Chicago-Kent Law Review

Volume 82
Issue 3 *Symposium: Intellectual Property, Trade and Development: Accommodating and Reconciling Different National Levels of Protection*

Article 17

June 2007

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Recommended Citation
Mark D. Janis & Stephen Smith, *Technological Change and the Design of Plant Variety Protection Regimes*, 82 Chi.-Kent L. Rev. 1557 (2007).
Available at: https://scholarship.kentlaw.iit.edu/cklawreview/vol82/iss3/17

TECHNOLOGICAL CHANGE AND THE DESIGN OF PLANT VARIETY PROTECTION REGIMES

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INTRODUCTION

Two important debates in intellectual property policy have come into confluence in an unlikely setting. The first debate weighs the relative merits of the traditional intellectual property paradigms (patent and copyright) against new, *sui generis* paradigms.[1] The second debate asks how intellectual property rules should respond to contemporary technological advances.[2] The unlikely setting is plant variety protection, one of the least studied of all forms of intellectual property.[3] In this paper, we draw from both debates to derive some conclusions about the potential for intellectual property regimes—especially *sui generis*, industry-specific intellectual property regimes like plant variety protection—to become compromised as a result of technological change, and perhaps even face the prospect of eventual obsolescence. We also explore various responses. We lay out an alternative structure for plant intellectual property protection that differs radically in some respects from plant variety protection, and we investigate how our alternative structure might operate as a discussion model for improving existing plant variety protection regimes.

First generation plant variety protection ("PVP") systems appeared in the 1960s, following the conclusion of the UPOV treaty.[4] In 1970, the U.S.

1. This debate owes much to the work of Professor Reichman. *See, e.g.*, J.H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 COLUM. L. REV. 2432 (1994) (cataloguing and analyzing many *sui generis* regimes).

2. For example, in patent law, scholars have begun to explore how patent rules might be tailored to produce innovation policy for particular technology sectors. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003). William Landes and Judge Richard Posner have observed that a "radical restructuring of intellectual property law" that is "better informed by scientific and technological understanding and more heavily focused on current and likely scientific and technological advances . . . may be overdue." WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 423–24 (2003). And copyright, since its inception, has witnessed titanic struggles over the law's ability to accommodate new technologies for creating and delivering creative works. *See, e.g.*, PAUL GOLDSTEIN, COPYRIGHT'S HIGHWAY: FROM GUTENBERG TO THE CELESTIAL JUKEBOX (Hill & Wang 1996) (1994) (concisely summarizing the historical patterns).

3. As of 2002, when one of us (Janis) co-authored a study of the U.S. PVPA, PVP systems had been studied in very few law review articles. Mark D. Janis & Jay P. Kesan, *U.S. Plant Variety Protection: Sound and Fury . . . ?*, 39 HOUS. L. REV. 727 (2002) [hereinafter Janis & Kesan (2002)]. Since then, a few major studies were completed or are forthcoming. *See* LAURENCE R. HELFER, INTELLECTUAL PROPERTY RIGHTS IN PLANT VARIETIES: INTERNATIONAL LEGAL REGIMES AND POLICY OPTIONS FOR NATIONAL GOVERNMENTS (2004) (describing multiple forms of intellectual property protection for plants); MARGARET LLEWELYN & MIKE ADCOCK, EUROPEAN PLANT INTELLECTUAL PROPERTY (2006); Jim Chen, *The Parable of the Seeds: Interpreting the Plant Variety Protection Act in Furtherance of Innovation Policy*, 81 NOTRE DAME L. REV. 105 (2005).

4. "UPOV" refers to the French-language title of the treaty and its governing organization (*Union Internationale pour la Protection des Obtentions Vegetales*). The 1961 UPOV text, adopted December 2, 1961, supplied the framework for a number of domestic first-generation PVP systems. *See* International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 89 [hereinafter UPOV (1961)], *available at* http://www.upov.int/en/publications/ conventions/1961/pdf/act1961.pdf (English text of the 1961 Convention). The Convention officially came into

Congress enacted plant variety protection in the form of the Plant Variety Protection Act ("PVPA").[5] In the early 1990s, pressure from the plant breeding community and others led to the development of a second generation of PVP systems governed by an amended UPOV treaty.[6]

Plant variety protection now stands at a critical juncture.[7] Decisions in the U.S.[8] (confirming the availability of utility patent protection for plants, including plant varieties) and in Europe[9] (confirming the availability of utility patent protection for plants while excluding plant varieties as such) may draw breeders and seed companies away from plant variety protection systems. In the U.S., predictions that plant variety protection may become "the Neanderthal of intellectual property systems"[10] seem increasingly plausible, at least in the area of major cereal crops.

On the other hand, more than sixty countries now have enacted first- or second-generation PVP systems,[11] and over 61,000 PVP certificates are in force in UPOV member states (predominantly in major intellectual property jurisdictions,[12] but also in important agricultural economies[13]). In

force on August 10, 1968, after ratifications by Germany, the Netherlands, and the United Kingdom. *See* UPOV Convention, http://www.upov.int/en/about/upov_convention.htm (last visited Jan. 28, 2007).

5. 7 U.S.C. §§ 2321–2583 (2000). The U.S. PVPA complied with many, but not all, elements of the 1961 UPOV Convention.

6. *See* International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, as amended Mar. 19, 1991 [hereinafter UPOV (1991)], *available at* http://www.upov.int/en/ publications/conventions/1991/pdf/act1991.pdf (English text of the 1991 Convention). The U.S. became a UPOV member in 1981 by executive agreement, but did not ratify the treaty, and deposit its instrument of ratification, until early 1999. *See* Janis & Kesan (2002), *supra* note 3, at 745 n.89 (citing relevant legislative sources). The current version of the U.S. PVPA conforms to 1991 UPOV.

7. It is perhaps no coincidence that the UPOV organization recently released a major report lauding the successes of PVP systems. UPOV, REPORT ON THE IMPACT OF PLANT VARIETY PROTECTION, UPOV Pub. No. 353 (E) (2005) [hereinafter UPOV IMPACT REPORT].

8. *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001) (plants qualify as eligible subject matter under the utility patent statute); Monsanto Co. v. McFarling, 363 F.3d 1336, 1344 (Fed. Cir. 2004) (statutory exceptions that limit PVPA rights do not carry over to utility patent rights).

9. Case G 01/98, Novartis/Transgenic Plant, 2000 O.J. E.P.O. 111 (Enlarged Bd. App.1999), *available at* http://legal.european-patent-office.org/dg3/pdf/t961054eu1.pdf (holding that plants qualify as eligible subject matter for European patent protection; only claims to plant varieties as such are excluded); Council Directive 98/44, On the Legal Protection of Biotechnological Inventions, art. 4(2), 1998 O.J. (L 213) 13, 18 (EC), *available at* http://eur-lex.europa.eu/LexUriServ/site/en/oj/1998/l_213/l_21319980730en00130021.pdf (incorporating the ruling from *Novartis*).

10. CARY FOWLER, UNNATURAL SELECTION: TECHNOLOGY, POLITICS, AND PLANT EVOLUTION 152 (1994) [hereinafter FOWLER (1994)].

11. Called "plant breeder's rights" systems in some countries. For updated statistics, see UPOV, Members of the International Union for the Protection of New Varieties of Plants, http://www.upov.int/en/about/members/pdf/pub423.pdf (last visited May 30, 2007).

12. Including the U.S., Europe, and Japan. *See* UPOV, *Plant Variety Protection Statistics for the Period 1999–2003*, at 4–14, UPOV Doc. No. C/38/7 (Oct. 15, 2004), *available at* http://www.upov.int/en/documents/c/38/C_38_07.pdf.

13. For example, Australia and Argentina. *Id.* at 4. In China, the number of certificates is still relatively small but has grown rapidly since the turn of the century. *Id.* at 5; *see also* Bonwoo Koo et al.,

Europe, the investment in PVP legislation is particularly heavy: plant breeders may seek protection under national systems, or may seek EU-wide plant variety protection under the Community Plant Variety Protection regulation.[14] And, under the TRIPS agreement, member states may opt to enact "an effective *sui generis* system" of intellectual property protection for plant varieties as an alternative to according utility patent protection,[15] an option with vigorous advocates in some parts of the world.[16]

While others have focused largely on these geopolitical crosscurrents in assessing the future role of PVP systems, we focus on technological change. We argue that dramatic technological advances in plant breeding, particularly in the major cereal crops, have brought the threat of obsolescence to existing PVP systems. We observe that specialized *sui generis* systems like PVP systems are especially prone to early obsolescence because they tend to embed prevailing technological orthodoxies in their rules and institutions, but show little capability of adapting when new orthodoxies appear and supplant the old. Accordingly, we conclude that the future role of plant variety protection depends upon the willingness of government authorities and others to rethink its basic assumptions, and to consider responses that range from modest reforms to more ambitious structural changes.

Our examples are drawn primarily from the application of PVP rules to cereal crops. The technological changes that we describe have not af-

The Economics of Generating and Maintaining Plant Variety Rights In China 16–24 (Int'l Food Policy Research. Inst., Environment and Production Technology Division, Discussion Paper No. 100, 2003), *available at* http://www.ifpri.org/divs/eptd/dp/papers/eptdp100.pdf. India, another jurisdiction of interest, has adopted a PVP system that departs from UPOV principles. *See* Bonwoo Koo, Carol Nottenburg & Philip G. Pardey, *Plants and Intellectual Property: An International Appraisal*, 306 SCIENCE 1295, 1296 (2004) [hereinafter Koo (2004)] (describing the 2001 Indian legislation).

14. Council Regulation 2100/94, Community Plant Variety Rights art. 1, 1994 O.J. (L 227) 1 (EC) [hereinafter Community PVR Regulation], *reprinted with commentary in* P.A.C.E. VAN DER KOOIJ, INTRODUCTION TO THE EC REGULATION ON PLANT VARIETY PROTECTION (1997).

15. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27(3)(b), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Results of the Uruguay Round, 1869 U.N.T.S. 299, 33 L.L.M. 1197 (1994), *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (requiring WTO members to protect plant varieties "either by patents or by an effective *sui generis* system or by any combination thereof"). While existing forms of UPOV-compliant PVP systems would undoubtedly qualify as acceptable "*sui generis*" systems under TRIPS, Article 27(3)(b) is not limited to UPOV-compliant systems. HELFER, *supra* note 3, at 38–39.

