VIRGINIA JOURNAL OF LAW & TECHNOLOGY

WINTER 2009 UNIVERSITY OF VIRGINIA VOL. 14, NO. 235

From Penury to Prodigal:
Protection Creep for U.S. Plant Varieties

W. LESSER[†]

ABSTRACT

Intellectual property protection for traditionally-bred plant varieties in the U.S. is both recent and rapidly expanding. The simultaneous existence of three partially overlapping forms of protection complicates the understanding of intellectual property protection to plant varieties. While conceptually patentable subject matter, the nonobviousness standard for patentability is difficult to apply to plant varieties. Most breeding choices are "obvious to try" in the recent *KSR* context, but the requisite degree of unexpectedness and unpredictability have yet to be determined.

Intellectual property protection for plants has contributed to enhancements in investment and productivity. The intent of this analysis is not to restrict protection but to raise the nonobviousness standard for utility patents. After considering several alternative approaches, I propose recognizing nonobviousness only in agronomically beneficial attributes. I show that raising nonobviousness standards for utility patents will relegate Plant Patents and Plant Variety Protection to a lower tier of protection for generational improvements.

© 2009 Virginia Journal of Law & Technology Association, *at* http://www.vjolt.net.

[†] Susan E. Lynch Professor in Science and Business, Dept. Applied Economics and Management, Cornell University. I would like to thank Profs. Stan Kowalski and Jon R. Cavicchi, Franklin Pierce Law Center, for their comments and assistance with locating legal references for me. Michael Brown, Brown and Michaels P.C., first pointed out to me that the USPTO examines plant and plant utility patents in a similar way.

TABLE OF CONTENTS

I. INTRODUCTION

Intellectual property (IP) protection in the U.S. for traditionally-bred plant varieties, which categorically excludes plants with genetically modified components,[1] has followed a unique trajectory. Following a complete absence of protection for more than the initial century of U.S. IP statutes—which is to say until the passage of the 1930 Plant Patent Act—options were enhanced with the adoption of the Plant Variety Protection Act of 1970 (as amended) and the decision to allow utility patent protection in 1985 (details below). As a consequence of the multiple forms of protection available, particularly the interpretation of nonobviousness by the Patent Office, the protection available for new plant varieties exceeds that for other patentable subject matter. The result is the skewing of the balance of public and private benefits from the patent system strongly in favor of private benefits and away from public benefits. The Supreme

[1] Traditional breeding of plant varieties "typically consists of hybridization between varieties of the same species and screening for progeny with desired characteristics." Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992). Non-traditional breeding techniques "introduce variation either by using mutagenesis to alter the genome or by introducing or modifying DNA segments, including DNA segments derived from other organisms." *Id.*

Court in *Graham v. John Deere Co.* advanced that "[t]he Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby."[2] The Patent Office as an administrative body lacks as well the authority to enlarge the monopoly rights granted for plant variety patents, an authority they have overstepped. Redressing the balance will require elevating the nonobviousness standards for plant utility patents to allow only variety characteristics with practical agronomic merit.

Traditional plant breeding is constituted largely of incremental, sequential enhancements which involves selecting among the best of available varieties for pairings which express the preferred attributes of the parents. In this way, plants differ from many other forms of inventive activity where enhancements are not as sequential and depend less on research access to the best of existing prior art (genetic materials in this instance). But because utility patent protection restricts breeding access to protected varieties (see below), allowing utility patent protection for a modest inventive step impedes the process of incremental improvements at a considerable public cost. Furthermore, for the many open pollinated crops like (non-biotech) soybeans for which the crop can be and is saved as a seed source for subsequent seasons, the issuance of utility patents prevents that practice, resulting in a substantial cost for farmers and eventually food consumers. The focus here is not on limiting a variety patent owner's control over the use of his or her invention, and its use in subsequent breeding in particular. Rather, it is directed to raising the patentability standard for variety patents so as to provide a more equitable social balance.

The issues evaluated here apply to all types of cultivated plants. Corn and soybeans, however, will receive the bulk of the attention in this Article as they are the most important individual crops from both public and industry perspectives. Of the 303.8 million total acres harvested for all crops in the U.S. in 2007, respectively 28 and 21 percent were planted in corn and soybeans.[3] The focus is on plants claimed by variety or by phenotype, that is, claims to a particular variety by name. Plants can also be claimed in utility patents by genotype, whereby claims typically specify a transferable gene potentially applying to all plants containing that gene.[4] That approach to claiming plant varieties is not considered here.

The paper is structured as follows. The first section offers a brief review of the nonobviousness requirements for utility patents. The subsequent section provides a brief overview of the three forms of IP protection available for plant varieties including interpretations of key statutes. Following is an examination of how nonobviousness criteria are applied under Plant Patents, Plant Variety Protection, and Utility Patents. Subsequently, the claims from sample corn and soybean variety patents issued over time are used to demonstrate the similarity of the applications along with an exploration of the growth in scope as claim numbers rose from six to twenty-four. Finally, I make an assessment of the public costs of the current IP practices for variety patents and provide recommendations for more restrictive and socially balanced nonobviousness standards.

[2] Graham v. John Deere Co., 383 U.S. 1, 5-6 (1966).

[3] U.S. DEP'T OF AGRIC., AGRICULTURAL STATISTICS I-20, III-14, IX-17 (2008).

[4] *See* NICHOLAS J. SEAY, *Intellectual Property Rights in Plants*, *in* INTELLECTUAL PROPERTY RIGHTS: PROTECTION OF PLANT MATERIALS 61, 70-71 (P. Stephen Baenziger, Roger A. Kleese & Robert F. Barnes eds., 1983).

II. NONOBVIOUSNESS UNDER 35 U.S.C. § 103

A. 35 U.S.C. § 103(a)

Nonobviousness as patentability criteria is codified in 35 U.S.C. § 103(a), which states that:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.[5]

The Supreme Court made clear in *Graham v. John Deere Co.* that the codification was not substantive but rather a delineation of long standing Patent Office practice.[6] Indeed, § 103(a) reflects the conditions for patentability first specified by the Supreme Court in 1851 in *Hotchkiss v. Greenwood*.[7] The "*Hotchkiss* test" has come to be known as the "*Graham* Framework" from being reiterated in *Graham v. John Deere Co.*:

> [T]he scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances . . . .[8]

The patent at issue related to a release mechanism to prevent damage to plow chisels ("bottoms") when striking a sub-soil obstacle such as a rock. The invention was essentially a hinge (in the form of a stirrup), one portion of which was attached to the plow frame and the other to a shank/chisel combination, such plows typically having multiple chisels. When a subsoil obstacle was encountered, the shank was allowed to move upward toward the hinge plate attached to the plow frame, dispelling the force. The petitioner, Graham, had two patents covering variants of the design, one of which[9] reversed the position of the hinge plate and shank to allow for greater vibration absorption than the other patented variant.[10] The Court found no nonobvious elements in the first of Graham's two patents:

> Certainly a person having ordinary skill in the prior art, given the fact that the flex in the shank could be utilized more effectively if allowed to run the entire length

[5] 35 U.S.C. § 103(a) (2006).
[6] *See Graham*, 383 U.S. at 17.
[7] Hotchkiss v. Greenwood, 52 U.S. 248, 267 (1851).
[8] *Graham*, 383 U.S. at 17.
[9] U.S. Patent No. 2,627,798 (filed Aug. 27, 1951) [hereinafter '798 Patent].
[10] U.S. Patent No. 2,493,811 (filed Feb. 26, 1947) [hereinafter '811 Patent].

> of the shank, would immediately see that the thing to do was what Graham did, *i. e.* [sic], invert the shank and the hinge plate.[11]

Attempting to provide more uniformity and consistency to the obviousness question, the Federal Circuit adopted its own "teaching, suggestion, or motivation" (TSM) test. The TSM test requires a showing that an explicit teaching, suggestion or motivation exists to combine known elements, the prior art references, to form a claimed invention.[12] That said, the Federal Circuit did not always apply its own test consistently.[13] In *KSR Int'l Co. v. Telefex Inc.*, the Supreme Court, revisiting the obviousness issue following four decades of inattention, cautioned against an overly rigid application of TSM while recognizing that TSM is one of a number of valid rationales that could be used to determine obviousness.[14] The Court explained that "the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ."[15] That is, the prior art teaching need not be applied to the specific subject area of the problem to be solved; a person of ordinary skill will naturally often fit the teachings of multiple patents together.

Teleflex was the licensee of a patent[16] on an adjustable vehicle accelerator pedal for greater operator comfort which included an electronic position sensor. Critical to the patent is Claim 4 which specified that the sensor be attached at a fixed pivot point. Subsequently, General Motors (GM) selected KSR to supply adjustable, electronic accelerator pedals for its light trucks. KSR had an existing patent on an adjustable fixed pivot pedal to which it added an electronic position sensor in line with the GM contract specifications, leading to the infringement suit. Validity was initially rejected, then supported prior to the Supreme Court's final rejection on obviousness grounds. Given the prior art teachings of wire chafing problems when the sensor was mounted on a movable part of the pedal, a stationary point was the obvious preferred location, and the pivot the obvious choice among them.

Other insights from *KSR* include:

- "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art."
- A person of ordinary skill in the art when attempting to solve a problem will normally look beyond techniques in the prior art to solve the same problem: familiar items may have obvious uses beyond their primary purpose.
- In certain cases, obviousness may be proven by showing that the combination of elements was obvious to try.[17]

---

[11] *Graham*, 383 U.S. at 25.

[12] *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 407 (2007).

[13] Ashley Houston, KSR International Co. v. Teleflex Inc.*: The Supreme Court Declines to Finally Set the Record Straight and Articulate One Clear Standard for Determining Obviousness in Patent Cases*, 4 J. BUS. & TECH. L. 219, 236 (2009).

[14] *KSR*, 550 U.S. at 418–19.

[15] *Id.* at 418.

[16] U.S. Patent No. 6,237,565 (filed Aug. 22, 2000).

[17] *See KSR*, 550 U.S. at 418–21.

The general conclusion is that *KSR* will make patent claims easier to invalidate, but more so in some technology fields than others.[18]

The U.S. Patent and Trademark Office (USPTO) has incorporated the *KSR* standards for establishing obviousness into the Examiners Handbook as follows:

> Exemplary rationales that may support a conclusion of obviousness include:
>
> (A) Combining prior art elements according to known methods to yield predictable results;
>
> (B) Simple substitution of one known element for another to obtain predictable results;
>
> (C) Use of a known technique to improve similar devices (methods, or products) in the same way;
>
> (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
>
> (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
>
> (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
>
> (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.[19]

Additional insights can be gained from the "obvious to try" dimension, which is particularly pertinent to conventional plant breeding. In *In re Tomlinson*, Judge Rich wrote, "Slight reflection suggests, we think, that there is usually an element of 'obviousness to try' in any research endeavor, that it is not undertaken with complete blindness but rather with some semblance of a chance of success . . . ."[20] As several commentators have observed, "It is clear that Judge Rich based his decision on the *unexpectedness* and *unpredictability* of the behavior of polymer stabilizers [the subject of the challenged patent]."[21] What was not specified in *In re Tomlinson* was the minimum degree of unexpectedness and unpredictability required to establish nonobviousness. The standard for obviousness had to await another Judge Rich decision, *In re O'Farrell*, which still stands, holding, "all that is required is a reasonable expectation of success."[22]

---

[18] *See* Theresa Stadheim, *How* KSR v. Teleflex *Will Affect Patent Prosecution in the Electrical and Mechanical Arts*, 91 J. PAT. & TRADEMARK OFF. SOC'Y 142, 152 (2009).

[19] U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2141, at 2100-19 (8th ed., rev. 2008) [hereinafter MPEP].

[20] *In re* Tomlinson, 363 F.2d 928, 931 (C.C.P.A. 1966).

[21] Anna C. Chau & Irving N. Feit, *The Obvious to Try Doctrine: Its Use, Misuse, and Abuse*, 91 J. PAT. & TRADEMARK OFF. SOC'Y 89, 92 (2009).

[22] *In re* O'Farrell, 853 F.2d 894, 904 (Fed. Cir. 1988).

