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WIPO-UPOV/SYM/02/8
ORIGINAL: English
DATE: October 3, 2002

WORLD INTELLECTUAL PROPERTY ORGANIZATION

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

WIPO-UPOV SYMPOSIUM ON THE CO-EXISTENCE OF PATENTS AND PLANT BREEDERS' RIGHTS IN THE PROMOTION OF BIOTECHNOLOGICAL DEVELOPMENTS

organized by
the World Intellectual Property Organization (WIPO)

and
the International Union for the Protection of
New Varieties of Plants (UPOV)

Geneva, October 25, 2002

ARE THERE TRIPS-COMPLIANT MEASURES FOR A BALANCED CO-EXISTENCE OF PATENTS AND PLANT BREEDERS' RIGHTS? SOME LESSONS FROM THE U.S. EXPERIENCE TO DATE

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This paper will attempt to answer the question posed in its title by drawing on the United States of America's (U.S.) experience to date under its dual—or more accurately, its tripartite-system of patent and *sui generis* plant variety protection for plant innovation which I will briefly summarize in Part I of this paper.[1] The paper as a whole is based in significant measure on the work of Professor Mark D. Janis, of the University of Iowa College of Law, who, together with Professor Jay P. Kesan, of the University of Illinois College of Law, is publishing a series of studies on optimizing intellectual property regimes for plant innovation. In Part II of this paper, I will expand on a point that Professor Janis makes in his recently published article, *Sustainable Agriculture, Patent Rights, and Plant Innovation,*[2] with respect to how patent regimes might be modified, consistent with the TRIPS Agreement, to accommodate concerns traditionally addressed in *sui generis* plant variety protection regimes.

I am also indebted to Professor Janis and Kesan for making available to me the manuscript of a soon-to-be published article[3] that offers a critical reassessment of U.S. approaches to intellectual property protection for plant innovation in light of the recent decision of the United States Supreme Court in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*,[4] which confirmed that plants and seeds are eligible subject matter for utility patent protection, notwithstanding the availability of concurrent protection under the Plant Patent Act (PPA) of 1930[5] or the Plant Variety Protection Act (PVPA) of 1970.[6] I am likewise indebted to Professor Jerome Reichman, of the Duke University School of Law, for his pioneering studies both on developing pro-competitive strategies for implementing the TRIPS Agreement,[7] and on the problem of "legal hybrids" between the patent and copyright paradigms.[8] I will rely on the work of all three of these colleagues in Part III of this paper, which will consider whether the measures identified in Part II are indeed necessary for a balanced co-existence between patents and plant breeders' rights.

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1 In summary, under U.S. law, plants are eligible for utility patent protection, plant patent protection, and plant variety protection, as will be explained in Part I of this paper. Although plant patent protection is nominally treated as a mere "variety" of patent protection, in reality it comes closer to being an entirely different "species" of intellectual property protection—or at the very least a "hybrid" variety of protection, falling somewhere between utility patent and plant variety protection. As we will see, the patent-contributed "genes" in this hybrid variety of protection are recessive, and the resulting protection, or "fruit," of this hybrid bears far more similarity to *sui generis* plant variety protection than to utility patent protection.

2 Mark D. Janis, *Sustainable Agriculture, Patent Rights, and Plant Innovation,* 9 IND. L. REV. 91, 116 (2001).

3 Mark D. Janis & Jay P. Kesan, *U.S. Plant Variety Protection: Sound and Fury . . .?,* __ HOUSTON L. REV. 727 (2002). A manuscript of an earlier version of this article is on file with the author. Unless otherwise noted, page citations are to the published article.

4 534 U.S. 124 (2001).

5 35 U.S.C. §§ 161-164

6 7 U.S.C. §§ 2321-2583.

7 *See, e.g.,* J. H. Reichman, *From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement,* 29 N.Y.U. J. INT'L L. & POL. 11(1997).

8 *See, e.g.,* J. H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms,* 94 COLUM. L. REV. 2432 (1994).

I. THE TRIPARTITE U.S. SYSTEM FOR THE PROTECTION OF PLANT INNOVATION

As a result of the United States of America Supreme Court's recent decision in the *J.E.M Ag Supply* case, three distinct forms of legal protection for plant innovation are now clearly available in the U.S. In order of their historical development, these forms of protection are as follows:

The Plant Patent Act (PPA) of 1930, as amended in 1954 and 1998, provides protection for anyone who invents or discovers and asexually reproduces any distinct and new variety of plant, other than a tuberpropagated plant or a plant found in an uncultivated state, that meets a variant of the utility-patent standard of non-obviousness.[9] A plant patent holder has a right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States.[10]

The Plant Variety Protection Act of 1970, as amended in 1994, provides protection to the breeder of any sexually reproduced or tuberpropagated plant variety (other than fungi or bacteria) who has so reproduced the variety, or the successor in interest of the breeder, if the variety is "new," "distinct," "uniform," and "stable," within the meaning of the PVPA.[11] Unlike the Plant Patent Act, the PVPA contains no non-obviousness requirement. Moreover, unlike plant patent protection, plant variety protection is not unconditionally available to nationals of other countries. Foreign nationals are entitled to protection only to the extent such protection is required by treaty or, in the absence of a treaty, only to the extent that protection "is afforded by said foreign state to nationals of the United States for the same genus and species"[12]—in other words on the basis of material reciprocity. A plant variety protection certificate confers on the owner the exclusive right, for a term that is now 20 years from date of issue (25 years for trees and vines) to exclude others from selling the variety, or offering it for sale, or reproducing it, or importing or exporting it, or using it in producing, as distinguished from developing, a hybrid or different variety, or marketing, tuber-propagating as a step in marketing, or to condition a variety for the purpose of propagating (except by farmers replanting their own holdings), or to stock a variety for any purpose that constitutes infringement.[13] The 1994 amendment eliminated a proviso that allowed farmers to sell saved seed.[14] Nevertheless the scope of a certificate holder's exclusive rights is quite narrow and subject to a number of limitations. Among these limitations are an exemption for any act