16. *E.g.*, 2 THE CRUCIBLE II GROUP, SEEDING SOLUTIONS: OPTIONS FOR NATIONAL LAWS GOVERNING CONTROL OVER GENETIC RESOURCES AND BIOLOGICAL INVENTIONS 135–82 (2001), *available at* http://www.bioversityinternational.org/Publications/Pdf/689.pdf (describing detailed legislative proposals for *sui generis* PVP systems that generally adopt the UPOV model, but allow for options that are in some regards more protective than second-generation PVP systems, and in other regards less protective. The proposals purport to improve on existing PVP systems by giving greater recognition to farmer contributions and by offering incentives to preserve and promote biodiversity.).

fected all crops equally and, hence, the concerns that we raise about threats of PVP obsolescence are more significant for some crops than for others.

We have organized our study as follows. In Part I, we supply the context for analyzing the obsolescence problem in PVP systems. We place PVP systems in their intellectual property context, observing that they consist of a complex mixture of copyright, patent, and other concepts. We also describe the technological context, pointing out that PVP systems originated at a time when plant breeders conceptualized plants primarily in terms of observable characteristics (phenotype), but must operate today within a new paradigm of plant breeding in which breeders can characterize plants by molecular information (genotype).

In Parts II and III, we show that the old technological paradigm oriented around phenotype is embedded in the substantive rules of PVP systems, rules that govern both the obtaining of PVP rights (Part II) and the scope of PVP rights (Part III). Using a range of historical and technical sources, in addition to sources from legal literature, we show that PVP systems are infused with phenotype-centered rules, and that attempts to adapt PVP systems to the paradigm of genotype through concepts such as the "essentially derived variety" have produced incremental short-run benefits, but are not likely to be satisfactory in the long run.

In Part IV, we construct an alternative model for plant intellectual property protection that conceives of plants as datasets and employs unfair competition principles to allocate liability. The model is not intended as a legislative proposal, but rather as a mechanism for initiating a debate, in concrete terms, about the premises that underlie existing PVP systems, and, ultimately, about the best systemic responses to the challenge of obsolescence.

I. PLANT VARIETY PROTECTION: SHIFTING PARADIGMS AND THE PROSPECTS OF OBSOLESCENCE

In this section, we place PVP systems in their intellectual property and technological contexts, respectively. We show that (1) PVP systems mix both classical and unique intellectual property concepts in a scheme that has generated a confused incentives structure, and (2) PVP systems have operated against a highly volatile technological backdrop.

A. *The Intellectual Property Paradigm*

PVP systems are among the least studied of all intellectual property regimes. Often likened to patent protection,[17] PVP is better characterized as a muddle of concepts: quasi-copyright protection that incorporates some limited patent concepts along with other concepts unique in intellectual property law.

Structurally, PVP systems are organized along classic lines, employing (1) a rubric that defines the object of protection (namely, the "variety"); (2) a set of rules governing the grant of protection; (3) a set of rules governing the scope of protection; and (4) a provision establishing a fixed term (twenty years from issuance for most varieties). However, PVP systems diverge substantially from the classic patent and copyright model in ways that are important to the issue of obsolescence.[18]

First, PVP systems employ neither copyright's minimal originality criterion nor patent law's more rigorous novelty-plus-non-obviousness requirements for obtaining protection.[19] PVP systems require that a plant variety be new,[20] as well as distinct, uniform, and stable (collectively, the "DUS" criteria).[21] Both the variety rubric and the DUS concepts are bound

17. *See, e.g.*, J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 138 (2001) (PVPA provides "limited patent-like protection for certain sexually reproduced plants"); Asgrow Seed Co. v. Winterboer, 513 U.S. 179, 181 (1995) (PVPA provides "patent-like protection to novel varieties of sexually reproduced plants (that is, plants grown from seed) which parallels the protection afforded asexually reproduced plant varieties (that is, varieties reproduced by propagation or grafting) under [the plant patent provisions]"); *Plant Variety Protection Act: Hearing Before the Subcomm. on Agric. Research and Gen. Legis. of the Comm. on Agric., Nutrition, and Forestry*, 96th Cong. 1 (1980) (remarks of Sen. Donald W. Stewart).

18. For other discussions emphasizing the differences between PVP and patent regimes, see generally UPOV, INDUSTRIAL PATENTS AND PLANT BREEDERS' RIGHTS—THEIR PROPER FIELDS AND POSSIBILITIES FOR THEIR DEMARCATION 73–83, UPOV PUB. NO. 342(E) (1985); Janis & Kesan (2002), *supra* note 3, at 745–52; *see also* World Intellectual Prop. Org. & Int'l Union for the Prot. of New Varieties of Plants [WIPO-UPOV], *WIPO-UPOV Symposium on the Co-existence of Patents and Plant Breeder's Rights in the Promotion of Biotechnological Developments*, WIPO-UPOV/SYM/02/7 (Oct. 23, 2002), *available at* http://www.upov.int/en/documents/Symposium2002/pdf/wipo-upov_sym_02_7.pdf (collecting symposium proceedings).

19. For the relevant U.S. patent provisions, see 35 U.S.C. § 102 (2000) (novelty); *id.* § 103 (nonobviousness). PVP systems also lack patent law's utility and disclosure provisions. *See id.* § 101 (utility); *id.* § 112 (disclosure); *see also* Janis & Kesan (2002), *supra* note 3, at 748 (explaining the difference between patent law's requirement for a publicly accessible deposit of biological material to satisfy § 112 requirements, and the U.S. PVPA's requirement for a sample deposit without any public access requirement to satisfy the goal of preserving viable seed samples).

20. 7 U.S.C. § 2402(a)(1) (2000); UPOV (1991), *supra* note 6, art. 6.

21. 7 U.S.C. §§ 2402(a)(2)–(4); UPOV (1991), *supra* note 6, arts. 7–9. In PVP schemes, novelty is defined solely by reference to the breeder's own acts. For example, when the breeder exploits the variety more than a year before filing for protection, novelty is destroyed. 7 U.S.C. § 2402(a)(1)(A); UPOV (1991), *supra* note 6, art. 6(1)(i). Distinctness is measured against the body of "common knowledge" as of the PVP application filing date, which embraces knowledge that resulted from the activities of third parties. 7 U.S.C. § 2402(a)(2); UPOV (1991), *supra* note 6, art. 7. Collectively, these rules

up so intimately with underlying technological concepts that PVP systems are especially susceptible to technological obsolescence, as we will discuss.[22]

Second, rules on the scope of protection track the rules of copyright scope, but only partially. Copyright infringement rules impose liability for acts such as unauthorized copying and distributing, but not for the act of independent creation—copyright infringement presupposes access to the protected work and the appropriation of some or all elements of it, measured by assessing similarities between the works.[23] PVP infringement provisions[24] function like anti-copying rules: the unauthorized acts triggering liability (e.g., the unauthorized use of a protected variety for "production" or "multiplication,"[25] selling, conditioning for propagation, or stocking) presume access to the protected plant material.[26] The Senate report accompanying the 1970 U.S. PVPA made explicit this copyright orientation, observing that the PVPA infringement provision "more resembles copyright law than patent law" and "infringement is expected almost never to be by independent work, but by willful reproduction starting from the protected variety itself."[27] In addition, second-generation PVP systems have adopted provisions that extend PVP protection to "essentially derived varieties"

resemble the patent law rules for novelty in first-to-file jurisdictions—that is, all jurisdictions other than the United States.

22. *See infra* Part II.

23. *See, e.g.*, Ellis v. Diffie, 177 F.3d 503, 506 (6th Cir. 1999) (reciting the standard). By contrast, patent infringement rules impose liability for any unauthorized exploitation of the claimed invention, even where the alleged infringer independently created the invention. For example, U.S. patent law forbids third parties from making, using, selling, offering to sell, or importing the patented invention without authority, 35 U.S.C. § 271(a), irrespective of whether the infringer independently developed the infringing subject matter.

24. 7 U.S.C. § 2541(a) (defining infringing acts); UPOV (1991), *supra* note 6, art. 14(1)(i)–(vii) (same).

25. 7 U.S.C. § 2541(a)(4) (liability for making unauthorized use of the variety in "producing . . . a hybrid or different variety therefrom"); UPOV (1991), *supra* note 6, art. 14 (1)(i) (liability for unauthorized "production or reproduction (multiplication)").

26. Relatedly, the infringement provision in § 2541, proscribing unauthorized dispensing of PVP'd seed, has been construed to require that the alleged infringer have notice that the seed at issue is protected. *See* Syngenta Seeds, Inc. v. Delta Cotton Co-operative, Inc., 457 F.3d 1269, 1275 (Fed. Cir. 2006) (stating that the unauthorized dispensing of a protected variety under § 2541(a)(6) triggers liability only where the dispenser had notice that the seed it was dispensing was protected under the PVPA; it is error to construe the provision as a strict-liability provision); Delta & Pine Land Co. v. Sinkers Corp., 177 F.3d 1343, 1355 (Fed. Cir. 1999) (stating that notice or independent knowledge of protected status is required).

27. S. REP. NO. 91-1138, at 11 (1970). PVP schemes do not say anything explicitly about independent creation. If it became feasible for a breeder to constitute a whole variety gene by gene, and the constituted variety turned out to be identical to a protected variety, the question of independent creation would come into issue.

("EDVs") in some circumstances,[28] provisions that may be likened to derivative-rights provisions in copyright law.[29]

However, the analogy to copyright scope is imperfect, because copyright law's infringement regime coexists with a traditional fair use doctrine,[30] whereas PVP infringement provisions are subject to different and more extensive infringement exemptions. Most importantly, PVP systems allow parties to use PVP-protected seed to breed varieties that compete commercially with the protected variety.[31] For example, 1991 UPOV-compliant PVP systems shield from liability "acts done privately and for non-commercial purposes,"[32] "acts done for experimental purposes,"[33] and, most critically, "acts done for the purpose of breeding other varieties."[34] Copyright fair use insulates many types of uses, but certainly not those that might potentially reduce or eliminate the market for the copyrighted work. Patent law's experimental use exemption from infringement is narrower still, precluding follow-on improvement and other unauthorized exploita-

28. 7 U.S.C. § 2541(c) (relevant substantive provisions); *id.* § 2401(a)(3) (relevant definitions); UPOV (1991), *supra* note 6, art. 14(5). We discuss EDVs in Part III.

29. 17 U.S.C. § 106(2) (2000) (derivative works right); *id.* § 101 (relevant definition of "derivative work").

30. *Id.* § 107.

31. Another exemption, albeit of less importance to our discussion, is the so-called "saved seed" exemption, allowing farmers to harvest and save the seed of protected varieties for replanting in a subsequent season, subject to limitations. 7 U.S.C. § 2543 (implementing the exception); *id.* § 2401(b)(1) (supplying relevant definitions); UPOV (1991), *supra* note 6, art. 15(2) (optional exception); Asgrow Seed Co. v. Winterboer, 513 U.S. 179 (1995) (refusing to shield "brown bag" sales of saved seed under the saved seed exemption as it stood before being amended to its current form).