KSR and *In re Tomlinson* dealt respectively with the mechanical and chemical arts, ordered in terms of increasing unpredictability of outcome. Applications of "obvious to try" for life forms were not considered until *Abbott Laboratories v. Sandoz, Inc.* where the plaintiff "stressed the difference between new biological compositions whose performance and effectiveness in combination cannot be confidently predicted but must be made and evaluated, and new mechanical combinations of known elements each of which predictably performs its known function in the combination."[23]

Fromer, in a recent article, approaches the nonobviousness issue from a different perspective by asking whether it is properly applied to the conceptualization of an invention or to the reduction to practice. She concludes both apply but to different degrees depending on the subject matter.[24] In the case of plant varieties, reduction to practice is clearly the prevailing nonobviousness component.

B. 35 U.S.C. § 103(b)

> (b) (1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if [filed in same application or filing date and owned by same individual or assignee].[25]

This subsection is one of the more complex applied to biotechnology and, subsequently, plants and other inventions. It applies to methods of using a new product or the method of making a new product when the method is obvious. For plants, these issues arise for claims such as those found in two particular patents[26] for example:

> [Claim] 7. A method for producing corn seed comprising growing the plant of claim 2 until the plant is pollinated and seed is produced.[27]
>
> [Claim] 24. A method of producing an inbred corn plant derived from the corn variety EX6389 . . . .[28] [or]
>
> [Claim] 15. A method of introducing a heritable trait into hybrid corn variety CH672515 comprising the steps of: (a) crossing a first plant of a first inbred corn variety selected from the group consisting of variety I054029 and variety I285302 with another corn plant that heritably carries the trait to produce progeny plants, at least some of which heritably carry the trait. . . .[29]

---

[23] Abbott Laboratories v. Sandoz, Inc., 544 F.3d 1341, 1348 (Fed. Cir. 2008).

[24] Jeanne C. Fromer, *The Layers of Obviousness in Patent Law*, 22 HARV. J.L. & TECH. 75 (2008).

[25] 35 U.S.C. § 103(b) (2006).

[26] *See, e.g.*, U.S. Patent No. 7,423,207 (filed Apr. 26, 2006) [hereinafter '207 Patent]; U.S. Patent No. 7,504,569 (filed May 9, 2007).

[27] '207 Patent.

[28] *Id.*

[29] '569 Patent.

In all three claims the method is obvious; what is new is the starting material, the corn variety EX6389, and the resultant plant/seed. Under *In re Durden* the Federal Circuit concluded, "an otherwise old process becomes a new process when a previously unknown starting material, for example, is used. But it does not mean the whole process has become unobvious."[30] For breeders, the limitation imposed by *In re Durden* is that the use of the nonobvious seeds to produce other seeds was not patentable as there is nothing inventive about the propagation process. Indeed, method claims of the variety as above (claim numbers 7 and 24) can be seen as an alternative way of claiming the disclosed invention. However, method claims of all varieties containing heritable trait(s) (claim number 15 above) extends patent protection to all transformed varieties created by standard cross breeding with a pure line containing the heritable trait.

In re Durden was the rule for ten years until it was overruled for biotech applications only (although many of the same process issues apply to chemical compounds as well) with the adoption of the current U.S.C. § 103(b)(1).[31] That same year, *In re Ochiai*[32] was decided, leading the USPTO to adopt a "Guidance on Treatment of Product and Process Claims"[33] extending § 103(b)(1) treatment broadly, including to plant varieties.

III. PROTECTION SYSTEMS FOR PLANT VARIETIES

Plant varieties, prior to the extension of utility patent protection in 1985, were (and are) protectable by Plant Patents (PP) (1930), and Plant Variety Protection (PVP) (1970). Due to the unique history of intellectual protection of plant varieties which will be unfamiliar to some readers, the legislative history of each is reviewed in brief first, along with their unique statutory characteristics. In the subsequent section, interpretations of nonobviousness under each system are examined.

A. Plant Patents

Background: Agricultural-related inventions were long excluded from IP protection internationally, partly out of concern that they were not "manufactured" industrial property. That interpretation was formally dispelled in the Paris Convention statutes in that: "[i]ndustrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour."[34]

Nonetheless, countries continued to exercise the right to exclude some forms of subject matter to disallow protection for plants and other agricultural applications. The underlying

[30] *In re* Durden, 763 F.2d 1406 (Fed. Cir. 1985).

[31] Biotechnological Process Patents, Pub. L. No. 104-41, 104th Cong., 1st Sess. (Nov. 1, 1995) (amending 35 U.S.C. § 103 with respect to patents on biotechnological processes).

[32] *In re* Ochiai, 71 F.3d 1565 (Fed. Cir. 1995).

[33] Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b), http://www.uspto.gov/go/og/con/files/cons104.htm (last visited May 27, 2009).

[34] World Intellectual Property Organization, Paris Convention for the Protection of Industrial Property, art. 1(3), Mar. 20, 1883, amended July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 306.

objection appeared not to be practical or ethical but rather economic: "protection might increase the price of food . . . necessary for the greater masses of the population, and that all might suffer from the privilege granted to a single person."[35] To a degree, that opinion still exists.[36]

The United States was the first specifically to allow protection for plants in the Plant Patent Act of 1930,[37] but to the limited extent of asexually propagated plants only.[38] Congress seemingly responded to the words of the famous breeder Luther Burbank, developer in 1880 of the "Burbank potato," that "[a] man can patent a mouse trap or copyright a nasty song, but if he gives to the world a new fruit that will add millions to the value of earth's annual harvests, he will be fortunate if he is rewarded by so much as having his name connected with the result."[39] Congress eventually recognized that the absence of IP protection could lead to higher prices as the breeder sought to recoup the investment in a few seasons before competing with copies of his/her own creation. Or, conversely, breeders lacked the incentive to invest in the costly and uncertain area of breeding.

Unique Statutes and Interpretations[40]

- The "asexually reproduces" stipulation is a departure from traditional practice in that it requires the invention be reduced to practice prior to receiving protection.[41]
- The provisions of this title relating to patents for inventions [35 U.S.C.] shall apply to patents for plants, except as otherwise provided.[42]
- No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible.[43]
- Only a single claim is allowed which applies to the plant in its entirety, although a subsequent amendment added use of "any parts thereof" without authorization is an infringement.[44]
- Infringement applies only if the plant has been asexually propagated.[45] Moreover, as it is essentially impossible to replicate a plant exactly without direct copying, the

[35] Andre Heitz, *The History of Plant Variety Protection, in The First Twenty-Five Years of the International Convention for the Protection of New Varieties of Plants*, 53, 60 (UPOV 1987).

[36] *See, e.g.*, ETC Group, Intellectual Property & Patents, http://www.etcgroup.org/en/issues/intellectual_property_patents.html (last visited May 27, 2009) ("Intellectual property has become a powerful tool to enhance corporate monopoly and consolidate market power. Monopoly control over plants, animals and other life forms jeopardizes world food security, undermines conservation and use of biological diversity, and threatens to increase the economic insecurity of farming communities. The ETC group opposes exclusive monopoly control over living organisms and biological processes.").

[37] Act of May 23, 1930, ch. 312, 46 Stat. 376 (codified as amended at 35 U.S.C. §§ 161-64 (2006)).

[38] 35 U.S.C. § 161 (2006) (excluding tubers, practically speaking including only round or Irish potatoes, and Jerusalem artichokes); *see also* Heitz, *supra* note 35, at 63 (stating the underlying justification again appears to be economic: disallowing IP protection for major food products).

[39] CARY FOWLER, UNNATURAL SELECTION: TECHNOLOGY, POLITICS, AND PLANT EVOLUTION 86 (1994) (quoting a letter sent by Burbank to Paul Stark).

[40] *See* KENNETH J. BURCHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT, at ch. 17 (1995).

[41] 35 U.S.C. § 161 (2006).

[42] *Id.*

[43] 35 U.S.C. § 162 (2006) (removing a key barrier to patentability).

[44] *Id.*

[45] 35 U.S.C. § 163 (2006).

patentee is required to document that the allegedly infringing plant is "the progeny of the patented plant."[46]

- "Where the examiner considers it necessary to the examination of the plant patent application, a copy of the file and drawing of the application are forwarded to the National Program Leader for Horticultural Crops, Agricultural Research Service (ARS), U.S. Department of Agriculture, along with a request for a report as to whether the plant variety disclosed is new and distinct over known plant varieties . . . ."[47]
- "The report may embody criticisms and objections to the disclosure, may offer suggestions for correction of such, or the report may merely state that: Examination of the specification submitted indicates that the variety described is not identical with others with which our specialists are familiar."[48]

A review of the folios of PP for major crops, published only since 1997, suggests however that the input of the USDA is rarely if ever sought.

B. Plant Variety Protection[49]

Background: Unlike PP, approaches to PVP were led by Europeans with the United States following as a later adopter. Serious attention did not begin until the mid-19th century with the rise in scientific breeding, but specific approaches appeared only in the immediate pre-World War II era. Early attempts strove to balance the recognition of rights of the breeder with continued access to cheap (if often low quality) seed by various combinations of copyright, trademark, and patent approaches. Two prevailing ideas emerged from Germany during this period which shaped future law: (a) food plants needed to demonstrate not only distinctness but also agronomic (practical) value, and (b) two tiers of protection were envisioned, one (patents) for plants with entirely new characteristics and a lesser one for lesser contributions. Serious actions however did not get underway until the Diplomatic Conference of 1957-61 which led to the establishment of the International Convention for the Protection of New Varieties of Plants (UPOV from its French acronym). UPOV adopted conventions in 1961 (amended 1972), 1978 and 1991.[50]

The UPOV Conventions are *sui generis* systems structured largely after patent law, but with some special aspects responding to the particular characteristics of plant breeding, as well as the economic considerations which have long been focused more on food than other inventive activities. In the U.S. as elsewhere, PVP is administered by the Department of Agriculture, not the national patent office.[51] The United States did not become a signatory to the UPOV until 1981.

---

[46] Imazio Nursery Inc. v. Dania Greenhouses, 69 F.3d 1560, 1569 (Fed. Cir. 1995).
[47] MPEP, *supra* note 19, § 1609, at 1600-08 (authorized by 35 U.S.C. § 164 (2006)).
[48] *Id.*
[49] This subsection draws in part on Heitz, *supra* note 35.
[50] UPOV, UPOV Acts: 1961, 1978, 1991, *available at* http://www.upov.int/en/publications/conventions/ (last visited May 27, 2009).
[51] 7 U.S.C. § 2321 (2006).

Unique Statutes and Interpretations: Section 2402 (2)-(4) sets out the so called DUS – distinct, uniform and stable standards – requirements for protection. Uniformity and stability are technical requirements that ensure a variety has been propagated for sufficient generations to reproduce true-to-form. To a large degree, enhancements in plant breeding since the 1930 passage of the Plant Patent Act convinced legislators that sexually pollinated varieties could be sufficiently stable across generations to be identifiable. Presently, molecular markers and other techniques serve many of the variety identification requirements. Stability and uniformity are technical and species-specific factors for which UPOV provides guidelines and data.[52] In the United States, a "statement concerning whether the variety is uniform and stable and how many generations the variety has been observed to determine this" is required, along with a "full disclosure of the genealogy."[53] Distinctness, the PVP requirement corresponding to nonobviousness, is discussed in the following section.

There is no utility requirement as in patent law; presumably an intended use of a variety is evident.

Unlike patent practice, mandatory deposits made under PVP are not publically available until abandonment or expiration at which time they enter the public domain.[54]

(a) **Acts constituting infringement**

> "[I]t shall be an infringement of the rights of the owner of a protected variety to perform without authority, any of the following acts:
>
> . . .
>
> (4) use the variety in producing (as distinguished from developing) a hybrid or different variety therefrom;"[55]

This subsection is known informally as "Breeders' Rights" and is a general experimental use exemption for breeders once a variety is made available on the market. Section 2544 of title seven of the U.S.C. further formalizes this exemption: "[t]he 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."

In the longstanding tension between public access to breeding materials and incentives

---

[52] UPOV, General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants, TG/1/3, http://www.upov.int/en/publications/tg-rom/tg001/tg_1_3.pdf (last visited May 27, 2009); *see also* UPOV, Species-Specific Guidelines, http://www.upov.int/en/publications/tg_rom/tg_index.html (last visited May 27, 2009).