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[9] The non-obviousness requirement is incorporated in the PPA by virtue of the concluding sentence of 35 U.S.C. § 161, which states that '[t]he provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise noted. *See* Yoder Bros., Inc. v. California-Florida Plant Corp., 537 F.2d 1347 (5th Cir. 1976) *cert. denied* 429 U.S. 1094 (1977) (holding that a version of the non-obviousness requirement did apply to plant patents). Section 162 goes on to specify that a plant patent is not to be declared invalid for non-compliance with the disclosure provisions required for utility patents if the description is "as complete as is reasonably possible." 35 U.S.C. § 162.

[10] 35 U.S.C. § 163.

[11] 7 U.S.C. § 2402. As Janis and Kesan point out, the definition of "new" is actually a statutory bar provision, not a first-to-invent novelty provision; the definition of "distinct" comes closest to a patent law novelty requirement. Janis & Kesan, *supra* note 3, at 746.

[12] 7 U.S.C. § 2403.

[13] 7 U.S.C. §§ 2483, 2541.

[14] Pub. L. 103-349, § 10 (1994).

done privately and for non-commercial purposes, another for the use and reproduction of a protected plant variety for plant breeding or other *bona fide* research, and a grant of authority to the Secretary of Agriculture to order compulsory licensing of plant varieties when necessary to insure an adequate supply of fiber, food, or feed in the U.S at a price reasonably deemed fair.[15]

Finally, as a result of a series of cases, beginning with the decision of the Board of Patent Appeals and Interferences in *Ex parte Hibbard*[16] in 1985, and culminating with the recent U.S. Supreme Court decision in *J.E.M. Ag Supply*, plant innovators may obtain utility patent protection for plant genomes, coding for non-plant proteins, plant tissue, cells and cell cultures, seeds, or whole plants, provided that the substantive utility patent requirements of utility, novelty and non-obviousness and the procedural requirements of an enabling written disclosure (and in some cases an "enabling" deposit of plant material)[17] are met. Plant innovation that meets these more exacting requirements will grant the patent holder to the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, the right to exclude others from using, offering for sale or selling throughout the United States or importing into the United States products made by that process.[18]

Although the U.S. has chosen this tripartite system of protection for plant innovation, WTO members are, of course, under no obligation to adopt a similar approach. Indeed, Article 27.3(b) of the TRIPS Agreement seems to envision a variety of possible approaches to the protection of plant innovation. In the next part of this paper, I will identify various possible TRIPS-compliant measures for achieving a different balance than the one adopted in the U.S. and in both Parts II and III of this paper I will assess the desirability of these measures.

II. TRIPS-COMPLIANT MEASURES FOR BALANCING PATENTS AND PLANT BREEDERS' RIGHTS

In his article, *Sustainable Agriculture, Patent Rights, and Plant Innovation,* Professor Janis is specifically concerned with exploring various patent law doctrines that might serve as possible vehicles for furthering sustainable agricultural policy initiatives. However, his points are equally pertinent with respect to measures that might be employed consistently with TRIPS to achieve a balanced co-existence of patents and plant breeders' rights.

In his article, Professor Janis first considers the doctrine of subject matter eligibility as applied to plant innovation. Under Article 27.3(b) of the TRIPS Agreement, of course, WTO members may exclude from patentability "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological processes and microbiological processes," so long as members

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[15] *See* 7 U.S.C. §§ 2541(e) (private commercial uses); 2544 (research exemption); 2404 (compulsory licensing).

[16] 227 USPQ 443 (Bd. Pat. App. & Int., 1985).

[17] *See* 1 CHISUM ON PATENTS § 1.05[3].

[18] 35 U.S.C. §§ 154, 271.

provide for the protection of plant varieties "either by patents or by an effective *sui generis* system or by any combination thereof." On this point, however, Professor Janis concludes that "while proponents of sustainable agriculture may be tempted to support efforts to impose restrictions on patent eligibility for plant innovation, it is very doubtful that any such subject matter restrictions on patent protection would advance a policy agenda of sustainable agriculture concepts."[19] I draw a similar conclusion about the use of subject matter restrictions on patent eligibility for plant innovation to achieve a balanced co-existence between patents and plant breeders' rights.

Professor Janis then considers the doctrine of experimental use--which, as a defense to patent infringement, provides a means for shaping patent scope—and finds that doctrine to be more promising as a policy tool, though he counsels caution in its use.[20] Again, I come to the same general conclusions, though for slightly different reasons than Professor Janis offers.