32. UPOV (1991), *supra* note 6, art. 15(1)(i); *accord* 7 U.S.C. § 2541(e) ("It shall not be an infringement of the rights of the owner of a variety to perform any act done privately and for noncommercial purposes.").

33. UPOV (1991), *supra* note 6, art. 15(1)(ii).

34. *Id.* art. 15(1)(iii); *accord* 7 U.S.C. § 2544 ("The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this chapter."). The U.S. PVPA additionally exempts the unauthorized use of a protected variety in "developing" (as distinguished from "producing") a new variety. *Id.* § 2541(a)(4) (distinguishing between producing and developing for purposes of imposing liability). The PVPA legislative history attempts to explain the distinction:

> Producing (as distinguished from developing) a hybrid or different variety means that use of the protected variety in producing the commercial class of seed of a variety constitutes infringement. Use of the protected variety as one source of germ plasm to breed a novel variety is permissible. As an example, the use of a protected inbred line of corn to cross it with another inbred line to produce a hybrid for commercial use, or production of a composite variety which is repeatedly reconstituted for commercial sale by intercrossing a set of seed lines one of which is protected, shall constitute an infringement. The use of such inbred line for hybridization with other materials to develop through breeding a novel inbred line as provided in [the breeding research exemption, 7 U.S.C. § 2541(a)(4)], however, does not constitute infringement; nor does the production of such new inbred line for the general market constitute infringement.

H.R. REP. NO. 91-1605, at 11 (1970).

tion of the patented invention that has a commercial nexus.[35] As we will discuss, the presence of such a capacious breeder's exemption exposes PVP regimes to obsolescence, because the scope of PVP rights may erode significantly as a consequence of rapid advances in breeding technologies.[36]

This unusual stew of provisions has generated a muddled policy debate over the nature of the incentives that PVP systems provide. In the U.S., the legislative history of the PVPA contains claims that the Act would provide patent-like incentives, stimulating private sector investments in the breeding of improved plant varieties.[37] However, given the jumble of provisions housed in PVP systems, intellectual property theory would predict that even well-implemented PVP systems would be unlikely to produce *ex ante* incentives resembling pure patent incentives. Indeed, theory might just as likely predict that PVP systems can do no more than encourage the proliferation of additional varieties, irrespective of whether they are improvements over existing varieties—an ambition akin to that of the copyright system.[38] Empirical studies of the PVP system have borne out this ambivalence. At least one early study expressed cautious optimism that PVP systems could supply meaningful incentives to invest in plant R&D,[39] but later studies have been mixed, some expressing skepticism, especially about claims that PVP systems would stimulate better yields,[40] others maintain-

35. Madey v. Duke Univ., 307 F.3d 1351, 1360–62 (Fed. Cir. 2002); Whittemore v. Cutter, 29 F.Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

36. *See infra* Part III.

37. *E.g.*, *Plant Variety Protection Act: Hearing on S. 3070 Before the Subcomm. on Agric. Research & Gen. Legis. of the Comm. on Agric. & Forestry*, 91st Cong. 49 (1970) (remarks of Sen. Jack Miller); COMM. ON AGRIC. & FORESTRY, PLANT VARIETY PROTECTION ACT, S. REP. NO. 91-1138, at 14 (1970) (views of Department of Agriculture). A similar assertion of Congressional intent appears on the face of the statute itself. *See* 7 U.S.C. § 2581 (expressing Congress's intent that the PVPA "afford adequate encouragement for research, and for marketing when appropriate, to yield for the public the benefits of new varieties").

38. Advocates of PVP systems appear to suggest that the proliferation of varieties alone is a substantial justification for PVP protection, even while citing other benefits. *E.g.*, UPOV IMPACT REPORT, *supra* note 7, at 26 (presenting pertinent statistics).

39. L.J. BUTLER & B.W. MARION, THE IMPACTS OF PATENT PROTECTION ON THE U.S. SEED INDUSTRY AND PUBLIC PLANT BREEDING, NORTH CENTRAL REGIONAL RESEARCH PUBLICATION 304 (1985) (expressing cautious optimism that PVP systems might stimulate plant R&D spending); *see also* R.K. PERRIN, K.A. KUNNINGS & L.A. IHNEN, SOME EFFECTS OF THE US PLANT VARIETY ACT OF 1970 (1983).

40. A further complication is the differential effectiveness (perceived or real) of PVP systems across different crops. In some agricultural sectors, PVP systems seem to be considered quite attractive, while they are scorned in others, without any obvious objective reason for the difference. For statistics showing the stratification of PVP certificates (and plant patents) by crop, see Koo (2004), *supra* note 13, at 1296; *see also* UPOV IMPACT REPORT, *supra* note 7, at 13, 23 (pointing out that the effectiveness of PVP systems may vary from crop to crop, and that ineffectiveness with respect to one crop need not be taken as an indictment of the entire system).

ing that PVP systems had succeeded for some crops[41] in some jurisdictions.[42] And students of the *realpolitik* of international intellectual property policy might well dismiss any incentives story, instead ascribing to PVP systems little more than a role as a political safety valve—a less-protective alternative to patents in jurisdictions where offering patent protection for plants is politically unpalatable.

In sum, an examination of PVP systems in their intellectual property context reveals inconsistencies about the design and goals of PVP systems. That, coupled with the fact that PVP systems must operate today in a technological paradigm that the originators of PVP systems could not have foreseen, suggests that thoughtful reconsideration of the basic premises underlying PVP systems may be in order. We explain the technological context next.

B. *The Background Technological Paradigms: Phenotype to Genotype*

Obsolescence is such a salient issue in plant variety protection because PVP systems have operated under two distinct technological paradigms of plant breeding.[43] PVP systems came into being in the 1960s when plant breeders operated under the paradigm of plant phenotypes, but PVP systems exist today in a technological milieu that is dominated by the new paradigm of plant genotypes.[44] Whether PVP systems are capable of being transformed into effective innovation drivers that respond to the imperatives of the genotype age is one of the central questions that we address in this article.

A brief elaboration on the differences between the paradigms will place the obsolescence problem in focus. A phenotype is a plant's set of

41. *E.g.*, Anwar Naseem et al., *Does Plant Variety Intellectual Property Protection Improve Farm Productivity? Evidence from Cotton Varieties*, 8 AGBIOFORUM 100 (2005) (asserting that U.S. PVP protection has stimulated the development of cotton varieties and has had a positive impact on cotton productivity).

42. *See* UPOV IMPACT REPORT, *supra* note 7, at § III (reporting studies in Argentina, China, Kenya, Poland, and South Korea in support of claims that PVP systems have led to increases in the number of varieties, improvements in varieties, and enhancements to the competitiveness of domestic breeding entities).

43. For our purposes, a paradigm of plant breeding is comprised of the systems, mechanisms, and techniques for (1) identifying plants (and, in particular, for distinguishing among similar plants) and (2) exercising control over the characteristics of identified plants as plants are bred from generation to generation.

44. Maarten Koornneef & Piet Stam, *Changing Paradigms in Plant Breeding*, 125 PLANT PHYSIOLOGY 156, 158 (2001) (asserting that "in plant breeding the paradigm has changed from selection of phenotypes toward selection of genes, either directly or indirectly," and describing relevant changes in the 1970s to 1990s); Steven D. Tanksley & Susan R. McCouch, *Seed Banks and Molecular Maps: Unlocking Genetic Potential from the Wild*, 277 SCIENCE 1063, 1064–65 (1997) (describing the old paradigm of "looking for the phenotype" and the new paradigm of "looking for the genes").

observable characteristics, a product of the plant's genes and its interaction with the environment.[45] A genotype is a plant's entire genetic makeup.[46] The paradigm of phenotype traces back some 10,000 years, when humans first began to domesticate wild plants.[47] Early farmers identified plants having desirable phenotypic characteristics (e.g., high or stable yield, disease or insect resistance, non-shattering seeds, desirable appearance, taste, or other observable physical characteristics) and selectively propagated those plants.[48] Farmers also experimented with simple cross-fertilization, attempting to blend characteristics from desirable parents.[49] These practices eventually resulted in the emergence of farmer's varieties ("landraces")—plant populations that may have been genetically heterogeneous, but possessed at least enough distinguishing phenotypic features that they could be told from other plant populations by observation.[50] Farmers began to develop names and naming systems to identify plant populations, implicitly internalizing both the conceptualization of plant populations as varieties and the use of phenotypic distinctions to determine what constituted a variety.[51] These practices—and with them, the paradigm of phenotype—

45. *See, e.g.*, CROP SCI. SOC'Y OF AM., GLOSSARY OF CROP SCIENCE TERMS 52 (1992) [hereinafter CSSA GLOSSARY] (defining phenotype as the "[o]bservable characteristics, resulting from the interaction between an organism's genetic makeup and the environment"). Included within a plant's phenotype are both its morphological characteristics (a reference to visible characteristics and their evolutionary history) and its physiological characteristics (a reference to the dynamic processes relating to plant characteristics). *See* ROBERT C. KING & WILLIAM D. STANSFIELD, A DICTIONARY OF GENETICS 254 (6th ed. 2002) (defining morphology).

46. *See* CCSA GLOSSARY, *supra* note 45, at 46 (defining genotype as the entire "[g]enetic makeup of an individual or group").

47. For a brief and accessible overview of the origin of cultivation practices, see MAARTEN J. CHRISPEELS & DAVID E. SADAVA, PLANTS, GENES AND CROP BIOTECHNOLOGY ch. 13 (2d ed. 2003).

48. That is, they practiced "mass selection." JOHN MILTON POEHLMAN & DAVID ALLEN SLEPER, BREEDING FIELD CROPS 475 (4th ed. 1995) (defining the phrase as "a system of breeding in which seed from individuals selected on the basis of phenotype is composited and used to grow the next generation"). Modern studies of traditional breeding practices have helped plant breeders reconstruct the narrative of the development of crop cultivation. *See, e.g.*, Nadir Alvarez et al., *Farmers' Practices, Metapopulation Dynamics, and Conservation of Agricultural Biodiversity On-Farm: A Case Study of Sorghum Among the Duupa in Sub-Sahelian Cameroon*, 121 BIOL. CONSERVATION 533 (2005) (modern study of traditional practices); D. Louette & M. Smale, *Farmers' Seed Selection Practices and Traditional Maize Varieties in Cuzalapa, Mexico*, 113 EUPHYTICA 25 (2000) (same).

49. *See* David A. Cleveland, Daniela Soleri & Steven E. Smith, *A Biological Framework for Understanding Farmers' Plant Breeding*, 54 ECON. BOTANY 377 (2000); *see also* Hugo Perales R., S.B. Brush & C.O. Qualset, *Dynamic Management of Maize Landraces in Central Mexico*, 57 ECON. BOTANY 21 (2003).