[53] U.S. Dep't of Agric., Agricultural Marketing Service, Plant Variety Protection Office, General Exhibit A – Origin and Breeding History, http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3003277 (last visited May 27, 2009).

[54] 7 U.S.C.A. § 2422 (2009). In particular, see the Plant Variety Protection Office list of certificates identifying seed samples as being "unavailable" from USDA National Plant Germplasm System, at http://www.ars-grin.gov/cgi-bin/npgs/html/pvplist.pl (last visited Nov. 23, 2009). *See also* Paul T. Nelson, Nathan D. Coles, James B. Holland, David M. Bubeck, Stephen Smith & Major M. Goodman, *Molecular Characterization of Maize Inbreds with Expired U.S. Plant Variety Protection*, 48 CROP SCI. 1673, 1674 (2008) (addressing the characterization of maize inbreds accessible following the expiration of PVP certificates).

[55] 7 U.S.C. § 2541 (2006).

for plant breeders, PVP clearly favors the former. Therein, however, lies a problem which was not addressed until the 1991 UPOV Act: that Breeders' Rights removed any incentive for the long (15 years) and costly process of transferring material like disease resistance from non-commercial genetic materials. To provide the necessary two levels of protection, 7 U.S.C. § 2541(c) was added:

> (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.[56]

Functionally, the initial/essentially derived approach operates like dependent patents but the delineation of what characterizes dependency is incompletely described. There are few, if any examples of applications worldwide and none in the United States. Indeed, Lesser and Mutschler argue that the system as proposed is not workable.[57] In any event, proposals are for essential derivation not being pyramidal, e.g., if variety B is derived from A, and C from B, C is nonetheless essentially derived from A, not B.[58] This interpretation means that a variety can have but one initial variety, a limitation not applied to dependant utility patents. The term "essentially derived variety" is defined in 7 U.S.C. § 2401(a)(3):

> § 2401(a)(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,

[56] 7 U.S.C. § 2541(c) (2006).

[57] W. Lesser & Martha A. Mutschler, *Balancing Investment Incentives and Social Benefits when Protecting Plant Varieties: Implementing Initial Variety Systems*, 44 CROP SCI. 1113, 1120 (2004).

[58] UPOV, Sixth Meeting with International Organizations, *Essentially Derived Varieties*, IOM/6/2 (Oct. 30, 1992).

> 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.
>
> (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.[59]

The final reference in § 2401(a)(3)(B) to "genetic engineering" suggests that one justification of the initial variety approach is to protect the traditional breeder from losing rights to a variety when a genetically engineered trait is transferred and used as the new distinguishing characteristic.[60]

> Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 2541 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 . . . .[61]

This exemption, also known as the "Farmers' Privilege," allows farmers to save the harvest as a seed source for future planting, but only on his or her own farm. The practice of seed saving is common for "self breeders" like wheat, which are stable over generations, used for "out breeders" like soybeans and cotton which suffer genetic erosion over generations, but not practical for F-1 hybrids (corn, sorghum) which do not reproduce true to form.

C. Utility Patents

Background: The lead in applying utility patents to plant varieties was taken by, and largely remains with, the United States. Underlying the extension was the path breaking 1980 Supreme Court decision in *Diamond v. Chakrabarty*, where the Court held that "[a] live, human-made micro-organism is patentable subject matter under [Title 35 U.S.C.] § 101."[62] The Court observed that Congress had previously stated, "[A]nything under the sun that is made by man [is patentable]"[63]; and, particular, "the work of the plant breeder 'in aid of nature' was patentable invention."[64]

The extension of utility patents to higher plants, however, remained uncertain and sporadic until declared to be patentable subject matter under 35 U.S.C. § 101 on internal appeal

[59] 7 U.S.C. § 2401(a)(3) (2006).
[60] Stephen Smith, *Intellectual Property Protection for Plant Varieties in the 21st Century*, 48 CROP SCI. 1277 (2008).
[61] 7 U.S.C. § 2543 (2006).
[62] Diamond v. Chakrabarty, 447 U.S. 303, 303 (1980).
[63] *Id.* at 309.
[64] *Id.* at 312.

in *Ex parte Hibberd*.[65] The Board of Patent Appeals and Inferences, drawing on *Diamond v. Chakrabarty*, rejected the examiner's contention that the prior passage of the PP and PVP Acts indicated that Congress intended that those two forms of protection were to be exclusive.[66] *Ex parte Hibberd* was affirmed by the Supreme Court in *J.E.M. Ag Supply Inc. v. Pioneer Hi-Bred Int'l Inc.* on two bases.[67] The Court, upon examining the legislative history, found no indication that the two Acts specific to plants were intended to be exclusive.[68] Moreover, while there is some potential overlap in protection, the multiple acts can be reconciled due to the differing scope of protection allowed.

Key Statutes and Interpretations:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[69]

A variety can be described in a written description setting out the phenotypic characteristics, along with the origin and breeding history. Description though, does not equate with enablement for a chance-based undertaking like plant breeding; so a seed deposit is typically required at one of the internationally-recognized depository authorities (in the United States, typically the American Type Tissue Collection, or ATCC).[70] Deposited seed is "considered to be readily available" to the public, but use of the seed is severely limited by the circumscribed experimental use exemption under utility patents.[71]

The utility requirement seemingly is not a significant impediment for seed for a commercial crop. A typical statement related to the utility of an "improved" corn seed is as follows:

> North American farmers plant tens of millions of acres of corn at the present time and there are extensive national and international commercial corn breeding programs. A continuing goal of these corn breeding programs is to develop corn hybrids that are based on stable inbred plants and have one or more desirable characteristics. To accomplish this goal, the corn breeder must select and develop superior inbred parental plants. [72]

D. Comparisons

The salient aspects of these three protection systems are summarized in Table 1.

---

[65] *Ex parte* Hibberd, 227 U.S.P.Q. 443 (B.P.A.I. 1985).
[66] *Id.* at 448.
[67] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001).
[68] *Id.* at 133.
[69] 35 U.S.C. § 112 (2006).
[70] 37 C.F.R. § 1.802 (2009); MPEP, *supra* note 19, § 2403.02, at 2400–03.
[71] 37 C.F.R. § 1.802 (2009)*; see* Madey v. Duke Univ., 307 F.3d 1351, 1362–63 (Fed. Cir. 2002); *see also* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984) (narrowing experimental use to "amusement, to satisfy idle curiosity or for strictly philosophical inquiry").
[72] '207 Patent, *supra* note 26.

Table 1: Synopsis of Plant IP Protection Statutes			
Act	Year Effective	Plants Covered	Key Statutes/ Interpretations
Plant Patent Act	1930	asexually propagated (exc. tubers)	• Single claim – to entire plant • Description – complete as is reasonably possible • Must show derivation for infringement
Plant Variety Protection Act	1970	sexually propagated (hybrids since 1994)	• Research and farmer seed saving exemptions • Two tiers of protection – initial and essentially derived (since 1994) • Deposit required – not publicly available
Utility Patents	1985 (*Ex parte Hibberd*)	all	• Deposit often required – so fully reduced to practice • Seed savings, breeding use infringe

The prosecutorial history of PP, the oldest form of IP protection for plants, is useful for understanding the development of the nonobviousness interpretation, as discussed below. Commercial comparability, however, is largely limited to PVP and UP which apply to the greatest number and highest harvested value of crops.

At present there are approximately 715 certificates of PVP for pure lines of corn, 900 certificates of PVP for soybeans, but less than 250 for lettuce.[73] Factors that help to explain the numerical differences are the complexity of the species, and hence the number of possible distinguishing characteristics, as well as the required degree of local adaptation. For example, soybeans are very photo-period sensitive, meaning multiple varieties are required for optimal production; wheat is not. Mark D. Janis and Jay P. Kesan estimate that 85 and 80 percent of applications for PVP certificates for soybeans and corn, respectively, are successful.[74]

However, the number of certificates of PVP obscures temporal changes. Figures 1 and 2 (below) show the number of certificates of PVP and UP for corn and soybeans respectively from 1971 to 2001. The figures show differing trends which can be inferred from knowledge of concurrent events. For corn, certificates apply to both pure lines and F-1 hybrids. As PVP for hybrids was available only from 1994 onwards, the upturn in 1997 possibly shows a limited response to that new protection opportunity. Clearly there was little interest in PVP for pure lines from 1971-81. That appears to have changed in the later 1980s with *Pioneer Hi-Bred International v. Holden Foundation Seeds*, when it became clear that trade secret protection was insufficient to protect pure lines, a small quantity of which is inadvertently self-pollinated and

[73] Plant Variety Protection Office, Plant Variety Protected Crops, http://www.ars-grin.gov/cgi-bin/npgs/html/pvplist.pl (last visited Aug. 25, 2009) (follow the hyperlinks to corn, soybeans, and lettuce).

[74] Mark D. Janis & Jay P. Kesan, *U.S. Plant Variety Protection: Sound and Fury . . . ?*, 39 HOUS. L. REV. 727, 755 (2002).

mixed with the hybrid seed.[75] While *Pioneer* did not specifically address this "chasing the selves" issue, corn seed companies did appear to begin utilizing PVP to protect their valuable pure lines.[76] UP protection was specifically extended to plants in 1985; its use for corn began soon thereafter. However, the real acceleration in interest began in 1994, which just preceded the commercialization of genetically engineered crops.[77] For soybeans, incidentally the largest recipient of PVP protection, interest was immediate with the passage of the PVP, but accelerated prior to the commercial introduction of genetically engineered varieties in 1996. The same applies for UPs.

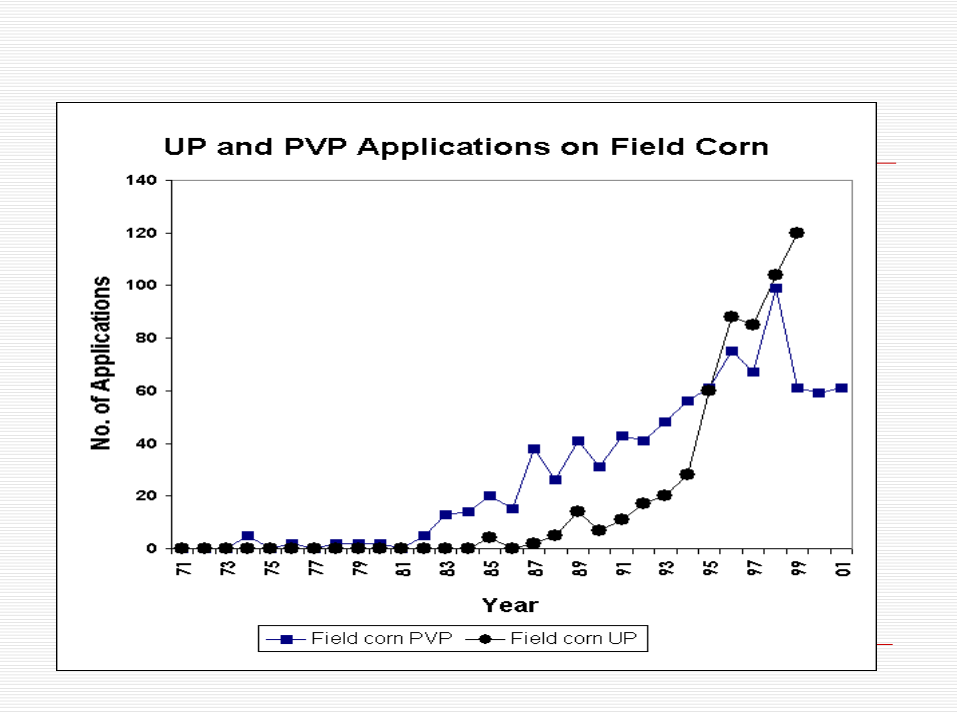

Figure 1[78]

[75] Pioneer Hi-Bred Int'l v. Holden Found. Seed, Inc., No. 81-60-E, 1987 WL 341211, at *32–33 (S.D. Iowa Oct. 29, 1987).

[76] Smith, *supra* note 60, at 1277.

