician. Although Phenergan's labeling warned of the danger of gangrene and amputation following inadvertent intra-arterial injection, Levine alleged that the labeling was defective because it failed to instruct clinicians to use the IV-drip method of intravenous administration instead of the higher risk IV-push method.

The question presented is whether federal law pre-empts Levine's claim that Phenergan's label did not contain an adequate warning about using the IV-push method of administration.

Wyeth first argues that Levine's state-law claims are pre-empted because it is impossible for it to comply with both the state-law duties underlying those claims and its federal labeling duties. The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label. Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application. There is, however, an FDA regulation that

*Wyeth and PLIVA are technically failure-to-warn products liability cases. But if you think of an "adequate warning" as a statement required to make a product's label not misleading, they have a lot in common with false advertising law.*

permits a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things, this "changes being effected" (CBE) regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval.

Wyeth suggests that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. Yet through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. Of course, the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application, just as it retains such authority in reviewing all supplemental applications. But absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.

**PLIVA, Inc. v. Mensing**

131 S. Ct. 2567 (2011)

Metoclopramide is a drug designed to speed the movement of food through the digestive system. The Food and Drug Administration (FDA) first approved metoclopramide tablets, under the brand name Reglan, in 1980. Five years later, generic manufacturers also began producing metoclopramide. The drug is commonly used to treat digestive tract problems such as diabetic gastroparesis and gastroesophageal reflux disorder. Evidence has accumulated that long-term metoclopramide use can cause tardive dyskinesia, a severe neurological disorder. Accordingly, warning labels for the drug have been strengthened and clarified several times [in 1985, 2004, and 2009].

Gladys Mensing and Julie Demahy, the plaintiffs in these consolidated cases, were prescribed Reglan in 2001 and 2002, respectively. Both received generic metoclopramide from their pharmacists. After taking the drug as prescribed for several years, both women developed tardive dyskinesia.

In separate suits, Mensing and Demahy sued the generic drug manufacturers that produced the metoclopramide they took. Each alleged, as relevant here, that long-term metoclopramide use caused her tardive dyskinesia. Mensing and Demahy have pleaded that the

Manufacturers knew or should have known of the high risk of tardive dyskinesia inherent in the long-term use of their product. They have also pleaded that the Manufacturers knew or should have known that their labels did not adequately warn of that risk. The parties do not dispute that, if these allegations are true, state law required the Manufacturers to use a different, safer label.

Federal law imposes far more complex drug labeling requirements. [Under Hatch-Waxman,] brand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's.

According to the FDA, the Manufacturers could have proposed – indeed, were required to propose – stronger warning labels to the agency if they believed such warnings were needed. If the FDA had agreed that a label change was necessary, it would have worked with the brand-name manufacturer to create a new label for both the brand-name and generic drug.

Where state and federal law directly conflict, state law must give way. We have held that state and federal law conflict where it is impossible for a private party to comply with both state and federal requirements.

We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them.

If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. Taking Mensing and Demahy's allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.

The federal duty to ask the FDA for help in strengthening the corresponding brand-name label, assuming such a duty exists, does not change this analysis. Although requesting FDA assistance would have satisfied the Manufacturers' federal duty, it would not have satisfied their state tort-law duty to provide adequate labeling. State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label.

In 2013, the FDA announced a complex proposed rule to allow generics to update their labels. As of 2016, the final rule was still pending.

This appeal arises out of a copyright action alleging infringement of appellant's copyright in a user's guide and audiotope developed for its Nicorette-brand gum. Appellees, in obtaining approval to sell a competing generic nicotine gum product, were directed by the FDA to use labeling almost identical to appellant's copyrighted guide and tape.

Appellees cannot be liable for copyright infringement because the Hatch-Waxman Amendments require generic drug producers to use the same labeling as was approved by the FDA for, and is used by, the producer of the pioneer drug.

Appellant SmithKline manufactures and sells Nicorette nicotine polacrilex gum, an over-the-counter product designed to help smokers overcome the cigarette habit.

Appellee Watson obtained FDA approval for the OTC marketing of a generic version of nicotine gum intended to compete directly with Nicorette. To obtain that approval from the FDA, Watson had to comply with the requirement imposed by the Hatch-Waxman Amendments that "the labeling proposed for [its] new drug [be] the same as the labeling approved for" Nicorette. Thus, Watson's generic nicotine gum was accompanied by a user guide and audio tape that were virtually identical to SmithKline's.

Watson asserts that this copying, having been dictated by the FDA, is a "fair use" protected under 17 U.S.C. § 107. The United States, in its *amicus curiae* brief, argues instead that in submitting its copyrighted materials for FDA approval, SmithKline gave the FDA an implied, nonexclusive license to permit or require generic drug applicants to copy the user's guide and audiotope in their own nicotine gum packaging.

In our view, the case can more easily be disposed of on the straightforward ground that the Hatch-Waxman Amendments to the FDCA not only permit but require producers of generic drugs to use the same labeling as was approved for, and is used in, the sale of the pioneer drug, even if that label has been copyrighted. Because those Amendments were designed to facilitate rather than impede the approval and OTC sale of generic drugs, the FDA's requirement that Watson use much of SmithKline's label precludes a copyright infringement action by SmithKline.

If SmithKline's copyright claim has merit, then Watson cannot realistically use the ANDA process to sell its generic nicotine gum because it will either have to change the label and lose FDA approval or be enjoined from using a label that infringes SmithKline's copyright. We are thus faced with a conflict between two statutes. The Hatch-Waxman Amendments require generic drug producers to use labeling that will infringe upon copyrights in labels of pioneer drugs. The Copyright Act seems to prohibit such copying. However, applying

the familiar canon that, where two laws are in conflict, courts should adopt the interpretation that preserves the principal purposes of each, the conflict is less stark and more easily resolved than it might seem. The purposes of the Hatch-Waxman Amendments would be severely undermined if copyright concerns were to shape the FDA's application of the "same" labeling requirement.

Our point here is not only that Congress would have provided explicitly that the Hatch-Waxman Amendments trump the copyright laws had it foreseen the statutory conflict exposed by the present action, although we firmly believe that to be obvious. Our point is also that the profit sought by the creator of the pioneer drug label flows primarily from the administrative approval of the drug and the patent and exclusivity periods free from competition that follow. The pertinent purpose of the copyright laws – to encourage the production of creative works by according authors a property right in their works so that authors will not have to share profits from their labors with free riders – is not seriously implicated by allowing the "same" labeling requirement to trump a copyright under the Hatch-Waxman Amendments. It is simply not conceivable that, if we reject SmithKline's claim, pioneer drug producers will so fear the copying of labels by future generic drug producers that some pioneer producers – or even one of them – will lack the incentive to create labeling needed for FDA approval.