50. *See* POEHLMAN & SLEPER, *supra* note 48, at 243 (defining landraces as "[f]armer-selected cultivated forms"); *see also* OTTO H. FRANKEL ET AL., THE CONSERVATION OF PLANT BIODIVERSITY 57 (1995) ("Landraces . . . 'have a certain genetic integrity. They are recognized morphologically; farmers have names for them and different landraces are understood to differ in adaptation to soil type, time of seeding, date of maturity, height, nutritive value, use and other properties.'" (quoting Jack R. Harlan, *Our Vanishing Genetic Resources*, 188 SCIENCE 618 (1975))).

51. For example, Theophrastus's *Enquiry into Plants* (circa. 300 B.C.) and Cato's *De Agri Cultura* (circa 160 B.C.) both listed vernacular names for many cultivated plants. CARY FOWLER & PAT

persisted well into the twentieth century. Even after the emergence of plant breeding as a formal scientific discipline in 1900, when breeders rediscovered Mendel's laws of genetic inheritance and began to understand plant breeding as the work of selecting for genotypes,[52] plant breeders remained dependent on viewing or measuring plants' phenotypic attributes in selecting for desirable agronomic traits.[53]

The paradigm of phenotype is still relevant: the conceptualization of plants as varieties based on phenotype is still well entrenched,[54] and plant breeders still practice selection by phenotype. However, since the 1970s, advances in biotechnology have allowed plant breeders to move away from sole reliance on plant phenotypes and towards direct characterization and manipulation of plant genomes.

The paradigm of genotype involves two principal points of departure. First, genotyping technologies make it possible to identify and discriminate among plants directly by their DNA profiles or other molecular characteristics, rather than indirectly by their phenotype alone. Effectively, this is an

MOONEY, SHATTERING: FOOD, POLITICS, AND THE LOSS OF GENETIC DIVERSITY 26 (1990) ("Plato's pupil Theophrastus wrote in his *Enquiry into Plants* of the many types of wheat which differ in 'color, size, form, and individual character, and also as regards their capacities in general and especially their value as food.'"); W.T. Stearn, *Historical Survey of the Naming of Cultivated Plants*, 182 ACTA HORTICULTURAE 19 (1986) (alluding to Cato's work). Archeological evidence points to similar efforts among peoples in most parts of the world. For one example involving corn, see MARY W. EUBANKS, ANCIENT ARTISANS AND THE EVOLUTION OF MAIZE (2002) (reporting on descriptions of ears of maize made on ceramic pots which today allow classification of racial types that were cultivated in A.D. 500).

52. FOWLER (1994), *supra* note 10, at 24 (noting that prior to 1900 "formal plant breeding was virtually unknown"). The rediscovery of Mendel's laws resulted from the work of a number of plant breeders working independently around the turn of the century. For one illustrative account, involving plant breeder William Spillman's experiments relating to recessive traits in wheat at the dawn of the era of "scientific" breeding, see Laurie Carlson, *Forging His Own Path: William Jasper Spillman and Progressive Era Breeding and Genetics*, 79 AGRIC. HIST. 50 (2005).

53. For example, breeders of hybrid crops have utilized detailed knowledge of pedigrees and replicated yield trials of an array of early generation F1 hybrids to measure the genetic potential of segregants in breeding populations. However, all of these developments relied upon the plant's physical appearance and thus remained, at best, indirect approaches to genotypic selection.

54. Indeed, indigenous naming systems based on phenotype still exist for important crops in many cultures. For example, the Aguarana Jivaro community in northern Peru has developed its own phenotypically based description system to discriminate among manioc (cassava root) landraces. *See* James Shilts Boster, *Selection for Perceptual Distinctiveness: Evidence from Aguaruna Cultivars of Manihot esculenta*, 39 ECON. BOTANY 310 (1985). The literature contains scores of additional examples. *See, e.g.*, Mauricio R. Bellon & Stephen B. Brush, *Keepers of Maize in Chiapas, Mexico*, 48 ECON. BOTANY 196 (1994); S.H. Costanza, J.M.J. DeWet & J.R. Harlan, *Literature Review and Numerical Taxonomy of Eragrostis tef (T'ef)*, 33 ECON. BOTANY 413 (1979) (landraces of T'ef, a native cereal, distinguished by inflorescence morphology, grain color, time to maturity, and uses); R. Ishikawa et al., *Genetic Resources of Primitive Upland Rice in Laos*, 56 ECON. BOTANY 192 (2002); Xu Jianchu et al., *Genetic Diversity in Taro (Colocasia esculenta Schott, Araceae) in China: An Ethnobotanical and Genetic Approach*, 55 ECON. BOTANY 14 (2001); J.J. Sanchez G., M.M. Goodman & J.O. Rawlings, *Appropriate Characters for Racial Classification in Maize*, 47 ECON. BOTANY 44 (1993) (landraces of Maize in Mexico and Central and South America identified by characteristics such as the number of leaves per plant, the kernel width, the ear diameter/length, among others).

exercise in the genetic "fingerprinting" of plants, a task facilitated by technological advances in molecular marker systems.[55] In fact, it is increasingly possible to reconceptualize plants altogether as genetic datasets,[56] a conceptualization that may diverge radically from the variety rubric.

Second, plant breeders are developing new molecular breeding methodologies—i.e., methodologies that operate at the level of DNA sequences to directly manipulate the plant's genotype, rather than using phenotype as the sole reference point.[57] Techniques such as marker-assisted selection ("MAS") are enhancing (or even displacing) the traditional phenotype-based breeding methodologies that dominated commercial plant breeding when PVP systems were designed.[58]

Moreover, in the course of exploring these techniques, plant breeders are beginning to discard long-held assumptions about the relationships between phenotype and genotype. Discoveries in plant genomics have moved plant breeders away from a "one-gene, one-phenotype mentality" towards a new appreciation of the complex relationship between genotype and phenotype, in which plant breeders recognize that plant physiology is dynamic and responsive to external factors such as environment, and expect to find intricate gene networks controlling "complex phenotypes."[59]

55. We describe molecular markers in more detail *infra* Part II.A.

56. Stephen Smith, *Genotyping and Sequencing*, 7 BIO-SCIENCE L. REV. 9, 13 (2004) (noting that the "use of DNA genotypic data to describe varieties *de novo*" is "possible but controversial").

57. For a brief characterization of molecular breeding strategies, see, for example, Mark Cooper et al., *Genomics, Genetics, and Plant Breeding: A Private Sector Perspective*, 44 CROP SCI. 1907, 1907–08 (2004). Molecular breeding builds upon a number of basic techniques, such as methods for cloning genes in crop plants and transformation techniques for moving exogenous genes into target plants. For accessible brief overviews of these basic techniques, see, for example, ADRIAN SLATER, NIGEL W. SCOTT & MARK R. FOWLER, PLANT BIOTECHNOLOGY: THE GENETIC MANIPULATION OF PLANTS chs. 3–4 (2003); Jack M. Widholm, *Plant Genetic Modification Technologies*, *in* GENETICALLY MODIFIED ORGANISMS IN AGRICULTURE: ECONOMICS AND POLITICS 275 (Gerald C. Nelson ed., 2001). For representative current research on gene cloning in crop plants, see, for example, Li Huang et al., *Map-Based Cloning of Leaf Rust Resistance Gene Lr21 from the Large and Polyploid Genome of Bread Wheat*, 164 GENETICS 655 (2003); Nabila Yahiaoui et al., *Genome Analysis at Different Ploidy Levels Allows Cloning of the Powdery Mildew Resistance Gene Pm3b from Hexaploid Wheat*, 37 PLANT J. 528 (2004); L. Yan et al., *Positional Cloning of the Wheat Vernalization Gene VRN1*, 100 PROC. NATL. ACAD. SCI. USA 6263 (2003). Whole genome sequencing will also assist breeders in identifying genes associated with phenotypes. *See* Michael J. Havey, *Application of Genomic Technologies to Crop Plants: Opportunities and Challenges*, 44 CROP SCI. 1893 (2004). Researchers have mapped the genome sequences of Arabidopsis and rice, and projects are underway to map other plant genomes, including maize and alfalfa. *See* Plant Genomes Central, Genome Projects in Progress, http://www.ncbi.nlm.nih.gov/genomes/PLANTS/PlantList.html (last visited May 31, 2007) (listing plant genome mapping projects).

58. We assess the consequences of MAS *infra* Part III.

59. Justin O. Borevitz & Joseph R. Ecker, *Plant Genomics: The Third Wave*, 5 ANN. REV. GENOMICS HUM. GENETICS 443, 444 (2004). Borevitz and Ecker identify a first wave of plant genomics characterized by single-gene sequencing, primitive markers, and the assumed correlation between single genes and single discrete phenotypes; a second wave involving whole genome sequencing and more sophisticated markers, but still directed to "the continued goal of finding genes that correspond to

In sum, the technological foundation on which PVP systems were designed is being entirely reconstituted. Genotype now predominates over phenotype. Genotypes are assessed directly, and relationships between genotype and phenotype are being revealed as more complex than previously assumed. Each of these developments presents challenges for the variety concept as used in PVP systems and for the core rules of protection and scope employed in those systems, as we detail in Parts II and III.

II. OBSOLESCENCE IN RULES OF PROTECTION

In this Part, we assess the potential obsolescence of (1) the concept of variety (the object of protection in PVP systems) and (2) the DUS criteria (the principal rules for obtaining PVP protection). We conclude that the variety concept has outlived its usefulness as an organizational rubric for a plant intellectual property system, although the concept has become so well entrenched that the cost of switching away may be difficult to justify. We conclude that the DUS criteria are based on outmoded concepts and should be candidates for substantial reform. We applaud near-term efforts to adapt the DUS criteria to new molecular technologies and seek to draw useful lessons from those efforts, but we question whether retaining modified DUS criteria serves well as a long-term solution.

A. Plants as "Varieties" and Plants as Datasets

Although "variety" is the organizing rubric around which PVP systems are built, very little about the concept can be gleaned from PVP legislative texts.[60] Definitions in first-generation PVP legislation—the 1961 UPOV and the 1970 U.S. PVPA—left little room for any independent significance for the variety concept in that the primary criteria for qualifying as a variety were homogeneity and stability (predecessors to the DUS criteria). [61] The official negotiating history of the 1961 UPOV is silent as to the

specific phenotypes"; and a third wave, now emerging, that discards assumptions about simple relationships between phenotype and genotype.