A. Restrictions on Patentable Subject Matter

Professor Janis notes that restrictive patent eligibility rules make especially clumsy policy instruments for two major reasons. First, U.S. (and European) experience to date "has demonstrated that eligibility restrictions stimulate counterproductive ancillary litigation over efforts by patent lawyers to draft around the restrictions."[21] Second, "whereas policymakers may assume that restricting utility patent eligibility forces innovation into the public domain, the fact is that in some areas of technology—especially plant breeding—restricting utility patent eligibility may simply divert innovation either to less socially desirable intellectual property regimes or to other protection schemes."[22]

To illustrate his first point, Professor Janis notes that while a superficial policy analysis might suggest that a rule excluding plants from the subject matter of patent protection will have major policy ramifications, in actuality such a rule is likely simply to stimulate "gamesmanship in the semantics of claim drafting."[23] Claims drawn expressly to a plant will obviously fall within the rule, but what about claims to 1) a seed or other plant parts, such as pollen, 2) cells or tissue cultures, 3) a method of producing a hybrid or transgenic seed, or 4) a hybrid seed or a transgenic cell or seed produced by a biotechnological process? As Professor Janis notes, these are not hypothetical questions, as he bases all of his specific examples on an actual, litigated U.S. case—namely the *Pioneer Hi-Bred* case.[24] He then demonstrates how a more focused restriction excluding claims to "plant varieties" would run into similar problems, using illustrations drawn from the European experience under the European Patent Convention.[25]

If the scenario Professor Janis describes has an oddly familiar ring to it, he points out that it should, as the U.S. patent system has occupied itself for at least three decades with the question whether and to what extent computer software inventions should qualify as

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[19] Janis, *supra* note 2, at 93.
[20] *Id.*
[21] Janis, *supra* note 2, at 95.
[22] *Id.*
[23] *Id.* at 99.
[24] *Id.*
[25] *Id.*at 100-101.

patent-eligible subject matter.[26] That experience, he notes, should inform any debate over patent restrictions on plants, and the lesson to be learned is quite clear: eligibility restrictions have the potential to create considerable chaos, but lack demonstrated ability to force major policy reform.[27]

Professor Janis goes on to note that, even if an ideal subject matter restrictions on patent protection could be drafted, that does not mean that plant innovation would necessarily be freely available in the public domain. Rather, it will simply be redirected towards other forms of protection, such as *sui generis* plant variety protection, trade secret protection, or even technological protection measures, such as the notorious "Terminator technology." While redirecting plant innovation toward plant variety protection may be precisely the underlying policy for creating a restriction on patent eligibility, it should be noted that there is no guarantee that innovators will in fact choose this form of protection over the two other alternatives that Janis lists. Indeed, as illustrated in the data presented in the unpublished Janis and Kesan article, which I will discuss in Part III of this paper, the U.S. experience under its Plant Patent Act and Plant Variety Protection Act is not very reassuring in this regard.

B. Restrictions on Patent Scope—Experimental Use and Compulsory Licensing

While Janis concludes that the doctrine of patent eligibility is a demonstrably ineffective instrument for shaping the scope of patent protection, he does identify a number of other patent doctrines which might serve better to fine-tune the patent system to promote principles of sustainable agriculture, and discusses at some length the possibilities offered by the experimental use exception. He notes that the notion of liability-free experimentation is intuitively appealing because it seems consonant with one of the core aspirations of the patent system.[28] While he does not explicitly address the issue of compulsory licensing, his points with respect to a TRIPS-compliant, plant-specific experimental use limitation seem equally applicable to a plant-specific compulsory licensing provision.

The judicially developed experimental use exception in the U.S. is exceedingly narrow and has had virtually no impact on actual litigated cases, and yet even so has been severely criticized in a recent Federal Circuit concurring opinion.[29] Nevertheless, Congress did consider adding a generic experimental use exception to U.S. patent law in 1990,[30] just as it had previously enacted a narrower provision stating that it is not an infringement to make, use or sell a patent invention (other than certain new animal drugs or veterinary biological products) solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.[31]

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[26] *Id.* at 101-102.

[27] *Id.* at 102.

[28] *Id.* at106.

[29] *Id.* at 107-108, *citing* Embrex, Inc. v. Service Engineering Corp., 216 F.3d 1343, 1352-53 (Fed. Cir. 2000) (Judge Rader's concurring opinion).

[30] Janis, *supra* note 2, at 109.

[31] 35 U.S.C. § 271(e). This 1984 amendment legislatively modified the extremely narrow version of the judicially developed experimental use rule articulated in Roche Prod., Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984, *cert. denied*, 469 U.S. 856 (1984).

Janis suggests that one explanation for both the narrowness of the judicially developed experimental use rule and the failure of Congress to enact a more robust legislative version may be due to the difficulty in crafting a satisfactory *generic* experimental use rule.[32] However, he points out that proposals for a plant-specific experimental use rule could arise, because the courts or Congress might be tempted to borrow the very broad experimental use concepts from the Plant Variety Protection Act and use them to formulate a rule for patented plant innovation.[33] While he explains in some detail why U.S. courts, at least, should resist that temptation,[34] he does acknowledge the possibility of a legislatively created plant-specific experimental use provision, and considers whether such a provision would violate the TRIPS Agreement.

Because Article 27.3(b) allows members to exclude plants from patent eligibility altogether, so long as they enact an effective *sui generis* regime for plant variety protection, Professor Janis notes that some may argue that members necessarily have the lesser authority to place plant-specific limitations on the utility patent right.[35] He also notes that the same issue has been raised by a 1996 amendment of U.S. patent law, which effectively prevents patent owners of medical procedure patents from obtaining any relief against medical doctors or related health care activities for infringing medical activities.[36]

While I agree with Professor Janis that a WTO member could choose to amend its patent statute to provide a plant-specific experimental use exception patterned on experimental use provisions of the sort contained in the U.S. PVPA without violating the TRIPS Agreement, I base my conclusion, not on the "implied lesser authority" argument that Professor Janis suggests, but rather on the specific language of Article 27.3(b) itself, which states that WTO members are to provide for the protection of plant varieties "either by patents or by an effective *sui generis* system *or by any combination thereof*." This language, explicitly permitting "any combination" of patent and *sui generis* protection for plant varieties, seems to offer ample authority for the enactment of a broad, plant-specific experimental use exception (and for that matter, a "saved seed" or even a "brown-bag sale" exception) to utility patent protection, thus making it unnecessary to rely on the more controversial "lesser implied authority" argument.[37]

If such an exception is TRIPS-compliant, it would seem to follow that a compulsory licensing provision of the sort that is also a part of the U.S. PVPA would likewise be TRIPS-compliant, so long as the provision meets the exacting standards contained TRIPS Article 31.[38] Of these two possible measures for achieving a balance between private rights and public access to plant innovation, however, the experimental use provision would seem to

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[32] Janis, *supra* note 2, at 108-109.