[77] ECON. RESEARCH SERV., U.S. DEP'T OF AGRIC., ADOPTION OF GENETICALLY ENGINEERED CROPS IN THE U.S. (2009), http://www.ers.usda.gov/Data/BiotechCrops/ (last visited Aug. 25, 2009).

[78] W. Lesser & Martha Mutschler, *Lessons From the Patenting of Plants, in* INTELLECTUAL PROP. RIGHTS IN ANIMAL BREEDING AND GENETICS, 103, 108 (M.F. Rothschild & Scott Newman eds., 2002).

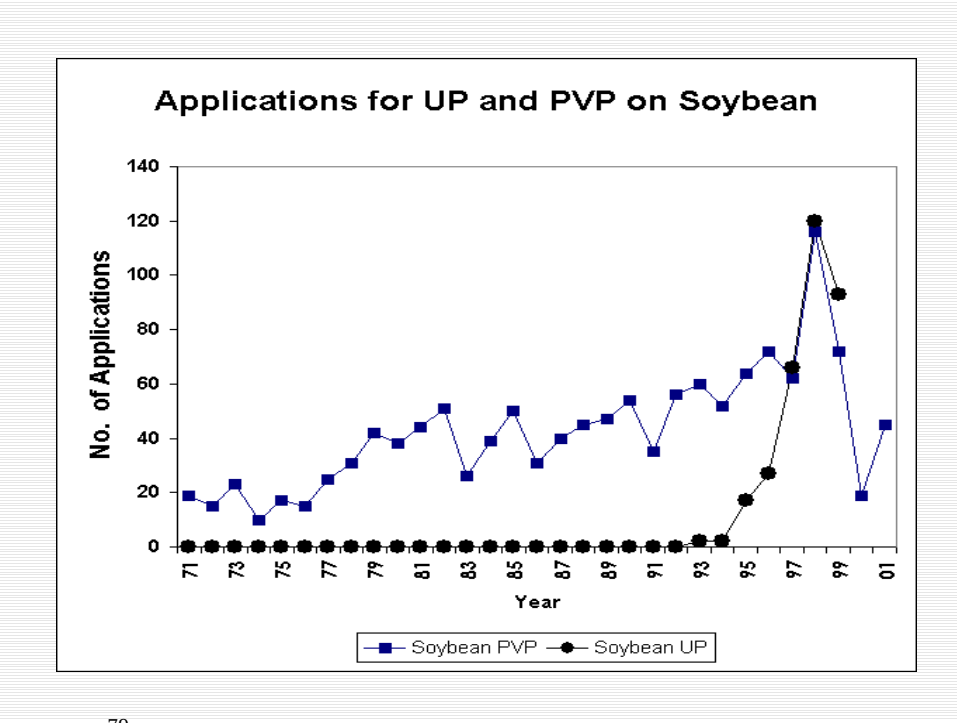

Figure 2[79]

In the wake of *Hibberd* (and even before), utility patenting of plant varieties has increasingly gained popularity. At the time of this writing, there were approximately 1,000 corn (hybrid plus pure line), and about the same number of soybean variety patents, plus smaller numbers of a range of other crops.[80] The reason for the popularity is evident: a greater scope of protection. Utility patents are not limited to sexual production (as with PVP) or asexual production (as with PP) nor are the PVP research and farmer exemptions present. UP claims can extend the scope of pure line patents to all hybrids produced by crossing that inbred with another. In exchange for the greater protection, there is an expectation of more stringent protection requirements. The *Pioneer* court explained the more stringent requirements by noting, "it is much more difficult to obtain a utility patent than to obtain a plant variety certificate because a patentable plant must be new, useful, and nonobvious."[81] The court further stated that "because of the more stringent requirements, utility patent holders receive greater rights of exclusion than holders of PVP certificates."[82] We turn now to the question of how much more difficult it is to obtain a UP in practice than a PVP certificate or PP.

Breeders can, and sometimes do, seek simultaneous PVP and UP protection for the same variety. While UP protection generally dominates PVP, PVP does specifically prohibit both importing and exporting a variety from the United States[83] while UP do not specifically prohibit

[79] *Id.*

[80] USPTO Patent Full-Text and Image Database, http://www.uspto.gov/web/patents/classification/uspc800/sched800.htm#C800S320:001 (follow the red "P" hyperlinks for "320.1 Maize" and "312 Soybean") (last visited Nov. 21, 2009).

[81] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 (2001).

[82] *Id.* at 143.

[83] 7 U.S.C. § 2541(a)(2) (2006).

exporting.[84]

IV. INTERPRETATIONS OF NONOBVIOUSNESS

This section examines interpretations of nonobviousness in its several forms as applied to PP, PVP, and UP.

A. Plant Patents

Nonobviousness as a 35 U.S.C. § 103 requirement applies to PP, but is acknowledged as "the hardest to apply to plants."[85] In *Yoder Bros. Inc. v. California-Florida Plant Corp.*, the Fifth Circuit stated, "We see no meaningful way to apply the third criterion to plants i.e. the level of ordinary skill in the prior art . . . Thus, if we are to give obviousness an independent meaning, it must refer to something other than observable characteristics."[86] The Court turned by default to the "invention" requirement and noted that "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."[87] Of course, there is nothing in the statutes which mandates that a new variety represent an "improvement," at least in any practical sense.

Elisa Rives refers to the expenditure of effort with no predictable outcome as the "'sweat of the brow' doctrine" underlying nonobviousness under the U.S. patent system.[88] The Supreme Court in *KSR* discussed four erroneous conclusions made by the Court of Appeals, the third of which was "that a patent claim cannot be proved obvious merely by showing that the combination of elements was 'obvious to try.'"[89] Particularly emphasized was the fact that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.[90] For plant varieties the elements–germplasm–may be familiar, at least to the breeders of a firm, and the breeding method may be obvious, but given the probabilistic aspect of heredity, a particular outcome is anything but predictable. This test would seem to satisfy the *Yoder Bros.* requirement, except for the expectation that the improvement be "significant."[91]

Any plant variety, of course, has myriad characteristics, both observable and unobservable, with only a small number having any practical relevance: for example, the color or smell of a flower; and the yield, disease, or stress-resistance of a food or fiber crop. On this point, the Senate Report on the 1930 Plant Patent Act states that "it is immaterial whether in the judgment of the Patent Office the new characteristics are inferior or superior to those of existing

[84] 35 U.S.C. § 271(a) (2006).
[85] Yoder Bros., Inc. v. California-Florida Plant Corp., 537 F.2d 1347, 1378 (5th Cir. 1976).
[86] *Id.* at 1379.
[87] *Id.*
[88] Elisa Rives, *Mother Nature and the Courts: Are Sexually Reproducing Plants and Their Progeny Patentable Under the Utility Patent Act of 1952?*, 32 CUMB. L. REV. 187, 215 (2001).
[89] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 402 (2007).
[90] *Id.* at 402-03.
[91] *Yoder Bros.*, 537 F.2d at 1379.

varieties."[92]

B. Plant Variety Protection

Distinctness replaces nonobviousness in PVP, but only in the context of being different. Like PP, both the goals of breeding (yield, stress resistance, flower color, etc.) and the methods used might be considered "obvious" at some level, but skill and effort are required for success in meeting the DUS requirements. The key then is determining to what extent and in what respects must a variety be different to be judged "distinct." Distinctness is defined as:

> 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.[93]

Applications require a statement of the "most similar previously existing variety" or varieties, and the "characteristic or characteristics that clearly distinguish the applicant's variety from [similar existing ones]."[94] "Objective Description of Variety" forms by species specify which characteristics may be used to describe a variety (blanks are permitted for this portion of the application). For corn, characteristics include the region where best adapted, as well as the species' maturity, cob, reaction to insects and disease, agronomic traits, and physical dimensions of the plant, ear and tassel. Descriptions are to include the number of plants measured and the standard deviations of measurements.[95] Yield is specifically excluded as a distinguishing characteristic due to its highly complex character.[96] Burchfiel notes that the greater description requirements of PVP compared to PP (and UP) mean that "the more restricted this coverage will be, the easier to demonstrate that the accused variety differs in one or more of the recited characteristics."[97]

The PVP Office recognizes ten groups of characteristics for distinctness for corn,[98] in contrast to UPOV's guidelines which identify thirty-four.[99] With no doctrine of equivalents for PVP,[100] any form or degree of distinctness appears sufficient for the grant of PVP. To pick one example—a corn pure line—the "novelty statement" indicates the distinguishing differences from the most similar variety as "silk color."[101] Secondary differences are "tassel branch angel" (shown to be statistically different at the five percent level in two trials), and inclination of the

---

[92] S. REP. NO. 71-315 (1930).
[93] 7 U.S.C. § 2401(b) (5) (2006).
[94] PLANT VARIETY PROTECTION OFFICE, U.S. DEP'T OF AGRIC., GUIDELINES EXHIBIT B–STATEMENT OF DISTINCTNESS [hereinafter GUIDELINES EXHIBIT B], *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3003279 (last visited Nov. 21, 2009).
[95] Objective Description of Variety – Corn, *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3002683 (last visited Nov. 21, 2009).
[96] GUIDELINES EXHIBIT B, *supra* note 94.
[97] BURCHFIEL, *supra* note 40, at 423.
[98] GUIDELINES EXHIBIT B, *supra* note 94.
[99] UPOV, Species-Specific Guidelines, *supra* note 52.
[100] Janis & Kesan, *supra* note 74, at 749.
[101] *See, e.g.*, U.S. Patent No. 5,773,683 (filed Dec. 6, 1996).

kernels.[102] Other distinguishing characteristics are identified as "excellent staygreen, very good test weight and grain quality, favorable plant height and ear height and very good leaf disease tolerance . . . ." but susceptibility to corn borer.[103] However, there is no data available concerning the degree of differences with similar varieties, so no reasoned judgment can be applied regarding the relevance of these claims.

The allowance of distinguishing characteristics of trivial relevance has been called "cosmetic breeding,"[104] which significantly restricts the scope of PVP, as minor phenotypic changes are relatively easy and quick to introduce through breeding since Plant Breeders' Rights (PBR) makes protected varieties available for breeding purposes. Initial or essentially derived classifications can go far to resolve this severe limitation on the scope of PVP protection once implemented in a systematic manner. Note also that the PVP Office does not conduct grow-out trials nor cause them to be conducted, limiting itself to accepting data from trials structured in the most basic ways.

Not all countries apply PVP in this manner, especially for food (row) crops. The European Union requires farmers to select seeds from a "Common Catalogue" of varieties which have simultaneously been tested for Value in Cultivation and Use (VCU). In simple terms, this means the applicant variety must outperform a reference variety in one of the identified characteristics.[105] Of course, there are limitations to the VCU approach as well, including cost, delays, a limited number of approved varieties, and regional adaptation difficulties. The point being made here is simply to highlight that the scope of PVP protection in the United States is a consequence of implementation as well as statutes.

C. Patents

UP applications for major crops typically do include comparisons with other "selected hybrids of commercial value"[106] like those shown in Table 2 (corn) and Table 3 (soybeans).

---

[102] *Id.*

[103] *Id.*

[104] Crucible Group Staff, 1 SEEDING SOLUTIONS: POLICY OPTIONS FOR GENETIC RESOURCES: PEOPLE, PLANTS AND PATENTS REVISITED 95 (2000).

[105] *See, e.g.*, United Kingdom National List Trials: Protocol for Official Examination of Value for Cultivation and Use (VCU) (2009), http://www.fera.defra.gov.uk/plants/plantVarieties/nationalListing/documents/protocolPotatoVcu.pdf (last visited Nov. 23, 2009) [hereinafter VCU] (testing applicant and reference varieties in the United Kingdom).

[106] '207 Patent, *supra* note 26, § VI (B) (noting that the comparisons of experimental hybrids are made against "competitive hybrids to determine if there was any advantage to further development of the experimental hybrids").