60. *But cf.* Andre Heitz, *Plant Variety Protection and Cultivar Names Under the UPOV Convention, in* TAXONOMY OF CULTIVATED PLANTS: THIRD INTERNATIONAL SYMPOSIUM 59, 65 (Susyn Andrews, Alan Leslie & Crinan Alexander eds., 1999) (claiming that the "most prominent achievement" of UPOV "is perhaps the clarification of the [variety] concept"). As we detail in this section, we see little evidence supporting this claim.

61. Article 2(2) of UPOV (1961), *supra* note 4, ("Meaning of Variety") read, "For purposes of this Convention, the word 'variety' applies to any cultivar, clone, line, stock or hybrid which is capable of cultivation and which satisfies the provisions of subparagraphs 1*(c)* [homogeneity] and *(d)* [stability] of Article 6." Homogeneity was the predecessor to the current uniformity requirement, one of the DUS criteria. The definition does not reference the distinctness requirement. Except for the exclusion of hybrids, the 1970 U.S. PVPA defined variety similarly: "The term 'novel variety' may be represented

reasons for employing this definition,[62] and the legislative history of the 1970 U.S. PVPA is no more forthcoming. Second-generation PVP legislation employs a new definition[63] that characterizes "variety" taxonomically (as a plant grouping at the lowest known rank) and makes some other changes that further liberalize the concept.[64]

These legislative texts show that the variety concept in PVP systems has operated as a conduit for importing meanings developed elsewhere

by, without limitation, seed, transplants, and plants, and is satisfied if there is [distinctness, uniformity, and stability]." 7 U.S.C. § 2401(a) (1970) (current version at 7 U.S.C. § 2401 (2000)). A separate provision exempted from PVP protection "the seeds, plants, or transplants of okra, celery, peppers, tomatoes, carrots, and cucumbers," for reasons apparently related to the interests of the Campbell's Soup Company, not to any logical delineation of the variety concept. 7 U.S.C. § 2583 (1970) (repealed 1980); *see* FOWLER (1994), *supra* note 10, at 113–14 (recounting the special interest lobbying that led to the exemption).

62. The history is collected in ACTES DES CONFERENCES INTERNATIONALES POUR LA PROTECTION DES OBTENTIONS VEGETALES (1974). At the time of the UPOV negotiations, the variety concept was in use in various national plant registration systems in Europe, , and had been used in a German proposal for a *sui generis* intellectual property system in the 1953. HANS NEUMEIER, SORTENSCHUTZ UND/ODER PATENTSCHUTZ FUR PFLANZENZUCHTUNGEN (1990) (discussing the German proposal); Andre Heitz, *The History of the UPOV Convention and the Rationale for Plant Breeders' Rights*, *in* 1991 SEMINAR ON THE NATURE AND RATIONALE FOR THE PROTECTION OF PLANT VARIETIES UNDER THE UPOV CONVENTION 17, 25–27 (1994) [hereinafter Heitz (1994)]. Perhaps this explains why the UPOV negotiators seemed to take for granted the use of the variety concept as a foundational rubric.

63. The 1961 UPOV definition of variety was deleted in 1978, and no new definition was inserted until 1991. Under the 1991 UPOV,

> "variety" means a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be
>
> -defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
>
> -distinguished from any other plant grouping by the expression of at least one of the said characteristics and
>
> -considered as a unit with regard to its suitability for being propagated unchanged . . . .

UPOV (1991), *supra* note 6, art. 1(vi) (definitions); *see also* Community PVR Regulation, *supra* note 14, art. 5(2) (adopting identical definition); Council Directive 98/44, *supra* note 9, art. 2(3) (incorporating by reference the Community definition).

The definition appearing in the current U.S. PVPA differs only cosmetically from the UPOV 1991 definition:

> The term "variety" means a plant grouping within a single botanical taxon of the lowest known rank, that, without regard to whether the conditions for plant variety protection are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one characteristic and considered as a unit with regard to the suitability of the plant grouping for being propagated unchanged. A variety may be represented by seed, transplants, plants, tubers, tissue culture plantlets, and other matter.

7 U.S.C. § 2401(a)(9) (2000).

64. The new definition sets forth three criteria that are intended to be reminiscent of utility, distinctness, and stability, respectively, but call for lesser proofs. Barry Greengrass, *The 1991 Act of the UPOV Convention*, 13 EUR. INTELL. PROP. REV. 466, 467 (1991) [hereinafter Greengrass (1991)]. The objective is to ensure that subject matter that is not sufficiently uniform to qualify as a protectable variety can potentially be considered part of the "common knowledge" for purposes of assessing distinctness of other subsequent varieties. *Id.*

(and, in turn, has influenced the understanding of variety in those other contexts). Those meanings, it turns out, have as much to do with practical needs as they do with the facts of biology. As we show in the following sections, while variety is a concept that has come to have taxonomic and biological meaning, variety is also a construct that developed as a pragmatic response to marketplace needs and that came to be employed as a convenient legal construct to facilitate consensus on intellectual property rules. Neither motivation would be likely to arise in the same fashion today in the era of genotyping.

1. "Variety" and Commercial Practicality

The practice of identifying plants as "varieties" owes its origin more to farmers and practical considerations of commerce than to botanists and the rigors of science.[65] Out of commercial necessity, farmers developed vernacular naming schemes for their landraces, implicitly relying on a concept of plant varieties understood phenotypically.[66] Obviously the names signified some consistency, at least in phenotypic qualities—when Cato published his list of plant names, he surely "could assume that his fellow Romans knew and could obtain [the plants] under the same name"[67]—but it was a consistency dictated by commercial, not scientific, considerations, and necessarily founded on intuitive notions about the underlying genetics, at best.

Scientific conceptions of the plant variety lagged far behind these pragmatic conceptions. Not until the 1750s, with Linneaus's introduction of the now-familiar binomial nomenclature (naming genus and species) did the variety become understood as a subdivision of the species—a third term

65. Relatedly, others have observed that the concept of variety can be understood from many different perspectives—among them taxonomic, genetic, and economic perspectives. José María Elena Rosselló, *The UPOV Convention— The Concept of Variety and the Technical Criteria of Distinctness, Uniformity and Stability*, *in* 1991 SEMINAR ON THE NATURE OF AND RATIONALE FOR THE PROTECTION OF PLANT VARIETIES UNDER THE UPOV CONVENTION, UPOV PUB. NO. 727(E), *supra* note 62, at 57, 57–58.

66. *E.g.*, U. Löscher, *Variety Denomination According to Plant Breeders' Rights*, 182 ACTA HORTICULTURAE 59, 59 (1986) (reliable systems of plant variety names had always been "an indispensable factor in trade" because they "gave purchasers the possibility of effectively choosing the variety they desired").

67. Stearn, *supra* note 51, at 19. In intellectual property terms, vernacular naming practices effectuated a rudimentary trademark scheme for cultivated plants, facilitating market transactions by signifying the origin or consistent agronomic qualities of the plants with which the names were associated. On the basic functions of trademarks, see, for example, GRAEME B. DINWOODIE & MARK D. JANIS, TRADEMARKS AND UNFAIR COMPETITION: LAW AND POLICY ch. 1 (2004). The importance of trademarks in agriculture persisted long past Cato's time. For example, in the late 1800s, producers of the leading seed corn products normally identified their products by the name of the originator, a place name, or a descriptive name, like "Reid's Yellow Dent" or "Champion White Pearl." FOWLER (1994), *supra* note 10, at 54.

in the binomial nomenclature.[68] Nearly a century passed before the publication of the pioneering work on rules for naming cultivated plants,[69] and only in the 1950s, a few years before the drafting of the UPOV, did horticulturalists agree on a code of international rules for naming cultivated plants.[70]

Thus, as of the mid-twentieth century, when conferees began the process of drafting the UPOV, the concept of a plant "variety" was still more a matter of shared informal understanding—more of a response to pragmatic commercial considerations—than a precise technical concept.[71] Moreover,

68. Any standard biology text includes an explanation of the Linnean nomenclature and hierarchy. *See, e.g.*, WILLIAM K. PURVES ET AL., LIFE: THE SCIENCE OF BIOLOGY 487–89 (5th ed. 1998). *See generally* Stearn, *supra* note 51, at 21 (explaining that "before the introduction of binomial nomenclature . . . no clear distinction could be made in naming between a species and a variety" but that afterwards, growers could add a third word "to distinguish varieties within species"). For example, in the Linnean nomenclature, corn is *Zea mays*, and a corn variety B73 (the variety being used in the maize genome mapping project) would be designated "*Zea mays* var. B73."

69. The publication is *Lois de la Nomenclature Botanique* (Laws of Botanical Nomenclature), published in the mid-1800s by Swedish botanist Alphonse de Candolle. *See* J. McNeill, *Nomenclature of Cultivated Plants: A Historical Botanical Standpoint*, 634 ACTA HORTICULTURAE 29 (2004) (citing ALPHONSE DE CANDOLLE, LAWS OF BOTANICAL NOMENCLATURE (H.A. Weddell trans., 1868)).

70. Rules pertaining to cultivated plants first appeared as a supplement to the 1905 International Rules of Botanical Nomenclature. The rules formalized the concept of a variety as a subdivision of the species. *See* Stearn, *supra* note 51, at 23 (specifying that "[t]he name of a horticultural 'variety' should be placed after that of the species to which it belongs and its status should in general be indicated by the contraction 'var.'" (quoting INTERNATIONAL RULES OF BOTANICAL NOMENCLATURE, app VII, R. a (1935))). For an account of the drafting and adoption of the International Code of Nomenclature for Cultivated Plants in 1950–53, see *id.* at 25–27. For the current text of the Code, see C.D. BRICKELL ET AL., INTERNATIONAL CODE OF NOMENCLATURE FOR CULTIVATED PLANTS (7th ed. 2004), *reprinted in* 647 ACTA HORTICULTURAE 1 (2004). The Code is a matter of consensus among horticulturalists; it is not legally binding. For an overview, *see* C.D. Brickell, *The International Code of Nomenclature of Cultivated Plants—Present and Future Aims and Requirements*, 182 ACTA HORTICULTURAE 29 (1986).

The Code adopts the term "cultivar" in preference to "variety," and defines cultivar in phenotypic terms, albeit using some criteria that do not appear in PVP definitions of "variety." For example, the second edition of the Code (1958) defined "cultivar" as a plant grouping that is distinguished by characters that are "significant for purposes of agriculture, forestry or horticulture . . . ," whereas PVP concepts of protectable varieties do not depend on agronomic significance. P. Trehane, *50 Years of the* International Code of Nomenclature for Cultivated Plants*: Future Prospects for the* Code, 634 ACTA HORTICULTURAE 17, 17–18 (2004) (citing the Code definition).

71. FOWLER (1994), *supra* note 10, at 100 (asserting that "there was no agreement on what constituted a distinct variety" by the 1930s (citing a historical source)). It is not clear whether Fowler is speaking of disagreements about what constituted a "variety," what constituted distinctness, or both.