[33] *Id.* at 110.

[34] *Id.* at 110-115.

[35] *Id.* at 116.

[36] *Id.*, citing 35 U.S.C. § 287(c), and Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601 (2000). Professor Ho herself expresses concern that this provision does indeed violate the TRIPS Agreement, and will in any event be used as a precedent for creating other limitations on patent liability.

[37] My suggested interpretive approach seems more consistent with the interpretive principles enunciated by the WTO Appellate Body in India—Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/AB/R (WTO App. Body, Dec. 19, 1997).

[38] The compulsory licensing provision contained in the U.S. PVPA, 7 U.S.C. § 2404, seems to meet the standards of TRIPS Article 31.

be the more potent. The only remaining question is whether such an experimental use provision would indeed achieve a desirable and balanced co-existence between patents and plant breeders' rights. To answer that question, one must look at the underlying premises of plant variety protection and its practical effect on plant innovation.

III. ACHIEVING A BALANCED CO-EXISTENCE BETWEEN PATENTS AND PLANT BREEDERS' RIGHTS

In their soon-to-be-published paper, Professors Janis and Kesan analyze the emergence of the concept of breeders' rights in the United States and elsewhere, delineate the "essential traits" of the PVPA and its points of divergence from a patent-like model, and provide an empirical study of PVPA acquisition, licensing, and enforcement activity for corn and soybean crops. On the basis of this empirical study, Professors Janis and Kesan conclude that, contrary to the assertions of many, experience under the PVPA does not support the claim that it provides patent-like incentives for plant innovation, and that the PVPA in fact serves primarily as a marketing device and a vehicle by which to satisfy international obligations.[39]

In this part of my paper, I will summarize the basic points covered in the Janis and Kesan paper, add comments and empirical data of my own, and conclude with observations about what measures, if any, are indeed necessary for a balanced co-existence of patents and plant breeders' rights. My general conclusion is that the most pressing need is for greater conceptual clarity (of the kind provided by Professor Reichman) about what sort(s) of intellectual property protection should be given plant innovation and why. This matter takes on particular urgency in light of the obligation imposed by Article 27.3 of the TRIPS Agreement on all WTO members to provide for the protection of plant varieties either by patents or by an "effective *sui generis* system" or by any combination of the two—yet unaccompanied with any substantive standard for determining whether a given *sui generis* system is indeed "effective."

Conceptually, the choices of protection schemes for plant innovation seem to be three: 1) *Patent-like protection*-characterized by relatively high substantive standards and rigorous examination procedures for the acquisition of robust exclusive rights designed to provide strong incentives to innovate and prevent others from exploiting the innovation without authorization; 2) *copyright-like protection*-characterized by relatively low substantive standards and minimal procedural requirements for the acquisition of rights, resulting in broad but thin exclusive rights to prevent the "copying" (defined broadly to include the preparation of derivative works) of tangible expressions of the innovation; and 3) *constructive trade secret and/or misappropriation protection*-characterized by relatively low substantive standards and minimal procedural requirements to qualify for protection designed to provide a limited term of artificial lead-time protection for and/or prevent competitive misappropriation of plant innovation, as two variant species of unfair competition protection for "incremental innovation bearing know-how on its face."[40]

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[39] *See* Janis & Kesan, *supra* note 3, at 730 and 777.

[40] The phrase is Professor Reichman's. *See, e.g.,* Reichman, *supra* note 8, at 2444, where he notes that "incremental innovation bearing know-how on its face has become a dominant characteristic of key technological paradigms evolving at the end of the twentieth century."

The specific measures necessary for a balanced co-existence of patents and plant breeders' rights will depend in large measure on what sort of protection and limitations on protection are thought necessary and appropriate for plant breeders and plant innovation generally. My own conclusion, based on the U.S. experience to date, is that, while plausible arguments can be made for providing all three of the foregoing forms of protection for plant innovation, the *sui generis* forms of protection for plant innovation that are currently offered in the U.S. today are neither necessary nor particularly effective. Thus, before engrafting features of *sui generis* plant variety protection on the patent system, it is important to consider what sort of impact such features would have on plant innovation. To answer this question, it is necessary to examine how *sui generis* systems of plant variety protection, such as the U.S. PPA and PVPA, operate in practice.

A. An Empirical Analysis of Plant Variety and Plant Patent Protection in the U.S.

As a result of their empirical study of the acquisition, licensing, and enforcement of PVPA rights, Janis and Kesan conclude that these rights are burdensome to acquire, and yet the expected post-issuance licensing and enforcement activities common to other intellectual property regimes are virtually non-existent.[41] The more summary data that I have been able to gather about the PPA lead me to draw similar conclusions about the U.S. experience under that act. Following Janis and Kesan, I will first discuss the acquisition of rights under the PVPA and the PPA and then discuss licensing and enforcement activity.