Table 2: Example comparative performance data for a corn hybrid[107]

Comparative Data for Hybrids EX6389 as One Inbred Parent Versus Check Hybrids									
	Mean Yield	% M	Y/M	% Stalk	% Root	% Drop	Plant Height (cm)	Ear Height (cm)	Test Weight
2003									
HC33 x EX6389	188	20.22	9.31	4	4	0	111	49	53.01
HC33 x LH295	179	18.08	9.91	2	2	0	100	42	54.42
DIFF	9	2.14	-0.6	2	2	0	11	7	-1.51
2002									
HC33 x EX6389	218	21.55	10.12	2	8	0	113	41	53.30
HC33x LH295	209	18.72	11.16	2	3	1	104	35	56.15
DIFF	9	2.83	-1.04	0	5	-1	9	6	-0.85
2003									
HC53 x EX6389	207	18.49	11.18	1	1	0	108	49	54.97
HC53 x LH277	186	19.73	9.43	2	0	0	98	42	54.87
DIFF	21	-1.24	1.75	-1	1	0	10	7	0.10
2002									
LH244 x EX6389	194	20.19	9.59	3	0	0	106	49	55.31
LH244 x LH273	194	19.96	9.70	4	0	0	107	47	54.43
DIFF	0	0.23	-0.11	-1	0	0	-1	2	0.88

Table 3: Example comparative performance data for a soybean variety XB23L07[108]

Variety1	Variety2	Statistic	YIELD Bu/s 608 ABS	MATABS Count ABS	LDGSEV Score ABS	HGT in ABS	FEC score ABS	SDS Score ABS
XB23L07	92B38	Mean1	55.9	127.1	8	39.6	5	8.5
XB23L07	92B38	Mean 2	52.7	126.8	6.8	39.4	4.5	6.8
XB23L07	92B38	#Locs	19	15	5	7	7	3
XB23L07	92B38	#Reps	38	30	10	14	21	5
XB23L07	92B38	#Years	1	1	1	1	2	1
XB23L07	92B38	Diff	3.1	0.2	1.2	-0.3	0.6	1.7
XB23L07	92B38	SE Diff	0.8	0.64	0.25	0.6	0.23	1.01
XB23L07	92B38	Prob	0.001	0.7192	0.0093	0.6487	0.0453	0.2419
XB23L07	92M30	Mean1	55.3	125.2	8	37.7	5.3	8.6

[107] *Id.* § VI (C) tbl.2.
[108] U.S. Patent No. 7,470,833 tbl.3 (filed Feb. 28, 2007).

XB23L07	92M30	Mean2	50.4	124.2	7.3	36	4.8	6.8
XB23L07	92M30	#Locs	34	23	7	12	4	4
XB23L07	92M30	#Reps	56	40	13	20	12	6
XB23L07	92M30	#Years	2	2	2	2	1	2
XB23L07	92M30	Diff	4.9	1	0.7	-1.7	0.6	1.9
XB23L07	92M30	SE Diff	0.88	0.32	0.15	0.45	0.48	0.66
XB23L07	92M30	Prob	0	0.0054	0.003	0.0031	0.3101	0.065
XB23L07	92M32	Mean1	55.9	127.1	8	39.6	5.3	8.5
XB23L07	92M32	Mean2	52.4	128.6	7.7	32.1	5.5	6.3
XB23L07	92M32	#Locs	19	15	5	7	4	3
XB23L07	92M32	#Reps	38	30	10	14	12	5
XB23L07	92M32	#Year	1	1	1	1	1	1
XB23L07	92M32	Diff	3.5	-1.6	0.3	-7.5	-0.2	2.2
XB23L07	92M32	SE Diff	1.12	0.53	0.46	1.02	0.62	0.44
XB23L07	92M32	Prob	0.0056	0.0099	0.5529	0.0003	0.8043	0.039
XB23L07	92M33	Mean1	55.9	127.2	8	39.6	5.3	8.5
XB23L07	92M33	Mean2	55.9	126.7	7.3	40.1	4.1	7.5
XB23L07	92M33	#Locs	19	15	5	7	4	3
XB23L07	92M33	#Reps	38	30	10	14	12	5
XB23L07	92M33	#Years	1	1	1	1	1	1
XB23L07	92M33	Diff	-0.1	0.4	0.7	0.5	1.3	1
XB23L07	92M33	SE Diff	0.53	0.5	0.34	0.88	0.16	0.58
XB23L07	92M33	Prob	0.9192	0.4396	0.1079	0.5904	0.0043	0.2254
XB23L07	92M40	Mean1	55.3	125.2	8	37.7	5.3	8.6
XB23L07	92M40	Mean2	53.3	126.1	8.9	33.6	4.1	8
XB23L07	92M40	#Locs	34	23	7	12	4	4
XB23L07	92M40	#Reps	56	40	13	20	12	6

XB23L07	92M40	#Years	2	2	2	2	1	2
XB23L07	92M40	Diff	1.9	-0.9	-0.9	-4.1	1.3	0.6
XB23L07	92M40	SE Diff	0.77	0.45	0.24	0.59	0.37	0.55
XB23L07	92M40	Prob	0.0171	0.0488	0.0111	0	0.043	0.3416

XB23L07	92B38	Mean1	5.5	19.67	33.12	3101
XB23L07	92B38	Mean2	6.3	18.31	34.72	2715
XB23L07	92B38	#Locs	2	6	6	3
XB23L07	92B38	#Reps	6	6	6	4
XB23L07	92B38	#Years	1	1	1	1
XB23L07	92B38	Diff	-0.8	1.36	-1.6	386
XB23L07	92B38	SE Diff	0.5	0.137	0.104	62.5
XB23L07	92B38	Prob	0.344	0.0002	0	0.0253
XB23L07	92M30	Mean 1	5.7	19.9	33.31	3152
XB23L07	92M30	Mean2	7.3	19.08	34.26	2654
XB23L07	92M30	#Locs	3	11	11	7
XB23L07	92M30	#Reps	8	11	11	8
XB23L07	92M30	#Years	2	2	2	2
XB23L07	92M30	Diff	-1.7	0.81	-0.94	499
XB23L07	92M30	SE Diff	0.38	0.129	0.177	104.6
XB23L07	92M30	Prob	0.0494	0.0001	0.0003	0.0031
XB23L07	92M32	Mean 1	5.5	19.67	33.12	3101
XB23L07	92M32	Mean2	7	18.68	33.54	2795
XB23L07	92M32	#Locs	2	6	6	3
XB23L07	92M32	#Reps	6	6	6	5
XB23L07	92M32	#Years	1	1	1	1
XB23L07	92M32	Diff	-1.5	0.99	-0.43	307

XB23L07	92M32	SE Diff	0.83	0.217	0.392	141.9
XB23L07	92M32	Prob	0.3228	0.006	0.326	0.1632
XB23L07	92M33	Mean 1	5.5	19.67	33.12	3101
XB23L07	92M33	Mean2	7.7	18.23	34.89	2868
XB23L07	92M33	#Locs	2	6	6	3
XB23L07	92M33	#Reps	6	6	6	4
XB23L07	92M33	#Years	1	1	1	1
XB23L07	92M33	Diff	-2.2	1.43	-1.77	233
XB23L07	92M33	SE Diff	0.83	0.198	0.133	93.5
XB23L07	92M33	Prob	0.2338	0.0008	0	0.1299
XB23L07	92M40	Mean 1	5.7	19.9	33.31	3152
XB23L07	92M40	Mean2	6.9	18.67	34.65	2926
XB23L07	92M40	#Locs	3	11	11	7
XB23L07	92M40	#Reps	8	11	11	8
XB23L07	92M40	#Years	2	2	2	2
XB23L07	92M40	Diff	-1.3	1.23	-1.34	226
XB23L07	92M40	SE Diff	0.87	0.161	0.32	66.3
XB23L07	92M40	Prob	0.2809	0	0.0019	0.0143

Several interpretations are possible from the data in Tables 2 and 3. First it should be noted that the data are not useful for assessing the applicant varieties regarding either the description or nonobviousness. There is no indication of how the comparison varieties are chosen beyond noting they are "selected hybrids of commercial value."[109] With the multitude of varieties in use, comparative results are highly dependent on the comparison varieties selected. Second, there is no indication as to whether the differences are statistically significant. Indeed, the inter-year yield differences in Table 2 are greater than those between varieties, a frequent occurrence due to weather variations, but an indication of the difficulty of documenting yield differences empirically. For example, using public soybean variety trials from Illinois in 2008, up to seventy percent of varieties in one trial location had statistically insignificant yield differences.[110] Recall as well the PP applications bar yield as a differentiation characteristic.[111]

[109] '207 Patent, *supra* note 26, § VI (C).

[110] *See* UNIV. OF ILL. DEPT. OF CROP SCIENCES, PERFORMANCE OF COMMERCIAL SOYBEANS IN ILLINOIS, http://vt.cropsci.uiuc.edu/soybean08/SBtxtCR08.pdf (last visited Nov. 21, 2009) (describing statistical procedures used); UNIV. OF ILL. DEPT. OF CROP SCIENCES, SOYBEANS VARIETY TEST RESULTS IN ILLINOIS,

Interestingly, Stine Seed Farm (a Monsanto subsidiary) uses one soybean variety (CSR1902N)—ownership unclear—in performance comparisons of over ten of its own patented and patent-pending varieties.[112]

An examination of the patents is illuminating. Comparing Patents No. 7,468,477 ("the '477 patent") and No. 7,423,207 ("the '207 patent")—both for corn, but the '477 patent for a hybrid and the '207 patent for a pure line, and both licensed to Monsanto—indicates that they are identical but for a few differences. Citations differ, final references have one patent added and two deleted, and of course the particulars of the descriptions, ATCC deposit numbers, breeding history, and performance characteristics differ. But the background, summary plant characteristics, embodiments, regeneration, and other features are typically word for word identical. Claims, while both numbering twenty-four, are somewhat different (except for the first six, which are identical), but then the uses of hybrids and pure lines are different. A comparison with another pure line Monsanto patent shows that the patent references overlap in seven of eight instances, and the claims (while worded somewhat differently) are otherwise nearly identical.[113] Claims are examined further below. Nor are the similarities limited to Monsanto-licensed varieties. Pioneer Hi-bred International, another leading corn breeding firm, has also received patents that are near copies of each other and similar to Monsanto's.[114]

D. Assessment

The "distinctness" requirement for PVP protection, as is argued above, is de minimus. Seemingly any difference, no matter how trivial in a phenotypic or practical sense, is sufficient for a grant of PVP. That factor, combined with the statutory Breeders' Rights and Farmers' Privilege and the detailed description requirement, mean that PVP provides the least scope of protection among the three available plant protection statutes. This is not a new interpretation – the Supreme Court in *J.E.M. Ag Supply Inc. v. Pioneer Hi-Bred Int'l, Inc.* reached the same conclusion.[115]

On the other hand, the issue with PP and UP is different, as they are subject to the supposedly more stringent non-obviousness standard, including the *Graham* Framework,[116] the TSM test,[117] and the recent *KSR* factors.[118] For PP, however, the limitation to a single claim

---

http://vt.cropsci.uiuc.edu/soybean.html (last visited Nov. 21, 2009) (describing statistical procedures used for conventional trials).

[111] S. REP. NO. 71-315 (1930).

[112] *See* USPTO Patent Full-Text and Image Database, *available at* http://patft.uspto.gov/netahtml/PTO/search-bool.html (search using "CSR1902N" as "Term 1," "All Fields" as "Field 1," "Stine" as "Term 2," and "Assignee Name" as "Field 2") (last visited May 27, 2009) (providing a list of issued patents found in the U.S. Patent Collection); *see also* USPTO Patent Application Full Text and Image Database, *available at* http://appft.uspto.gov/netahtml/PTO/search-bool.html (search using "CSR1902N" as "Term 1" and "All Fields" as "Field 1") (last visited May 27, 2009) (providing a list of patent applications found in the USPTO's AppFT Database).

[113] U.S. Patent No. 7,468,476 (filed Apr. 21, 2006).

[114] *See, e.g.*, U.S. Patent No. 7,399,914 (filed Jan. 31, 2007); U.S. Patent No. 7,504,568 (filed Jan. 31, 2007).

[115] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 143 (2001).

[116] Graham v. John Deere Co., 383 U.S. 1, 6-7 (1966).

[117] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007).