The Secretary of the original UPOV Convention expressed a certain ambivalence about whether the variety rubric was sufficiently precise. B. Laclaviere, *The Convention of Paris of December 2, 1961, for the Protection of New Varieties of Plants and the International Union for the Protection of New Varieties of Plants*, 4 INDUS. PROP. 224, 226 (1965) (asserting that "*the notion of variety* is more or less precise" as a matter of biology, but acknowledging differences in tolerable levels of genetic heterogeneity in different countries and across different species, and concluding that "[t]he term 'variety' can thus be applied to very different categories of plants, according to the species involved and the States concerned").

Another Secretary of UPOV of more recent tenure put the point more forcefully:

> The variety was an abstract concept which had been developed by users of plant varieties such as agriculturalists and researchers such as botanists and taxonomists to assist in the clas-

variety took its meaning from plant characteristics that mattered in commerce—that is, observable morphological and agronomic characteristics. Accordingly, from the outset, the concept of variety necessarily bore a phenotypic bias.

Currently, after nearly a half century of experience under PVP systems, variety remains as much a commercial concept as a technical one.[72] Efforts in the breeding community to refine the concept have made little progress in resolving ambiguities[73] and have bound the concept even more tightly to potentially obsolete phenotypic qualities.[74]

2. Variety as a Legal Construct

As commerce in plants expanded, especially in the nineteenth century, crop-specific growers' organizations developed and attempted to formalize farmers' lexical practices through codes of nomenclature[75] and, eventually,

> sification of plant material. The concept was not a concise one. It had no existence on its own . . . . Many rules had been established to define the unit of plant material that would be considered as a variety, mainly in terms of the mechanism used for reproduction or propagation.

Barry Greengrass, *Report of the Committee of Experts on the Interface between Patent Protection and Plant Breeder's Rights*, WIPO/UPOV/CE/I/4 (1990). For additional commentary on the imprecision of the variety concept, see Case T 1054/96, Novartis/Transgenic Plant, 1998 O.J. E.P.O. 511 (TBA 1997), *available at* http://legal.european-patent-office.org/dg3/pdf/t961054ep1.pdf ("There is no generally agreed definition of plant varieties available from scientific textbooks.").

72. The concept has become a fixture in the technical literature. *E.g.*, POEHLMAN & SLEPER, *supra* note 48, at 480 (defining variety as a "subdivision of a species" and elaborating that the term refers to "a group of similar plants that by structural features and performance can be identified from other varieties within the same species"). Notably, there has been a feedback effect—the legal definition of variety found in PVP legislation may inform the colloquial understanding of the term in the breeding trade. In an apparent effort to lend clarity, the CSSA Glossary defines both "variety" and "botanical variety." CSSA GLOSSARY, *supra* note 45, at 5 (defining "botanical variety" as "[a]n infraspecific taxon in botanical nomenclature, below the rank of subspecies"); *id.* at 37 (defining "variety" in reference to the DUS criteria).

73. For an example of one potential source of imprecision, see Clement W. Hamilton, *Implications of the Equivalence of Subspecies and Variety, and of the Irrelevance of Forma*, 413 ACTA HORTICULTURAE 57, 57 (1995) (asserting, *inter alia*, that "[s]ubspecies and varieties are theoretically and practically indistinguishable, but both are currently used; and the choice relates more often to the geographic origin of the taxonomist than to the biology of the plants").

74. Important terms include "cultivar" ("cultivated variety"), "strain," "clone," and "line." Usage of these terms varies. For one set of definitions, see D. Whiting, M. Roll & L. Vickerman, *Taxonomic Classification*, COLORADO MASTER GARDNER NO. 7.701, http://www.ext.colostate.edu/pubs/garden/07701.pdf (last visited June 1, 2007) (defining "cultivar" as "a species sub-grouping of cultivated plants . . . displaying unique differences and when reproduced by seeds or cuttings retain its distinguishing characteristics"; "strain" as "a sub-group of cultivar with specific characteristics, like resistance to a disease or better color"; "clone" as "a sub-group of cultivar derived by asexual propagation (cuttings)"; and "line" as "a sub-group of cultivar propagated by seed"); *see also* CSSA GLOSSARY, *supra* note 45, at 34 (defining "strain" as "[a] selection within a variety lacking clear-cut morphological differences, but having distinguishing physiological or agronomic qualities such as drought resistance, superior yield, etc.").

75. *See, e.g.*, Stearn, *supra* note 51, at 22 (referring to a naming code adopted by the American Pomological Society in the mid-1800s); Freek Vrugtman, *The History of Cultivar Name Registration in*

through seed certification procedures.[76] Perhaps inevitably, given their potential use as protectionist measures,[77] domestic seed certification systems were eventually codified around the turn of the twentieth century in the form of state[78] and federal seed legislation in the U.S.,[79] and in European countries during the same time period.[80] Given their origins in the commercial sphere, it is not surprising that these regimes made use of the variety concept, notwithstanding its scientific imprecision.[81]

North America, 182 ACTA HORTICULTURAE 225, 225–26 (1986) (referring to registration programs for various ornamental flowers—e.g., roses, peonies, and orchids); *see also* FOWLER (1994), *supra* note 10, at 21 (citing NELSON KLOSE, AMERICA'S CROP HERITAGE: THE HISTORY OF FOREIGN PLANT INTRODUCTION BY THE FEDERAL GOVERNMENT ch. 6 (1950) (describing farmer development of wheat varieties in the early 1800s)) (noting an 1859 survey describing 135 varieties of wheat, as well as later surveys identifying some 7,000 varieties of apples and over 1,300 varieties of strawberries grown in the U.S.). Notably, notions of the "variety" concept seem to have come earlier to the nursery and ornamentals business than to other sectors of the agricultural economy, FOWLER (1994), *supra* note 10 at 74, perhaps because breeders believed that they had better control over varietal stability through the use of asexual breeding practices.

76. That is, procedures that allowed growers to have their products certified if the products were produced according to association guidelines. Kathy J. Cooke, *Expertise, Book Farming, and Government Agriculture: The Origins of Agricultural Seed Certification in the United States*, 76 AGRIC. HIST. 524 (2002) (detailing certification programs established in the early 1900s among organizations such as the Indiana Corn Growers' Association, the Minnesota Crop Improvement Association, and others). An International Crop Improvement Association appeared in 1920, issuing certifications with the avowed purpose of "ensur[ing] genetic purity and integrity" of plant varieties. Bernard R. Baum, *DNA Fingerprinting of Cereal Cultivars for Intellectual Property Rights Protection, in* TAXONOMY OF CULTIVATED PLANTS, *supra* note 60, at 231, 232 (noting that the Association sought to "prevent confusion in the marketplace" and to "unify and standardise the seed certification programmes that had been developed since the turn of the century in many countries").

77. By requiring a plant breeder to have seed registered in order to receive permission to market the seed in the jurisdiction "the government would be able to require that varieties sold in interstate commerce be discernibly different and perhaps better than those already being sold." FOWLER (1994), *supra* note 10, at 101 (alluding to fears about seed registration schemes, expressed in connection with the legislative debate over the PVPA).

78. *Id.* at 81 (noting the 1897 passage of the first U.S. state seed law regulating seed naming and labeling).

79. A federal "Seed Importation Act" was passed in 1912 and was replaced in 1939, which then underwent various amendments through the 1950s, incorporating the certification principles that had been developed by the growers' associations. For the current Federal Seed Act, see 7 U.S.C. §§ 1551–1611 (2000). For an overview, see Janice M. Strachan, *Plant Variety Protection in the USA, in* TAXONOMY OF CULTIVATED PLANTS, *supra* note 60, at 67, 71; *see also* BUTLER & MARION, *supra* note 39, at 10–11 (providing a brief overview); FOWLER (1994), *supra* note 10, at 101 (briefly noting the evolution of the federal seed legislation from 1912 onwards); Cooke, *supra* note 76, at 544 (noting that after seed certification systems became widespread in the U.S. by the late 1930s, federal seed law borrowed ideas from those systems).

80. *E.g.*, Heitz (1994), *supra* note 62, at 24 (noting that proposals for seed certification legislation began to appear in European countries in the 1920s and 1930s).

81. For the definition of variety as currently employed in the Federal Seed Act, see 7 U.S.C. § 1561(a)(12) ("The term 'variety' means a subdivision of a kind which is characterized by growth, plant, fruit, seed, or other characters by which it can be differentiated from other sorts of the same kind . . . ."). It appears likely that the drafters of UPOV assumed that because the variety concept met the needs of registration systems, it would also serve the needs of a plant intellectual property system, an assumption that we think is worth reexamining.

In hindsight, at least, the notion of "variety" may also be understood as having served an additional function: it has operated as a legal construct to facilitate exclusions from utility patent protection, and, more broadly, to mediate between the subject matter provisions of various plant intellectual property regimes. In Europe, the variety concept has functioned as a way to express the exclusion from utility patent eligibility embodied in Article 53(b) of the European Patent Convention.[82] It is surely the case that the framers of both the UPOV and the European Patent Convention were aware of the use of the variety concept in legal texts,[83] and it is plausible to suppose that the framers concluded that the variety concept could serve as a politically feasible mechanism for avoiding conflict over patent protection for plants, a conflict that may have threatened to derail the European Patent Convention altogether. In the U.S., the variety concept had already been employed for a similar purpose in the Plant Patent Act of 1930, which extended to distinct "varieties" that had been asexually reproduced.[84]

There are significant points here about the design of plant intellectual property systems. First, these observations reinforce the point that designing the UPOV system around the variety concept was not an inevitable consequence of biology. It is predominantly a commercial and even legal construct that can (and should) be discarded when circumstances change. Second, they suggest that the desirability of designing an intellectual property system around the variety concept may change when the legal environment changes. For example, the shift in attitudes about utility patent protection for plants in the U.S. and Europe affects whether the variety concept should be retained as a mechanism for defining exclusions from utility patent protection. To date, the variety concept has not proven very effective as a mediating concept, either between PVP systems and utility

82. The Convention language provides that European patents shall not be granted "in respect of . . . (b) plant or animal varieties or essentially biological processes for the production of plants or animals . . . ." Convention on the Grant of European Patents art. 53(b), Oct. 5, 1973, 1065 U.N.T.S. 199, *available at* http://www.european-patent-office.org/legal/ epc/pdf/epc_2006_v5_bm_en.pdf.

Evidence that the variety concept continues to function as a boundary mechanism comes from debates in 1991 over the new definition of variety. Concerns were expressed in European patent circles that the variety concept in UPOV might be construed broadly to cover a plant cell line, simultaneously broadening the Article 53(b) exclusion from patent protection. Greengrass (1991), *supra* note 64, at 467.