1. Acquisition of Rights

In the initial draft of their article, Janis and Kesan first note that in general the vast majority of PVP applications survive the examination process, though about 12-15% are either abandoned or withdrawn by the applications in the course of prosecution.[42] They then turn their attention to data provided by the PVP Office for soybean and corn applications over the past 30 years, viewing these as two good, complementary exemplars of U.S. plant variety protection.

They note that, as of May 3, 2002, 1,343 applications for soybean certificates have been filed in the past 30 years, the status of the disposition of which are summarized in their Figures 1 and 2. Excluding pending applications, over 85% of the soybean applications successfully issued as PVP certificates. Approximately 13% of the applications were ineligible, abandoned or withdrawn, and 11% are pending.

A detailed breakdown of the current holders of soybean certificates is provided in Figure 2A. Although over 109 companies, universities and research institutes currently hold PVP certificates, over half of the certificates are owned by just three companies—Pioneer Hi Bred International (206 or 27%), Novartis Seeds, Inc. (100 or 13%), and Asgrow Seed Company (100 or 13%). As for pending soybean applications, almost half are again from just three companies—this time, Asgrow Seed Company (36 or 23%), Delta and Pine Land Company (25 or 16%), and Pioneer Hi-Bred International (15 or 10%), as indicated in Figure 2B.

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[41] Janis & Kesan, *supra* note, at 754.

[42] Janis & Kesan, unpublished manuscript, *supra* note at 36-37.

The status of the disposition of PVP corn certificates is summarized in Janis and Kesan's Figures 3 and 4. Excluding pending applications, over 80% of the applications successfully issued as certificates. Approximately 15% have been withdrawn or abandoned, while 17% are still pending. A detailed breakdown of the current issues of corn certificates is contained in Figure 4A. More than 60% of the corn certificates belong to two companies—Pioneer Hi-Bred International (269 or 44%) and Holden's Foundation Seeds (110 or 18%). As indicated in Figure 4B, pending applications for corn certificates account for 17% of the total applications ever filed and almost 50% of these have been filed by one company, DeKalb Genetics Corporation, while an additional 34% were filed by two other companies, Pioneer Hi-Bred International, and Holden's Foundation Seeds.

Janis and Kesan report that the total number of PVP applications has increased from around 100 applications per year in the 1970s to a high of about 440 applications in 1999. Since 1999, however, the total number of applications has decreased steadily. As shown in Figure 5, the number of soybean and corn applications tracks this overall trend of increasing applications from 1971 to the mid-1990s, with a decline in the number of applications since 1999.

Janis and Kesan also examined the durations between the filing dates and the issue dates to determine durations for issued certificates and durations between filing dates and the end of the data set examined for pending durations. The object was to determine whether the simplified application and review process has shortened the waiting period, as compared with utility patent applications, which generally require 2-3 years (730-1095 days) of administrative prosecution. Janis and Kesan also examined durations in relation to the number of pages in the certificates to determine if the number of pages played any role in determining the duration of the process.

The soybean PVP certificate data reveals that the average duration of issued certificates is just below 600 days or over 1½ years. However, the average duration for pending applications is almost 1200 days, double the average duration of issued certificates. The corn PVP certificate data reveals that the average duration for issued certificates is 625 days and that the average duration for pending certificates is 714 days. Janis and Kesan conclude that the data do not support including numbers of pages as a statistically significant covariate in a model for issuing and pending durations for PVP certificates. Rather, the issuing durations seem to reflect the overall workload of the PVP Office in terms of the number of new applications filed per year, as the issuing durations increased steadily from the early 1970s to the mid 1990s and then as the number of applications decreased in recent years, the issuing durations have decreased as well.

While the data I have collected for plant patents is more general, it nevertheless reveals that plant patents and applications have accounted for only a miniscule part of the overall patent activity in the United States since 1931. As indicated in the attached table of yearly U.S. patent activity at ten-year intervals between the years 1931 and 2001, plant patent applications accounted for only .04% of the total patent applications in 1931 and .27% in 2001, while issued plant patents accounted for .009% of patents issued in 1931 and .31% of patents issued in 2001. To give you some idea of how plant patent and PVP activity compare with each other and other patent activity in the U.S. in the years 2000 and 2001, you will note that the USPTO granted 548 plant patents in the year 2000 and 584 in 2001. By comparison,

the PVP Office granted 241 PVP certificates in the year 2000 and 511 in 2001. [43] By contrast, the USPTO granted 157,495 utility patents in the year 2000 and 166,039 utility patents in 2001.

2. Post-Issuance Licensing and Litigation

Janis and Kesan conducted extensive interviews with numerous practicing attorneys and in-house counsel at DuPont/Pioneer to determine the magnitude of PVP licensing activities. They report a consensus among the persons they interviewed that there is no licensing activity for plant varieties protected solely by PVP certificates, apart from the bag-tag licensing that accompanies sales of the protected variety. DuPont/Pioneer were granted 381 certificates in the years 1997-2001 and yet report that they have neither licensed nor initiated infringement lawsuits based on PVP certificates. In contrast, during that same five-year period, Dupont/Pioneer has initiated 15 patent lawsuits and have been sued for patent infringement 11 times.