[118] *Id.* at 398.

incorporating the plant in its entirety, combined with the need to document derivation to support infringement leading by extension to an absence of a "doctrine of equivalents" for PP, means each applicant plant is distinct and nonobvious. Note further the limited role of the Department of Agriculture in comparing the applicant variety with those known to exist in the United States. Thus it appears that *any* distinctness whether taxonomic or functional is sufficient for a grant of a PP.[119] This approach to the awarding of PP does not say that the asexual development of a new variety is a trivial undertaking, but rather that the nonobviousness standard has been supplanted by a literal distinctness requirement. This approach reflects the view that the PP Act was designed to reward incremental progress in plant breeding.[120]

While the statutory requirements for nonobviousness of PP and UP are one and the same, the uniqueness of PP as noted above suggests the standards might be applied differently. UP applications for plants, however, would be subject to the full range of the *Graham* Framework,[121] TSM test,[122] and *KSR* requirements.[123] The *Graham* Framework provides few insights; even the "secondary considerations" of commercial success and unsolved needs are ambiguous when applied to plants. Applications are submitted prior to market release so there are no sales to be observed, and the unsolved needs for yet higher yields and enhanced stress resistance are well known but can be addressed only incrementally.

For the TSM test, no teaching would exist suggesting any particular bits of germplasm from the prior art be combined to produce a new variety. Groupings of germplasm might be identified, but the probabilistic aspect of breeding means that the outcome is not predictable. This probabilistic nature means that references to "predictable" results for establishing obviousness in the Patent Examiner's Manual do not apply;[124] even a "reasonable expectation of success" is questionable.[125] Regarding consideration of other fields of endeavor, conventional plant breeders would not look outside the species for germplasm as it would generally not breed.[126] *KSR* does say that obviousness cannot be demonstrated merely by showing that each element is known in the prior art.[127]

As an additional consideration, it is instructive to see if the *KSR* case, decided in 2007, has had any apparent affect on UP for plant varieties. During 2008 and the first quarter of 2009, 223 corn variety patents were granted.[128] Of those, approximately 115 were filed by Monsanto (pure lines plus hybrids) and 71 were filed by Pioneer (heavily pure lines). Over the five month period, there was little apparent change in the Monsanto filings, and there was also little change when compared to the pre-*KSR* period. The number of claims for Pioneer patents did vary considerably over the five quarter period from a high of 41 claims[129] to a low of a single

[119] *See* Kim Bros. v. Hagler, 276 F.2d 259 (9th Cir. 1960).
[120] *Id.*
[121] *Graham*, 383 U.S. at 6–7.
[122] *KSR*, 550 U.S. at 407.
[123] *Id.* at 419.
[124] MPEP, *supra* note 19, § 2141.
[125] *Id.* § 2143.02.
[126] *Id.* § 2141.
[127] *KSR*, 550 U.S. at 418.
[128] *See* USPTO Full-Text and Image Database, *supra* note 112.
[129] U.S. Patent No. 7,235,723 (filed Jan. 31, 2005).

claim.[130] However, there is no clear chronological pattern and nothing to suggest any relationship to *KSR*.

One can perform the same comparison for method claims before and after the 1995 *In re Ochiai* decision.[131] Presumably, when *In re Durden*[132] applied, breeding method claims for plant varieties would have been rejected as obvious. Method claims were indeed first added for variety patents granted during the 1995-96 period so that *In re Ochiai* likely expanded the scope of variety patents (with mixed practical effects).[133] Grubb refers to such claims as "analogy process" claims which allows firms to stop the importation of products made using the now patentable process.[134]

As noted, Rives refers to the expenditure of effort with no predictable outcome as the "sweat of the brow doctrine" underlying nonobviousness under the U.S. patent system.[135] Even more directly, Seay notes that "many breeders consider that most new varieties are nonobvious under the utility patent law. Indeed, if claims to a variety are limited to an exact assemblage of traits, any particular assembly may be nonobvious."[136] This conclusion may not apply in future years as genetic mapping and other breeding techniques might evolve to the point where combining particular traits becomes predictable and therefore obvious. But that stage has not been reached at the present and is not likely to be reached in the immediate, foreseeable future. In short, as with PP, a UP application for which there is not an identical example and which is novel is also nonobvious.

V. EVALUATION OF CLAIM SCOPE

Recipients of UP for plants receive a considerably expanded scope of protection compared to both PP and PVP with little, if any, apparent increase in the stringency of protection requirements. Many of the enhancements to scope are statutory – no research exemption,[137] no right to reuse seed, and the allowance of multiple claims. Other scope enhancements are attributable to UP claims, which are analyzed here. To this end, it is illuminating to contrast claims from near the beginning of UP plant patent grants with recent ones.

Hybrid Corn, 1988: What is claimed is (patent '596):

1. *Hybrid corn seed designated 3471.*
2. *A hybrid corn plant and its plant parts produced by the seed of claim 1.*
3. *Corn plants regenerated from tissue culture of the hybrid corn plant and plant parts of claim 2.*

---

[130] U.S. Patent No. 7,456,348 (filed Dec. 18, 2007).
[131] *In re* Ochiai, 71 F.3d 1565 (Fed. Cir. 1995).
[132] *In re* Durden, 763 F.2d 1406 (Fed. Cir. 1985).
[133] *Ochiai*, 71 F.3d at 1565.
[134] PHILIP W. GRUBB, PATENTS FOR CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY 225-26 (Oxford Univ. Press 2004) (1982).
[135] Rives, *supra* note 88, at 201.
[136] Seay, *supra* note 4, at 74.
[137] 37 C.F.R. § 1.802 (2009); *see also* Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002); Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984).

4. *A hybrid corn plant with the phenotypic characteristics of the hybrid plant of claim 2.*
5. *Hybrid seed having **ATCC** accession no. 40301.*
6. *A hybrid corn plant with the characteristics of the hybrid seed of claim 5.*[138]

Hybrid Corn, 2008: What is claimed is (patent '477):

1. *A seed of the hybrid corn variety CH824610, produced by crossing a first plant of variety I180581 with a second plant of variety I285291, wherein representative seed of said varieties I180581 and I285291 have been deposited under **ATCC** Accession numbers PTA-7927 and PTA-7994, respectively.*
2. *A plant of the hybrid corn variety CH824610 grown from the seed of claim 1.*
3. *A plant part of the plant of claim 2.*
4. *The plant part of claim 3, further defined as an ear, ovule, pollen or cell.*
5. *A tissue culture of cells of the plant of claim 2.*
6. *The tissue culture of claim 5, wherein cells of the tissue culture are from a tissue selected from the group consisting of leaf, pollen, embryo, root, root tip, anther, silk, flower, kernel, ear, cob, husk, stalk and meristem.*
7. *The seed of claim 1, wherein one or both of the first and second plants further comprises a transgene.*
8. *The seed of claim 7, wherein the transgene confers a trait selected from the group consisting of male sterility, herbicide tolerance, insect resistance, disease resistance, waxy starch, modified fatty acid metabolism, modified phytic acid metabolism, modified carbohydrate metabolism and modified protein metabolism.*
9. *The seed of claim 7, wherein the first and second plants each comprise a different transgene.*
10. *A method of producing hybrid corn seed comprising crossing a plant of variety I180581 with a plant of variety I285291, wherein representative seed of variety I180581 and variety I285291 have been deposited under **ATCC** Accession numbers PTA-7927 and PTA-7994, respectively.*
11. *The method of claim 10, defined as comprising pollinating a plant of inbred variety I180581 with pollen from a plant of variety I285291.*
12. *The method of claim 10, defined as comprising pollinating a plant of inbred variety I285291 with pollen from a plant of variety I180581.*
13. *A method for producing corn grain comprising growing the plant of claim 2 until grain is produced and collecting the grain.*
14. *A method of introducing a heritable trait into hybrid corn variety CH824610 comprising the steps of: (a) crossing a first plant of a first inbred corn variety selected from the group consisting of variety I180581 and variety I285291 with another corn plant that heritably carries the trait to produce progeny plants, at least some of which heritably carry the trait, wherein representative samples of seed of variety I180581 and variety I285291 have been deposited under **ATCC** Accession numbers PTA-7927 and PTA-7994, respectively; (b) selecting progeny plants that heritably carry the trait; (c) crossing selected progeny plants with another plant of the first inbred corn variety to produce next-generation progeny plants*

[138] U.S. Patent No. 4,737,596 (filed Jan. 29, 1987).

at least some of which heritably carry the trait; (d) selecting next-generation progeny plants that heritably carry the trait and exhibit morphological and physiological characteristics of the first inbred corn variety; (e) repeating steps (c) and (d) three or more times to produce at least a first selected progeny plant that heritably carries the trait and exhibits morphological and physical characteristics of the inbred corn variety; and (f) crossing a progeny plant of step (e) with a plant of the other inbred corn variety of the group consisting of I180581 and I285291 to produce a plant comprising the trait and characteristics of hybrid corn variety CH824610 when grown under the same environmental conditions.

15. *The method of claim 14, wherein the trait is selected from the group consisting of male sterility, herbicide tolerance, insect resistance, disease resistance, waxy starch, modified fatty acid metabolism, modified phytic acid metabolism, modified carbohydrate metabolism and modified protein metabolism.*
16. *The method of claim 15, further comprising repeating steps (a)-(f) at least once to introduce at least a second trait into hybrid corn variety CH824610, wherein the second trait is selected from the group consisting of male sterility, herbicide tolerance, insect resistance, disease resistance, waxy starch, modified fatty acid metabolism, modified phytic acid metabolism, modified carbohydrate metabolism and modified protein metabolism.*
17. *A plant produced by the method of claim 14.*
18. *A method of introducing a desired trait into hybrid corn variety CH824610 comprising the steps of: (a) introducing a transgene conferring the trait into a first inbred corn variety selected from the group consisting of I180581 and I285291 to produce a transgenic plant heritably carrying the trait, wherein representative seeds of varieties I180581 and I285291 have been deposited under* ***ATCC*** *Accession numbers PTO-7927 and PTA-7994, respectively; and (b) crossing the transgenic plant or an isogenic progeny plant thereof with a plant of the other inbred corn variety to produce seed of the hybrid corn variety CH824610 that heritably carries and expresses the transgene and otherwise has morphological and physiological characteristics of hybrid corn variety CH824610 when grown under the same environmental conditions.*
19. *The method of claim 18, wherein the desired trait selected from the group consisting of male sterility, herbicide tolerance, insect resistance, disease resistance, waxy starch, modified fatty acid metabolism, modified phytic acid metabolism, modified carbohydrate metabolism and modified protein metabolism.*
20. *The method of claim 18, further comprising repeating steps (a) and (b) at least once to introduce at least a second trait into hybrid corn variety CH824610, wherein the second trait is selected from the group consisting of male sterility, herbicide tolerance, insect resistance, disease resistance, waxy starch, modified fatty acid metabolism, modified phytic acid metabolism, modified carbohydrate metabolism and modified protein metabolism.*
21. *A plant produced by the method of claim 18.*
22. *The plant of claim 21, wherein the plant comprises a trait selected from the group consisting of male sterility, herbicide tolerance, insect resistance, disease resistance, waxy starch, modified fatty acid metabolism, modified phytic acid metabolism, modified carbohydrate metabolism and modified protein metabolism.*
23. *A method of producing a corn plant derived from the hybrid corn variety CH824610, comprising crossing the plant of claim 2 with a second corn plant to produce a progeny corn*

plant derived from the hybrid corn variety CH824610.

24. *The method of claim 23, further defined as comprising producing an inbred corn plant derived from the hybrid corn variety CH824610, the method comprising the steps of: (a) crossing the progeny corn plant derived from the hybrid corn variety CH824610 with itself or a second plant to produce a seed of a progeny plant of a subsequent generation; (b) growing a progeny plant of a subsequent generation from the seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and (c) repeating steps (a) and (b) for an addition 3-10 generations with sufficient inbreeding to produce an inbred corn plant derived from the hybrid corn variety CH824610.*[139]

A. Assessment

The ’596 patent claims the seed in claim 1 and the plant resulting from growing it in claim 2. Claim 2 may permit the patent holder to require a separate license for planting a patented seed, restricting the exhaustion doctrine. In practice, seed companies typically use “bag tag licenses” to control subsequent use of seed.[140] Claim 3 extends protection to asexually produced plants. By claiming all corn varieties with the observable characteristics of variety 3471, claims 4 and 6 are potentially the broadest claims. The scope of the claims depends on how similar the characteristics of a potentially infringing variety must be to those of 3471. If the characteristics must be identical, then these claims serve as an alternate way of defining the invention in the matter of “fingerprint claims.”[141] Claim 5 indicates the enablement requirement has been satisfied through the deposit of a sample of seed of variety 3471.