83. One commentator alludes to the matter, albeit more benignly, observing that some of the experts who were involved in formulating European patent rules were also involved in the negotiations that led to UPOV, which ensured "a welcome coordination" between the two efforts. Heitz (1994), *supra* note 62, at 32.

84. Currently codified at 35 U.S.C. §§ 161–164 (2000). For background, see Cary Fowler, *The Plant Patent Act of 1930: A Sociological History of its Creation*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 621 (2000).

patents in Europe,[85] or between plant patents and other intellectual property regimes in U.S. plant patent law.[86] That should cause us to to reexamine whether the variety concept remains as compelling as the touchstone of plant intellectual property protection.[87]

3. Plants as Datasets

Our review of the origins of the variety concept persuades us that plant intellectual property systems need not be bound to that concept. Variety emerged as a term of convenience in the phenotype era; it may become an encumbrance in the era of genotype. Designers of future plant intellectual property systems will need to consider whether genotype concepts can be addressed within the existing framework,[88] or whether the variety concept should be discarded altogether as an organizing rubric.

Thus far, second-generation PVP systems have failed to show how the existing framework organized around the variety concept might be reconceptualized to accommodate genotyping data. For example, the currently prevailing definition of variety refers to genotype, but merely as an acknowledgment of the genetic basis for phenotypic characteristics.[89] Ef-

85. *See, e.g.*, Mark D. Janis, *Sustainable Agriculture, Patent Rights, and Plant Innovation*, 9 IND. J. GLOBAL LEGAL STUD. 91, 96–101 (2001) (discussing the ease with which patent lawyers can draft claims to avoid patent eligibility restrictions).

86. In *Imazio Nursery, Inc. v. Dania Greenhouses*, the alleged infringer argued that "variety" should be construed to extend only to clones of the patented plant, a meaning that purportedly derived from the "vernacular sense" of the term, while the plant patent owner argued that "variety" should be construed more broadly, allegedly consistent with the "technical, taxonomical sense" of the term. 69 F.3d 1560, 1565 (Fed. Cir. 1995). Finding no clear guidance in the legislative history of the Plant Patent Act, the court turned to other language in the statute, ultimately concluding that the asexual reproduction requirement "informs the scope of protection of plant patents and hence directs the meaning of 'variety' in [the Plant Patent Act]"—specifically, directing the meaning in favor of the defendant's definition. *Id.* at 1565–67.

87. *See supra* notes 8-9(citing pertinent U.S. and European decisions); *see also* Greengrass (1991), *supra* note 64, at 467 (providing background on the debate over the elimination of the dual protection ban from the 1991 UPOV).

88. We are certainly not the first to observe the problem. As one commentator pointed out more than a decade ago,

> In the light of increasing knowledge and possibilities of genetic engineering, it might be necessary to discuss a new definition of the term "variety." It might no longer be sufficient to define a variety by a set of about 25 morphological characteristics. It would rather be necessary to define it by its whole genome, represented in the standard sample of the variety.

Georg Fuchs, *The UPOV Approach to the Examination of Applications for Protection—Past, Present and Future, in* UPOV SEMINAR ON THE NATURE OF AND RATIONALE FOR THE PROTECTION OF PLANT VARIETIES UNDER THE UPOV CONVENTION 59, 63 (1991).

89. The definition does refer to genotype, specifying that a plant variety is a plant grouping which can be defined by "the *expression* of the characteristics resulting from a given genotype or combination of genotypes." UPOV (1991), *supra* note 6, art. 1(vi) (emphasis supplied). The term "expression" is understood as referring to the phenotypic manifestation of genetic qualities. For example, according to the European Patent Office, "[t]he reference to the expression of the characteristics that results from a given genotype or combination of genotypes is a reference to the entire constitution of a plant or a set of

forts to bring genotyping concepts fully within the DUS criteria also have not yet succeeded, as we discuss in the next section.

It is time for policymakers to recognize the prospect that the variety concept may become obsolete—or at least unhelpful—when the genotyping era matures.[90] In the future, it may prove more sensible for intellectual property purposes to conceptualize plants not as varieties, but as genetic datasets.[91]

This new organizing principle builds on a number of technological developments, most obviously on the development of molecular markers. In the late 1970s, seed companies began to analyze plant protein data as a way to discern the underlying genetic content of individual plants, initially for the purpose of monitoring genetic purity of commercially important inbreds and hybrids.[92] Effectively, the protein data constituted a first-generation set of molecular markers for plant breeders. By the early 1980s, however, tools had become available that allowed the direct manipulation of DNA relatively easily, leading to the development of another set of molecular markers: restriction fragment length polymorphisms ("RFLPs").[93]

This second generation of molecular markers has in turn been succeeded by subsequent generations of markers that rely upon advances in

genetic information." Case G 01/98, Novartis/Transgenic Plant, 2000 O.J. E.P.O. 111 (Enlarged Bd. App. 1999) (citing commentary on the EC Regulation on Community Plant Variety Rights).

Nevertheless, one commentator has pointed out that nothing in the text of the definition expressly precludes interpreting "expression" to include expression in the form of genetic data. Michael S. Camlin, *Plant Cultivar Identification and Registration—The Role for Molecular Techniques*, 625 ACTA HORTICULTURAE 37, 39 (2003) [hereinafter Camlin (2003)] (acknowledging that this is not a mainstream interpretation).

90. We disagree fundamentally with the proposition that there is little or no connection between technological evolution and the evolution of PVP systems. *Cf.* 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, 54 (1987) (claiming that "[p]aradoxically—and contrary to a quite widely-held opinion—scientific and technical progress in the field of genetics has played only a minor part in the growth of plant variety protection law").

91. There are many discussions of the analogy between biological and digital information. For one brief excerpt, see, for example, TIMOTHY M. SWANSON, THE INTERNATIONAL REGULATION OF EXTINCTION 255, 262–63 (1994). Just as plants may be reconceptualized as genotypic databases, others have recognized that pharmaceuticals can be reconceptualized as information products. *See* Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 717 (2005) ("Drugs are information-rich chemicals that in many respects are more akin to other information products (such as databases) than they are to other chemicals (such as industrial solvents).").

92. Smith, *supra* note 56, at 10 (explaining that protein characterization provides a fairly high discrimination among maize inbreds but is less successful for other crops, such as wheat and soybeans).

93. When a DNA sequence is treated with a restriction enzyme, the DNA is cut into fragments whose lengths are predictable based on the DNA's sequence. When another DNA having a slightly different sequence (a polymorphism) is treated with the restriction enzyme, the resulting fragments vary from the predicted lengths. In this way, RFLPs highlight DNA sequence variations. *See, e.g.*, T.A. BROWN, GENOMES 2, at 130 (2d ed. 2002) (briefly explaining RFLPs).

DNA amplification (notably the polymerase chain reaction),[94] high speed computing, and automation, among many other fields. Newer generation molecular markers of interest in plant genotyping include some that require DNA sequence data[95] and others that do not.[96] For example, important current work in plant genomic mapping centers around SNPs.[97] A given genome is likely to contain hundreds of thousands (or more) SNPs, subsets of which are likely to provide information about an individual plant's identity and traits.[98]

In the long term, molecular marker technologies may render the variety concept superfluous, an argument that we develop more fully in Section IV. More immediately, these technologies will impact determinations under the DUS criteria, as we discuss below.

94. For an accessible explanation of the PCR technique, see, for example, KARL DRLICA, UNDERSTANDING DNA AND GENE CLONING: A GUIDE FOR THE CURIOUS 153–57 (3d ed. 1997).

95. For example, simple sequence repeats ("SSRs"), also known as microsatellites, and single nucleotide polymorphisms ("SNPs"). *See generally* CHRISTOPHER A. CULLIS, PLANT GENOMICS AND PROTEOMICS 148–52 (2004) (briefly describing types of marker systems).

Since these markers depend upon knowledge of sequence information, their use has depended upon advancements in sequencing and mapping tools used to elucidate that information. Of the many relevant advances, one of particular interest in intellectual property circles is the expressed sequence tag ("EST"), a DNA fragment derived from complementary DNA that is capable of uniquely identifying a location within the genome. *See In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005) (describing ESTs). In addition to completed maps for the genomes of Arabadopsis and rice, plant genomics researchers have sequenced more than 105,000 wheat ESTs, and hundreds of thousands of corn ESTs. *See* Keith J. Edwards & David Stevenson, *Cereal Genomics*, 34 ADVANCES BOTANICAL RES. 1 (2001) (corn ESTs); Havey, *supra* note 57 (wheat ESTs).

96. For example, amplified fragment length polymorphisms ("AFLPs") and random amplified polymorphic DNAs ("RAPDs").

97. The term refers to a variation between individuals of a single nucleotide within a genome. KING & STANSFIELD, *supra* note 45, at 363. For an excellent technical review of the discovery and uses of SNPs in plant breeding, see Antoni Rafalski, *Applications of Single Nucleotide Polymorphisms in Crop Genetics*, 5 CURRENT OPINION PLANT BIOLOGY 94 (2002). For recent studies, see Jacqueline Batley et al., *A High-Throughput SNuPE Assay for Genotyping SNPs in the Flanking Regions of* Zea Mays *Sequence Tagged Simple Sequence Repeats*, 11 MOLECULAR BREEDING 111 (2003); Ada Ching et al., *SNP Frequency, Haplotype Structure and Linkage Disequlibrium in Elite Maize Inbred Lines*, 3 BMC GENETICS 19 (2002); Xiu-Qiang Huang et al., *Genetic Mapping of Three Alleles at the* Pm3 *Locus Conferring Powdery Mildew Resistance in Common Wheat (*Triticum aestivum *L.)*, 47 GENOME 1130 (2004) (describing SNPs for individual alleles in wheat conferring resistance to powdery mildew); I. Vroh Bi et al., *Single Nucleotide Polymorphisms and Insertion-Deletions for Genetic Markers and Anchoring the Maize Fingerprint Contig Physical Map*, 46 CROP SCI. 12 (2006).

98. SNPs rapidly displaced RFLPs in plant genomics, in part because SNPs are amenable to detection by way of high-throughput, readily automated genomics processes. *E.g.*, BROWN, *supra* note 93, at 130–33 (explaining how DNA chips and microarray technology, and solution hybridization techniques, are used to screen for SNPs). SNPs and RFLPs are related, albeit in a limited way. If an SNP lies in a sequence that contains a restriction site, then treating the sequence with a restriction enzyme might result in an RFLP, and so the SNP provides little additional information. However, in any given genome, it is suspected that most SNPs do not lie in sites that would be recognized by restriction enzymes—so SNPs are expected to provide vast amounts of information that RFLPs alone would not provide. *Id.*

B. DUS Testing: Genotype Concepts in Embedded Phenotype-Centered Rules of Protection

As we have seen, the concept of variety is essentially a legal (or commercial, pragmatic) conclusion about phenotypic characteristics. To reach that conclusion, PVP authorities apply the DUS rules. Accordingly, the DUS requirements figure prominently in an assessment of the obsolescence of PVP systems.