Janis and Kesan state that there have been fewer than 10 reported PVP judicial decisions involving infringement of PVP rights in the last thirty years, and a continuously updated annotation on the construction and application of the PVPA confirms the paucity of reported PVP infringement litigation.[44] A similar annotation on the construction and application of the PPA likewise indicates that there has been little reported plant patent infringement litigation over the past 70 years.[45]

B. Achieving a Balance Between Patents and Plant Breeders' Rights

Not surprisingly, based on their own empirical study, as well as a number of other studies that they cite, Janis and Kesan conclude the PVPA regime as presently constituted "plays only a marginal role in stimulating plant breeding research in the United States," and that, indeed, its role in the U.S. appears to be "very modest."[46] They acknowledge that it may serve as a marketing tool, provide some non-propagation licensing rights akin to shrink-wrap licenses, enforceable against those who deal in "saved seeds," and perhaps provide a superior alternative to simple trade secret protection. However, because the PVPA is so easy to circumvent, and its research and saved seed exemptions are so broad, it simply does not provide patent-like *ex ante* innovation and investment incentives, nor has it generated substantial *ex post* licensing and enforcement activity. Given these results, Janis and Kesan question the appropriateness of future experimentation with *sui generis* IP regimes tailored to satisfy perceived needs in different technology areas.

In his many studies of legal hybrids between the patent and copyright paradigms, Professor Reichman makes much the same point. As Professor Reichman notes, "[t]inkering with the dominant paradigms or concocting hybrid variants lacking any solid theoretical or

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[43] *See* http:www.ams.usda.gov/science/pvpo/Current%20News/newsrealeases.htm.

[44] *See* Ann K. Wooster, *Construction and Application of Plant Variety Protection Act (7 U.S.C.A. §§ 2321 et seq.,* 167 ALR Fed. 343 (2001). By my count, there are only 4 reported cases alleging infringement under the PVPA.

[45] *See* Ann K. Wooster, *Construction and Application of Plant Patent Act (35 USCS §§ 161 et seq.,* 135 ALR Fed. 273 (1996). By my count, there are only 8 reported cases alleging infringement under the PPA.

[46] Janis & Kesan, *supra* note 3, at 777.

economic foundations merely aggravates the long-term disutilities resulting from a progressive inability of ancillary liability rules ... to mediate effectively between legal incentives to create and free competition."[47] In his view, "reformers should elaborate an improved set of ancillary liability rules ... [that will] emulate the functions of classical trade secret law while rationalizing and adapting its modalities to current conditions."[48]

In Reichman's view, this new intellectual property paradigm "should provide a limited, non-exclusionary form of relief for innovators who routinely apply unpatented, non-copyrightable know-how to publicly distributed industrial products."[49] While one embodiment of this kind of protection might provide a limited period of "artificial lead time" protection against any exact duplication of "incremental innovation bearing know-how on its face," another embodiment would provide an indefinite period of protection against any competitive "misappropriation" of such innovation. Indeed, the latter form of protection is currently available as a matter of state unfair competition law in the U.S.,[50] and Congress is currently considering creating similar federal statutory protection for the uncopyrightable contents of databases.[51]

Meanwhile, on the international front, in response to industrialized country demands that the developing world make greater efforts to combat intellectual property "piracy," the developing world has expressed its own widespread concerns over "gene piracy,"[52] leading to a recent upsurge in international attention to the interrelated issues of biodiversity and biotechnology protection, particularly as these issues relate to the protection of traditional knowledge, innovations and creativity. I need only refer you to work of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore,[53] as well as the recent "Doha Declaration," issuing from the Fourth WTO Ministerial Conference, specifically instructing the TRIPS Council to examine the relationship between the TRIPS Agreement and the Convention on Biological Diversity, giving particular attention to the protection of traditional knowledge and folklore.[54]

Much of the traditional knowledge in question is botanical or agricultural, and any of it that is widely known could be characterized as "incremental innovation bearing know-how on its face." Among the specific proposals for the protection of traditional knowledge are various suggested *sui generis* schemes of protection, and proposals to modify international standards for patent protection, requiring disclosure of the origin of genetic resources used in the development of inventions for which patents are subsequently sought, as well as evidence

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47 Reichman, *supra* note 8, at 2445.

48 *Id.*

49 *Id.* at 2444-2445.

50 *See, e.g.*, National Basketball Association v. Motorola, Inc., 105 F.3d 841 (2d Cir. 1997).

51 *See generally* Charles R. McManis, *Database Protection in the Digital Information Age*, 7 ROGER WILLIAMS U. L. REV. 7 (2001).

52 *See generally* Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L. Q'TLY 255 (1998); Charles R. McManis, *Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally*, __CARDOZO J. INT'L & COMP. L.__ (forthcoming).

53 *See, e.g.*, WIPO, Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore—An Overview, WIPO/GRTKF/IC/1/3, March 16, 2001.

54 Doha WTO Ministerial 2001: Ministerial Declaration, WT/MIN(01)DEC/1, Nov. 20, 2001, adopted Nov. 14, 2001, ¶¶ 17 and 19, http:www.wto.org (last visited Sept 29, 2002).

of prior informed consent by both national governments and local innovators providing those genetic resources.