Considering the ’477 patent, claims 1-6 are similar to claims 1, 2, 3, and 5 in the ’596 patent except that claim 1 is a method-of-production claim from crossing the two patent lines of CH824610. Since the method is obvious, this claim draws on *In re Ochiai* for its validity.[142] Many of the next sixteen claims apply to transgenic trait(s) which may subsequently be added to variety CH824610. In general, such method-of-making claims do not extend the scope of the protection allowed. However, Pioneer hybrid corn patent claims—such as claim 18 above—read not to the general “morphological and physiological characteristics of hybrid corn variety CH824610,” but to the listed morphological and physiological characteristics “at the 5% significance level.”[143] The inclusion of a statistical confidence interval in a claim essentially inserts an equivalence measure, and as we have seen with plants, annual environmental variability can induce wide changes in the expression of some characteristics. That factor implies a broad doctrine of equivalence not otherwise present for plant variety patents.

Claims 7–13 apply when one or both of the parent lines identified already contain a transgene. Claims 14–22 describe a method of transferring a transgene from a fourth variety to one of the parental lines from which it may be conferred to variety CH824610. Selecting for both the new trait and the characteristics of the parental line, however, requires multiple

[139] U.S. Patent No. 7,468,477 (filed May 9, 2007).
[140] *See* Janis & Kesan, *supra* note 74, at 771.
[141] *See* GRUBB, *supra* note 134, at 221.
[142] *In re* Ochiai, 71 F.3d 1565 (Fed. Cir. 1995).
[143] U.S. Patent No. 7,399,814, col.24, l.40 (filed July 24, 2006).

selections and generations which raises the issue of whether "undue experimentation"[144] would be required so that these claims are potentially inadequately enabled. Claims 23–24 apply to using variety CH824610 and an undisclosed variety to transform CH824610 into a pure line through multiple generations of self breeding and selection. Again, the production of a stable pure line is a lengthy and exacting process, raising the issue of undue experimentation.

VI. ECONOMIC CONSEQUENCES OF ENHANCED PATENT SCOPE UNDER UPS

The preceding sections draw the conclusion that plant utility patents are granted with a minimal nonobviousness standard at best, one akin to uniqueness in one or several characteristics which often have no effect on agronomic performance. Indeed, the standards for granting a plant utility patent are not notably different than for PVP, yet the scope of protection received is substantially greater. Standards for PP are similar, but that statute is of less consequence because the major food and fiber crops are sexually, not asexually, bred and hence are not eligible for PP. The economic consequences of the broader scope granted under UP directly impact farmers and other breeders, and have an indirect effect on the agricultural input sector. Eventually though, cost and efficiency gains in production agriculture are largely passed on to consumers. Therefore, food consumers are the ultimate losers when low nonobviousness standards are applied to plant varieties. In the following section, a first approximation of the direct costs in two areas, annual purchases of soybean seeds and reduced productivity advances in cotton seed, is developed.

A. Annual Purchases of Soybean Seed

Because soybeans are open pollinators, they reproduce true-to-type, meaning that the crop can be saved as a seed source for subsequent plantings. Not all farmers save seed, and for those who do there is a limit in the period due to annual genetic drift and the ongoing improvements in new varieties coming onto the market. For soybeans, Leibenluft determined U.S. farmers on average bought open pollinated seed (soybeans as well as wheat and cotton) every other year in the early 1980s.[145] The time period predates the transgenic era and so represents a steady-state period for farmers.

The analysis shown in Table 4 indicates soybean farmers in 2005 spent up to $ 62.9 million as a consequence of UP preventing seed saving. This figure represents only traditional, or non-transgenic, seed, about thirteen percent of the soybean seed used that year.[146] This paper is focused on traditional, non-transgenic varieties only. The $ 62.9 million figure will fluctuate from year to year due to changes in such factors as area planted, crop price, proportion planted to traditional varieties, and others. However, it does represent a reasonable approximation of costs imposed by the patenting of soybean seed. The figure also represents a ceiling cost as it assumes all soy seed is patented and hence cannot be saved as a seed source. In practice, some soybean seed is PVP protected, permitting seed saving. Of course, if seed prices were effectively lowered by a patent saved-seed option, the share of non-transgenic varieties purchased would likely be

[144] BURCHFIEL, *supra* note 40, at ch. 8.

[145] ROBERT F. LEIBENLUFT, FED. TRADE COMM'N, COMPETITION IN FARM INPUTS: AN EXAMINATION OF FOUR INDUSTRIES (1981).

[146] ECON. RESEARCH SERV., *supra* note 77.

higher.[147] A similar calculation can be carried out for cotton seed, but for wheat there are few patented varieties.

Table 4: Annualized Costs of Prohibiting Seed Saving for Traditional Soybean Seed, United States, 2005

Acres planted, m[148]	72.0
Seed required, m bu[149]	72.0
Seed price, $/bu.[150]	$ 19.10
Crop value, $/bu.[151]	$ 5.66
Total cost traditional seed,[152] $ m	$ 967.7
% crop using traditional varieties[153] @ 13%, $m	$ 125.8
@ 50% annualized seed saving,[154] $ m	$ 62.9
Estimated Annualized Cost, millions $	**$ 62.9**

B. Reduced Productivity of Cotton Seeds

Economists and Department of Justice (DOJ) officials have long identified a connection between very high sector concentration and declines in innovation, although the relationship is by no means straightforward.[155] In the simplest terms, firms in concentrated industries are under less competitive pressure to be innovative. Utility patents, by restricting access to the germplasm needed for breeding improved varieties, are a contributor to rising concentration in the seed sector.[156]

For estimating the effects of rising concentration on seed productivity, it is most useful to consider the cotton seed sector. Cotton seeds have several dimensions which facilitate the analysis:

- The U.S. Department of Agriculture annually compiles a report on "Cotton Varieties Planted" by firm, from which market shares can be calculated,[157] and

[147] G. Moschini, H. Lapan & A. Sobolevsky, *Roundup Ready® Soybeans and Welfare Effects in the Soybean Complex*, 16 AGRIBUSINESS 33, 55 (2000) (showing that soybean farmers, to take one example, purchase transgenic varieties largely for their economic benefits).

[148] AGRICULTURAL STATISTICS, *supra* note 3, at tbl.3-32.

[149] WILLIAM F. LAZARUS, UNIV. OF MINN., MINNESOTA CROP COST & RETURN GUIDE – 2009 (2009) (computed at 1 bu seed/acre).

[150] AGRICULTURAL STATISTICS, *supra* note 3, at tbl. 6-13.

[151] *Id.* at tbl. 3-32.

[152] Computed for 100% traditional seed.

[153] ECON. RESEARCH SERV., *supra* note 77.

[154] LEIBENLUFT, *supra* note 145.

[155] *See, e.g.*, WILLIAM L. BALDWIN, MARKET STRUCTURE AND TECHNOLOGICAL CHANGE (2002).

[156] *See* Complaint § III (A)(16), United States v. Monsanto Co., No. 1:07-cv-00992, 2008 WL 5636384 (D.D.C. Nov. 6, 2008), *available at* http://www.usdoj.gov/atr/cases/f223600/223677.htm (last visited Nov. 23, 2009) [hereinafter DOJ Complaint] ("The success of a cottonseed company's breeding program is dependent on many factors, the most important of which is the quantity and quality of available breeding materials, *i.e.* germplasm.").

[157] *See, e.g.*, AGRICULTURAL MARKETING SERVICE, U.S. DEP'T OF AGRIC., COTTON VARIETIES PLANTED (2008).

- The U.S. Department of Justice complaint[158] to the proposed 2007 acquisition of Delta & Pineland, the leading cotton seed breeding firm, led to systematic reviews of the cotton seed breeding sector.[159]

Cotton seed breeding has long been highly concentrated, with four firms providing less than fifty percent of total sales in 1981, increasing to ninety-five percent in 2005. One firm was instrumental in that growth in concentration, Delta & Pineland (DPL) whose share rose from twenty percent in 1981 to eighty percent in 2000 (but subsequently declined somewhat).[160] The DOJ considers an HHI value (a measure of sector concentration) above 1,800 for an industry to indicate "very high" concentration; for DPL alone the value in the Mid-South, a leading production region, is close to 6,000.[161]

Naseem, Oehmke and Schimmelpfennig examined the productivity of cotton varieties in major producing states over the 50 year period ending in 2000.[162] They found that while there was a general trend of higher yields over the total period, the trend shifted downward in 1982. As a consequence, cotton yields were found to experience a net annual decrease of 13.3 lb/acre. For 2000, that level of production loss resulted in a $ 89.6 million reduction in the crop value.[163]

The above figure is not specifically linked to patents as there were very few cotton variety patents issued by 2000. However, we do know that the concentration of UP is high for other crops. Taking corn inbreds as an example, of 835 patents awarded, 70.6 percent are held by Pioneer Hi-Bred International and Monsanto Technologies (incorporated subsidiaries), and forty-eight percent by Pioneer alone. The patented share of inbreds by Monsanto and subsidiaries represents less than the market share of seed sales, about 55 percent in 2006.[164] The distinction can be partly explained by the role of Holden's Foundation Seed, a Monsanto subsidiary, which sells its pure lines for production and sales by third-party seed companies.[165] One contributing factor to the concentration of ownership of pure lines is clear—the decline of importance of public sector breeding. In 1970, seventy-two percent of commercial hybrids contained at least one public sector parent; by 2008 the percentage was estimated to be less than one percent.[166] Patent ownership concentration is linked to seed sector concentration because patents restrict breeders' access to genetic resources, a key entry barrier. Some do argue that

---

[158] DOJ Complaint, *supra* note 156.

[159] BILL FREESE, CTR. FOR FOOD SAFETY & INT'L CTR. FOR TECH. ASSESSMENT, COTTON CONCENTRATION REPORT: AN ASSESSMENT OF MONSANTO'S PROPOSED ACQUISITION OF DELTA PINE AND LAND (2007).

[160] *Id.* at apps. 1, 2.

[161] DOJ Complaint, *supra* note 156, § IV (A)(40); U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES 1.51(c) (1992, rev. 1997), *available at* http://www.usdoj.gov/atr/public/guidelines/horiz_book/15.html (last visited Nov. 23, 2009).

[162] Anwar Naseem, James F. Oehmke & David E. Schimmelpfennig, *Does Plant Variety Intellectual Property Protection Improve Farm Productivity? Evidence from Cotton Varieties*, 8 AGBIOFORUM No. 2 & 3, Art. 6 (2005), *available at* http://www.agbioforum.missouri.edu/v8n23/v8n23a06-oehmke.htm (last visited Nov. 23, 2009).

[163] Computed as 13.053 m acres at $0.516 per lb. AGRICULTURAL STATISTICS, *supra* note 3, at tbl.2-1.

[164] MARK LEIDY, WORLD CLASS SEED MANUFACTURING: TRANSFORMING AN INDUSTRY (Monsanto Investor Meeting, Jul. 12, 2005), *available at* http://www.monsanto.com/pdf/investors/2005/07-12-05a.pdf (last visited Nov. 23, 2009).

[165] Marvin Hayenga, *Structural Change In The Biotech Seed And Chemical Industrial Complex*, 1 AGBIOFORUM 2, 43–55 (1998), http://www.agbioforum.missouri.edu/v1n2/v1n2a02-hayenga.pdf (last visited Nov. 23, 200).

[166] Nelson et al., *supra* note 54.

pure lines become available once the protection lapses (although that is not necessarily true for varieties protected by PVP but never made available on the market), but then twenty year old germ plasma would be of limited practical value.