The proposals to modify patent standards so as to require disclosure of genetic resources and evidence of prior informed consent seem to reflect an effort to construct patent rules designed to encourage private contractual arrangements that will hopefully ensure that traditional innovators receive an equitable share of the benefits emanating from the world's patent systems. While requiring disclosure of the origin of genetic resources and evidence of prior informed consent as a condition for obtaining patent protection would appear not be TRIPS-compliant and would thus require an amendment to the language of Article 27, Dr. Nuno Pires de Carvalho, currently Head of the Genetic Resources, Biotechnology & Associated Traditional Knowledge Section of the WIPO, has persuasively argued that conditioning enforcement of a patent on disclosure of the origin of genetic resources and evidence of prior informed consent would be TRIPS-compliant.[55] Yet, any proposal of the sort discussed in Part II of this paper to modify existing patent systems by engrafting upon them a broad experimental use exception of the sort found in *sui generis* plant variety protection schemes would seem to undercut the effort to create patent rules requiring disclosure of the origin of genetic resources and evidence of prior informed consent as a means of rewarding the contributions of traditional plant innovators. Indeed, rather than watering down the scope of available patent protection for plant innovation, a better way to protect traditional plant innovators and encourage plant innovation would arguably be to reduce the administrative obstacles to acquiring plant variety protection and broaden the scope of that protection to make it more "copyright-like"—i.e. inclusive of a right to authorize derivative works.

The current debate over the protection of traditional knowledge is useful, because it focuses on the fundamental question underlying any effort to achieve a balanced co-existence of patents and plant breeders' rights—namely, whether the interests of plant breeders and plant innovation generally are better served by 1) broad patent protection for qualifying plant innovation, together with some low-cost form of copyright-like, portable trade secret, or competitive misappropriation protection for incremental plant innovation bearing know-how on its face; or by 2) narrow or no patent protection for plant innovation, and a limited and low-cost form of portable trade secret or competitive misappropriation protection only? Under Article 27.3(b) of the TRIPS Agreement, WTO members have considerable discretion in how they answer this question. To be effective, however, any system for achieving a balanced co-existence between patents and plant breeders' rights must ensure that the cost of protection is commensurate with its scope.

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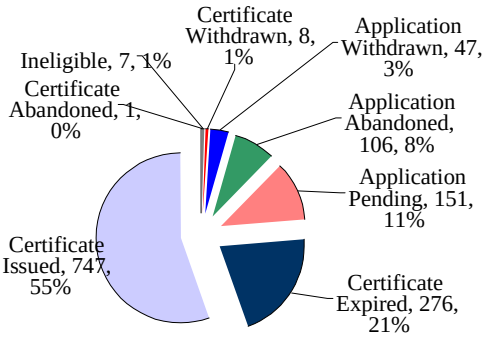
[55] *See* Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and The Solution*, 2 WASH. U. J. L. & POL'Y 371 (2000).

Slide 1

Figure 1: Disposition of Applications for PVP Certificates for Soybeans



Note: Figures show Status, Number of Applications in this Status, Percentage Share of the Applications in this Status

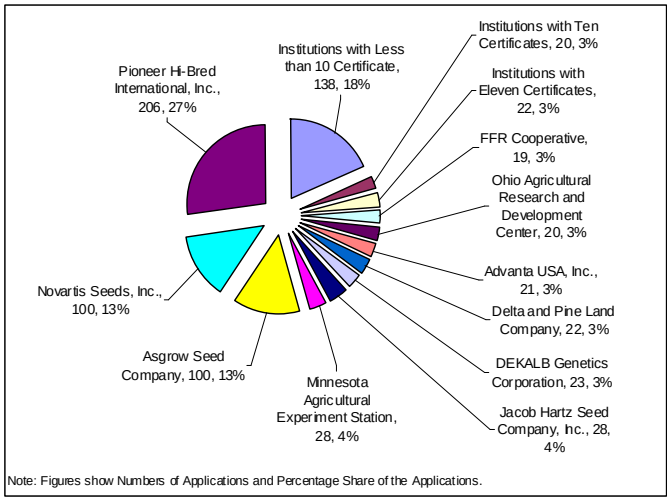
Slide 2

Figure 2: Disposition of Applications for PVP Certificates for Soybeans

Status	Counts
Certificate Abandoned	1
Ineligible	7
Certificate Withdrawn	8
Application Withdrawn	47
Application Abandoned	106
Application Pending	151
Certificate Expired	276
Certificate Issued	747
Total	1343