Using a modeling approach, Lence et al. examined the welfare effects of investments in seed breeding, concluding that "the optimum level of IPP [Intellectual Property Protection] is greater than that which existed in the North American seed corn market in 1996 and 1997…"[167] Their model is structured on a system in which breeding R&D enhances productivity, which is shared among breeders, farmers, and consumers. At low levels of protection, farmers and consumers receive the great bulk of the benefits, but since there is little incentive to produce improved seed, total welfare is lower. Conversely, with strong IPP, breeders benefit but at the expense of farmers and consumers. The "optimal" computed level which maximizes social welfare was found to exceed what was available for corn, leading to the quote above. Such a conclusion is potentially contrary to the point being made here, that IPP levels under UP for corn—among other crops—are too high for the breeding advances granted protection. The differences in conclusions can be reconciled by recognizing the structure of the Lence et al. model. The authors set the outcome to be x_1, a more productive corn seed variety. IPP then affects the *speed* with which the breeding industry reaches x_1, which is also dependent on the number of breeding firms. Importantly though, x_1 is exogenous to the model meaning it will be achieved, but at differential rates of progress. Here I am arguing that x_1 is in fact endogenous to the sector—jointly determined by the number of firms and the market structure.[168]

The actual values presented here for associated costs are preliminary, but hopefully sufficiently compelling to indicate the kinds of costs which are imposed on the food sector by low standards for the granting of UPs for plant varieties. Critiques are the easy part; offering reasonable alternative approaches is more complex.

VII. ALTERNATIVE APPROACHES TO IP PROTECTION FOR PLANT VARIETIES

Identifying the appropriate balance between breeders' needs and farmers and consumers of plant varieties is a matter that has perplexed policy makers for more than a century, so there are no readily identifiable alternatives. That said, it is instructional to consider the unique combination of dimensions that apply to plant varieties. Each individual dimension is not unique, but the combination is, and thus the combination is what must be considered. The dimensions are as follows, with emphasis placed on contrasting UP with PVP as PP are of much less importance in terms of crop value protected:

1. Multilevels of breeding contributions, from incremental annual enhancements to the occasional multistep advance;
2. Multiple phenotypic attributes of finished varieties, most of which have no practical effect on agronomic performance;

[167] Sergio H. Lence, Dermot J. Hayes, Alan McCunn, Stephen Smith & William S. Niebur, *Welfare Impacts of Intellectual Property Protection in the Seed Industry*, 87 AM. J. AGRIC. ECON. 951, 967–68 (2005).

[168] Alternatively, x_1 can be exogenous but T, the time to achieve it, endogenous.

3. Due to the small incremental enhancements made plus the co-evolution of plant diseases and predators, average commercial variety life is brief;
4. Since seeds of most crops reproduce true-to-form meaning farmers can save the crop as a future seed source, trade secret protection is not feasible; and
5. Much plant breeding is sequential, utilizing the best of existing varieties to enhance future ones. This means that it is not possible for a new entrant without breeding access ever to catch up with established firms with germplasm resources. That is, entry is essentially blockaded in crops with no meaningful public sector breeding presence if the IP protection system does not allow breeding access to private sector germplasm.

Regarding the first point, there is nothing unique to plants about having multiple levels of inventive step. With UP, some systems accommodate the differences with utility patents and utility models. The World Intellectual Property Organization describes the differences between patents and utility models as follows:

- The requirements for acquiring a utility model are less stringent than for patents. While the requirement of "novelty" is always to be met, that of "inventive step" or "non-obviousness" may be much lower or absent altogether. In practice, protection for utility models is often sought for innovations of a rather incremental character which may not meet the patentability criteria.
- The term of protection for utility models is shorter than for patents….
- In most countries where utility model protection is available, patent offices do not examine applications as to substance prior to registration. This means that the registration process is often significantly simpler and faster, taking, on average, six months.[169]

In some regards, PVP and UP have the same relationship as utility models and patents. However, by awarding both on seemingly any uniqueness/distinctness aspect, the functional distinction between multiple levels of protection evaporates.

In reference to the second point, the patent system has for a long time appropriately avoided judgments of practical or market value. The U.S. Senate has specifically applied that reluctance to plants.[170] Yet nonobviousness criteria are again involved. It is unlikely that the proverbial "better mousetrap" would be considered a nonobvious enhancement if chrome plated, even if the plating process turned out to be a complex and unpredictable process to master, involving both skill and investment. Yet by granting a patent for a corn variety with non-significant physiological and morphological characteristics that is essentially what the PTO does.[171] The third point describes a characteristic of commercial plant varieties, one that excludes differences in the term of protection as a means of achieving different levels of protection. Item number four merely states that some form(s) of IP protection are needed for

[169] World Intellectual Property Org., Protecting Innovations by Utility Models, *available at* http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm (last visited Nov. 21, 2009).

[170] S. REP. NO. 71-315 (1930).

[171] '207 Patent, *supra* note 26, § III (A) tbl.1.

plant varieties. Indeed, unlike many inventions with brief commercial lives for which trade secrets and/or first-mover advantage can be used, legal protection is the only possible protection presently available for nonhybrid crops for which the seed is marketed.

The final point is the critical distinction with living organisms, which does not generally apply to industrial inventions. Breeding access underlies the key distinction between UP and PVP and is unsurprisingly highly controversial, particularly for the breeding industry.[172] The current version of PVP with its "essential derivation"[173] component is of course exactly an effort to maintain breeding access while allowing for reasonable compensation for using another firm's germplasm.[174] However, the current approach is effectively unoperational because of the proposed delineation of the "initial variety" based on the proportion of genetic material contributed, while important changes can involve the addition of proportionally little genetic material. Further, the amount added can be increased during breeding by adding "junk" genes with no known function. Thus the potential for breeding around the requirements is too great to allow for a functional system.[175]

An alternative to respecifying the essential derivation system—if indeed that is possible—is over time to allow the courts when responding to private actions to develop a function system, as has been done with dependant patents. Yet the outcome of that approach is predictable; the few large breeding firms will have the resources to invoke the legal system meaning that entry via access to private sector germplasm for breeding purposes will still be severely restricted. Note that the Farmer's Privilege is not as difficult an issue for UPOV, which allows national legislation to require a royalty to be paid.[176] The US has not acted on that option, but the EU does require a royalty payment from all but "small farms."[177]

A modification to a court-based evolution of an essentially derived system would under PVP limit essential derivation to only the introduction of transgenes; a variety would be classified as essentially derived if (and only if) a transgene was added to an existing variety. Every variety would continue to have but one source variety for even if a second or third transgenic trait were added, the initial, conventionally bred variety would remain as the initial variety. This latter approach though could be readily, if inefficiently, circumvented by a

---

[172] *See, e.g.*, News Release, Am. Seed Trade Ass'n, *Position Statement On Intellectual Property Rights for the Seed Industry* (Jul. 15, 2004), *available at* http://www.amseed.org/newsDetail.asp?id=97 (last visited Nov. 23, 2009) ("However, open access to germplasm allowed under UPOV for breeding immediately upon commercialization has the effect of diminishing the developer's opportunity to earn a competitive return on research investments."). *But see* Int'l Seed Federation, *ISF View on Intellectual Property* (2003, rev. 2009), *available at* http://www.worldseed.org/cms/medias/file/PositionPapers/OnIntellectualProperty/View_on_Intellectual_Property_2009.pdf (last visited Nov. 23, 2009) ("Therefore ISF considers that a commercially available variety . . . containing patented elements should remain freely available for further breeding. Where followed, the savings from farmer seed saving would approach eight times that amount.").

[173] 7 U.S.C. § 2401 (2006).

[174] *See* John Vickers, *Competition Policy and Property Rights* 19–20 (Univ. of Oxford, Paper No. 436, 2009) (presenting a simple economic model showing that a full experimental use exemption, meaning no license fees, provides no incentive for fundamental innovations like background breeding).

[175] *See* Lesser & Mutschler, *supra* note 57.

[176] *See* UPOV, UPOV 1991 Act art. 15, *available at* http://www.upov.int/en/publications/conventions/1991/w_up911_.htm#_15 (last visited Nov. 23, 2009).

[177] *See* Commission Regulation 1768/95, 1995 J.O. (173).

competitor by adding a breeding step. A breeder need simply add a nonfunctional distinguishing characteristic, a straightforward if time consuming process, to interrupt the initial/essentially derived dependency relationship. Transgenes can then be added at will to the new variety with no requirement for paying royalties. Thus, in the absence of fundamental new approaches, the dependent variety approach for PVP is a dead letter, and with it the expectation that PVP can internalize the dual levels of protection needed for plant varieties. PVP though is suited to the role of secondary variety enhancement protection; it was after all specifically designed to protect just such incremental inventions.

Current PVP protection can be enhanced for seed companies by requiring a royalty payment be made when saving seed—a reasonable expectation—per the EU model. Monsanto has developed a number of approaches to tracking infringing seed saving for its transgenic varieties, which approach can be applied to royalty payments for traditional seeds as well.[178] Thus modified, PVP can serve to protect incremental variety improvements. Protection for varieties with significant new characteristics must now be considered. That adjustment will require that the nonobviousness standard for UP be enhanced.

The current PTO interpretation that all breeding is a probabilistic undertaking requiring skill and resources so that any resulting distinctness in a variety is nonobvious is not meaningful, leading as it does to no substantive nonobviousness standard. What is needed is limiting relevant nonobviousness only to certain plant characteristics, those with some practical relevance. The proposed approach then parallels the EU VCU system.[179] The agronomic value to be demonstrated can be crop specific and extend to dimensions like resistance to sprouting for stored onions. When possible, distinctness should be defined statistically: for example, no more than two percent sprouted onions after four months in storage.

Patent purists will object that establishing the acceptable types of distinctness puts the Patent Office in the position of determining usefulness and marketability of plants, contrary to the expressed position of the Senate.[180] But, utility patents are not copyrights, nor are they utility models; some discerning nonobviousness standard is essential for a meaningful system. What is proposed here in the form of limiting nonobviousness to useful plant characteristics with a quantified inventive step mandate serves that need. Operationally, the designated criterion would be included with the "comparative performance data" (see Tables 2 and 3). Trial procedures must be specified with reference varieties identified so that the comparative performance numbers are meaningful. None of this is new or untried elsewhere in the world. Should a variety application be rejected for not demonstrating nonobviousness in one of the identified criteria, the applicant can always appeal by requesting designation of a new criteria be added. That allowance provides important flexibility to the proposed system, but is likely to be invoked relatively rarely given the mature nature of the seed sector. Varieties not meeting the higher UP standards—presumably a notable proportion of applications for the two tiered system to have any functionality—can seek PVP protection.

---

[178] The most publicized case is that of Percy Schmeiser. *See* Kirk Makin, *Canada Rules in Favor of Monsanto over Seed Saving Farmer Percy Schmeiser*, GLOBE AND MAIL UPDATE, May 21, 2004, *available at* http://www.organicconsumers.org/ge/schmeiser.cfm (last visited Nov. 23, 2009).

[179] VCU, *supra* note 105.

[180] *See* S. REP. NO. 71-315 (1930).

VIII. SUMMARY AND CONCLUSIONS

Nonobviousness standards have been examined for Plant Patents, Plant Variety Protection, and Utility Patents for traditionally bred plant varieties. In all three cases, nonobviousness is interpreted as distinctness, with distinctness in any phenotypic characteristic being accepted for a grant. This means that plant breeders have a choice of two, and possible three, forms of protection—potentially simultaneously—but with UP dominating in terms of patent scope. For economically important crops like corn and soybeans, breeders are making the obvious choice by choosing UP protection. However, there is a public cost to this practice, which is preliminary estimated to be in excess of $150 million annually for soybeans and cotton, and is not clearly offset by additional public benefits. Indeed, the role of UP in further limiting entry to plant breeding by restricting access to germplasm can have greater long term public costs.

Given the nature of conventional plant breeding with its annual incremental improvements interspersed by occasional major advances, a two tier protection system is needed. The PVP system attempted to internalize such an approach with its "initial variety" distinction, but on further evaluation it is as presently construed unworkable and likely always unworkable. Proposed here is using the existing PVP system as the lower level of a two-tiered system (while requiring farmers to pay reasonable royalties for saved seed) and UP for the higher. The UP system though needs functional nonobviousness standards. Proposed here is the designation of a limited number of plant characteristics, all of practical agronomic importance, which must be achieved to establish nonobviousness. When possible, standards should be statistical with reference to an identified standard, such as a particular reference variety. Far from being unique, breeders routinely follow these practices when developing new varieties. The PTO should do likewise.