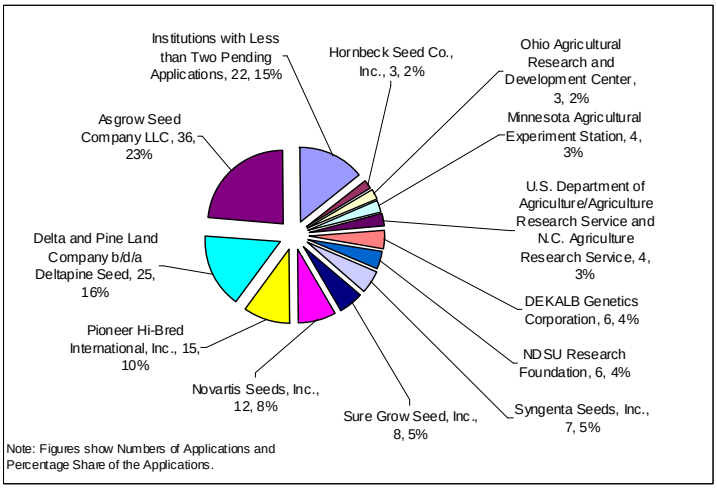
Slide 3

Figure 2A: Certificate Issuees with Effective PVP Certificates for Soybeans



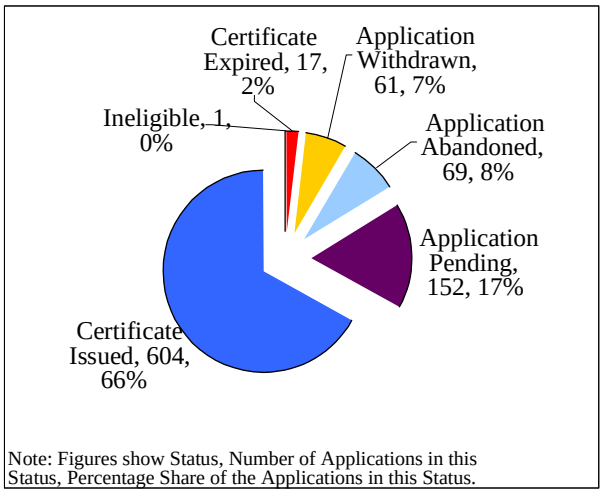
Slide 4

Figure 2B: Pending Applicants for PVP Certificates for Soybeans



Slide 5

Figure 3: Disposition of Applications for PVP Certificates for Corn



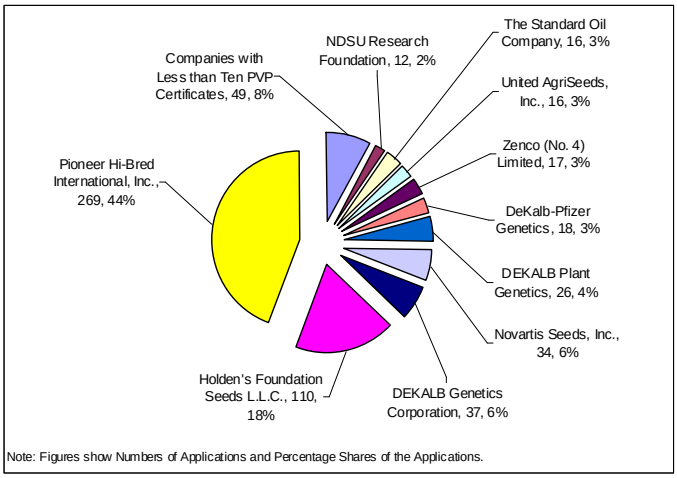
Slide 6

Figure 4: Disposition of Applications for PVP Certificates for Corn

Status	Counts
Ineligible	1
Certificate Expired	17
Application Withdrawn	61
Application Abandoned	69
Application Pending	152
Certificate Issued	604
Total	904

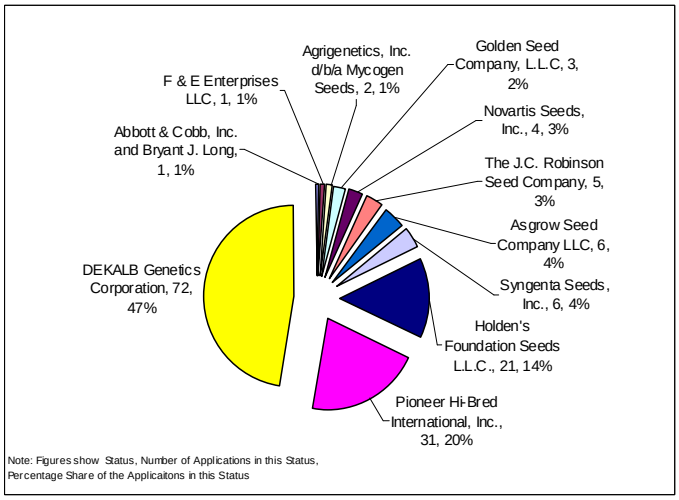
Slide 7

Figure 4A: Certificate Issuees with Effective PVP Certificates for Corn



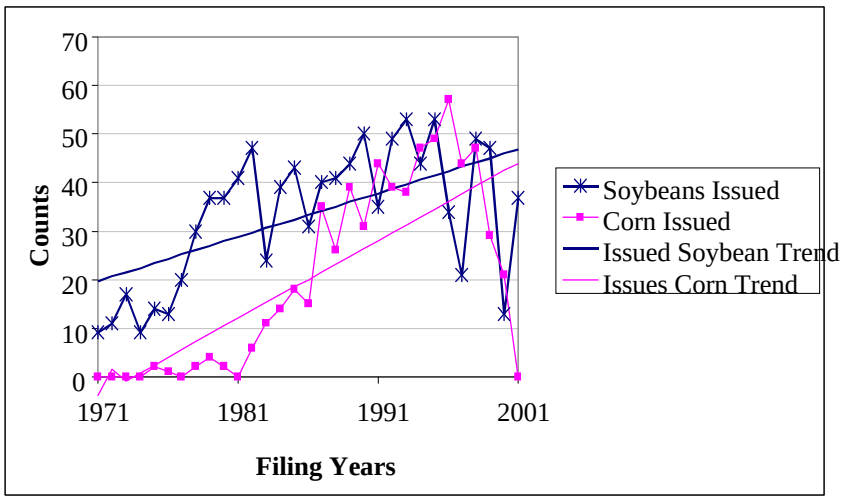
Slide 8

Figure 4B: Pending Applications for PVP Certificates for Corn



Slide 9

Figure 5: Trends in the Number of PVP Corn & Soybean Applications Issued



Slide 10

U.S. PATENT ACTIVITY

Applications			
Issue Year	**Patent Invention**	**Design**	**Plant**
1931	79,740	4,190	37
1941	52,339	7,203	67
1951	60,438	4,279	71
1961	83,100	4,714	107
1971	104,729	6,211	155
1981	106,413	7,375	178
1991	164,306	13,061	463
2001	326,508	18,280	944

Grants		
Patent Invention	**Design**	**Plant**
51,756	2,937	5
41,108	6,486	62
44,326	4,164	58
48,368	2,488	108
78,317	3,156	71
65,771	4,745	183
96,513	9,569	353
166,039	16,872	584

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