First-generation PVP systems made protection contingent on the variety satisfying requirements of distinctness, homogeneity, and stability.[99] The relevant provisions defined those requirements by reference to "characteristics" or "features"—i.e., phenotype.[100] For example, a variety was distinct if it was "clearly distinguishable by one or more important characteristics" from known varieties, those characteristics typically being "morphological or physiological characteristics."[101]

Second-generation PVP systems have retained this focus on phenotype by employing the rhetoric of "characteristics" in the definition of variety[102] and in the modern "DUS" requirements of "distinctness," "uniformity," and "stability." For example, the 1991 UPOV requires that a variety be distinct ("clearly distinguishable from any other variety," where variety is defined in terms of "characteristics"), sufficiently uniform in its "relevant characteristics," and stable "in its relevant characteristics."[103] The

99. For example, UPOV 1961 provided as follows:

> (a) . . . the new variety must be clearly distinguishable by one or more important characteristics from any other variety whose existence is a matter of common knowledge . . . . A new variety may be defined and distinguished by morphological or physiological characteristics. . . .
>
> (c) The new variety must be sufficiently homogeneous, having regard to the particular features of its sexual reproduction or vegetative propagation.
>
> (d) The new variety must be stable in its essential characteristics, that is to say, it must remain true to its description after repeated reproduction or propagation . . . .

UPOV (1961), *supra* note 4, art. 6(1). The 1970 U.S. PVPA employed a similar formulation, but substituted "uniformity" for homogeneity. 7 U.S.C. §§ 2401(a)(1)–(3) (1970) (current version at 7 U.S.C. § 2401 (2000)).

100. UPOV (1961), *supra* note 4, art 6(1).

101. *Id.*

102. *See supra* note 63.

103. Under the 1991 UPOV Act, the DUS criteria are contained in Articles 7–9: "The variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application." UPOV (1991), *supra* note 6, art. 7. "The variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in its relevant characteristics." *Id.* art. 8. "The variety shall be deemed to be stable if its relevant characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle." *Id.* art. 9.

U.S. PVPA contains analogous DUS rules[104] and separately defines distinctness in predominantly phenotypic terms.[105]

The rules and practices for implementing the DUS requirements confirm that the paradigm of phenotype fully permeates PVP systems. PVP authorities assess DUS either by reviewing the applicant's data[106] or by conducting tests themselves,[107] and the data overwhelmingly comprise phenotypic observations and measurements.[108] For the distinctness requirement, the information is used to determine whether the candidate variety differs from reference varieties in at least one characteristic.[109] To

104. The statute provides that a breeder shall be entitled to protection if the variety is both "new," 7 U.S.C. § 2402 (a)(1) (2000), and compliant with the DUS criteria, which specify that a variety must be

> (2) distinct, in the sense that the variety is clearly distinguishable from any other variety the existence of which is publicly known or a matter of common knowledge at the time of the filing of the application;
>
> (3) uniform, in the sense that any variations are describable, predictable, and commercially acceptable; and
>
> (4) stable, in the sense that the variety, when reproduced, will remain unchanged with regard to the essential and distinctive characteristics of the variety with a reasonable degree of reliability commensurate with that of varieties of the same category in which the same breeding method is employed.

Id. § 2402(a)(2)–(4).

105. Under the relevant "rule of construction,"

> 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.

Id. § 2401(b)(5).

106. UPOV IMPACT REPORT, *supra* note 7, at 28 (summarizing alternatives); UPOV, *General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants*, ¶ 1.1, UPOV Doc. TG/1/3 (Apr. 19, 2002) [hereinafter UPOV TG/1/3] (explaining that DUS can be assessed either by the applicant or by PVP authorities). In the U.S., the Plant Variety Protection Office requires applicants to submit a statement of distinctness, supported by evidence where the distinguishing characters are not readily detectable. *See* Plant Variety Prot. Office, Guidelines Exhibit B Statement of Distinctness, http://www.ams.usda.gov/science/PVPO/Forms/GuidelinesB.htm (last visited Apr. 18, 2007).

107. This approach predominates in European PVP systems, where varieties also must be tested for compliance with seed registration regulations. *See* Camlin (2003), *supra* note 89, at 40 (noting some differences between DUS assessments in the context of PVP systems and DUS assessments in the context of registration); Robert J. Cooke & James C. Reeves, *Plant Genetic Resources and Molecular Markers: Variety Registration in a New Era*, 1 PLANT GENETIC RESOURCES 81 (2003) (noting that the DUS requirements are also relevant to seed registration); Huw Jones et al., *The Management of Variety Reference Collections in Distinctness, Uniformity and Stability Testing of Wheat*, 132 EUPHYTICA 175 (2003) (commenting on the connection between variety protection and seed registration in Europe).

108. UPOV's 2002 *General Introduction to the Examination of Distinctness, Uniformity and Stability*, *supra* note 106, still speaks in terms of phenotypic characteristics, as we shall explain. *See also* Camlin (2003), *supra* note 89, at 46 (explaining that "[t]he basis for most technical examinations for the grant [of] Plant Breeders' Rights still remains a comparison of the morphology and physiology of the component plants of a candidate cultivar with appropriate reference cultivars" to assess DUS).

109. This is always true for "qualitative" characteristics, but true only sometimes for "quantitative" and "pseudo-quantitative" characteristics. Qualitative characteristics describe an independent state—e.g., sex of the plant—not a point on a continuous range. In contrast, quantitative characteristics do describe a point on a continuous range—e.g., whether a stem is short, medium, long, very long. Pseudo-qualitative characteristics are those that are only partly describable by continuous variation across a

apply such a standard, one must know which characteristics are deemed relevant and which methodologies are deemed appropriate for assessing differences. As to the identification of relevant characteristics, UPOV has developed guidelines for some 250 species, each listing phenotypic characteristics (typically fifteen to fifty for each species) that are deemed pertinent to distinctness assessments.[110] The guidelines articulate characteristics in subtle and minute detail.[111] As to the methodologies, although UPOV documents specify a variety of statistical methods for use in some circumstances,[112] in many circumstances distinctness assessments are performed visually,[113] perhaps over more than one growing cycle.[114]

PVP authorities also assess uniformity and stability by phenotypic criteria. The uniformity requirement calls for plants of the candidate variety to be no more likely to display phenotypic variation ("off-types") than a set of comparable reference varieties.[115] For self-pollinated and vegetatively

range—e.g., leaf shape. UPOV TG/1/3, *supra* note 106, ¶ 4.4. A difference in expression of at least one qualitative characteristic confers distinctness; a difference in pseudo-qualitative characteristics will have an effect specified in the relevant guidelines for the species; the effect of differences in quantitative characteristics is complex, and depends upon the methodology used and the features of the variety at issue. *Id.* ¶ 5.3.3.2.

110. Cooke & Reeves, *supra* note 107, at 82 (reporting that UPOV has produced guidelines for DUS testing in over 250 species); Fuchs, *supra* note 88, at 5 (referring to UPOV's efforts to establish technical guidelines for DUS examination); *see also* Rosselló, *supra* note 65, at 62–69 (describing the typical contents of test guidelines); F.A. van Eeuwijk & C.P. Baril, *Conceptual and Statistical Issues Related to the Use of Molecular Markers for Distinctness and Essential Derivation*, 546 ACTA HORTICULTURAE 35, 37 (2001) (noting that technical guidelines typically specify 15–50 characteristics for comparison).

111. Some are, quite literally, hair-splitting. *See, e.g.*, UPOV, *Guidelines for the Conduct of Tests for Distinctness, Uniformity and Stability: Barley*, at 11–15, UPOV Doc. TG/19/10 (Nov. 4, 1994) (listing twenty-nine characteristics for barley, including such seemingly obscure details as the Rachilla hair type (short or long); the ear attitude (erect, semi-erect, horizontal, semi-recurved, recurved), and the intensity of the anthocyanin coloration of the tips of the awns).

112. *E.g.*, UPOV TG/1/3, *supra* note 106, ¶ 5.5.3 (providing an overview of statistical methods usable for assessing measured characteristics).

113. *Id.* ¶ 5.4.1; Cooke & Reeves, *supra* note 107, at 82 (noting that DUS testing has traditionally relied upon direct phenotypic observation); van Eeuwijk & Baril, *supra* note 110, at 38 (visual assessments of distinctness commonplace for "genetically homogeneous" varieties). These visual assessments can be so intricate that authorities may need to resort to computer image analysis. *See, e.g.*, David Warren, *Image Analysis in Chrysanthemum DUS Testing*, 25 COMPUTERS & ELECTRONICS AGRIC. 213, 214 (2000) (proposing a software-based system for conducting morphological analysis of chrysanthemums, which are described by sixty-four characters, fifteen of which alone relate to leaf shape, leaf color, and leaf size).

114. van Eeuwijk & Baril, *supra* note 110, at 37. *See generally* UPOV, *Designing the DUS Tests*, UPOV Doc. UPOV/DATA/BEI/04/4 (May 19, 2004) (providing details on conducting grow-out tests for DUS evaluations).

115. UPOV, *Examining Uniformity*, ¶ 3, UPOV DOC. UPOV/DATA/BEI/04/8 (May 25, 2004) [hereinafter UPOV/DATA/BEI/04/8]. *See generally* UPOV TG/1/3, *supra* note 106, ch. 6. The language of the uniformity requirement specifies that a variety be "sufficiently uniform in its relevant characteristics," and UPOV practices hold that "relevant" characteristics for uniformity include at least those characteristics used for distinctness. *Id.* ¶ 6.2.

propagated crops, most uniformity assessments are done visually.[116] Stability—the requirement that a variety retain its distinct characteristics through a given number of propagation cycles—has little independent significance in current practice; stability is generally found when uniformity is established.[117]

The inadequacy of phenotype-centered DUS requirements is becoming more and more evident. Concerns are wide-ranging: (1) phenotypic observation is subjective[118] and costly,[119] (2) phenotypic characteristics are dependent on environmental interactions—a matter which may become more serious as PVP schemes begin to operate in new countries having climates that differ widely from traditional PVP jurisdictions,[120] and (3) distinctness assessments are becoming even more subtle as reference collections become larger and as marketplace pressures drive breeders towards incorporating very similar traits in phenotypically similar plants[121] that may be genotypically quite different.[122] Distinctness testing in soybean varieties provides a good illustration. Characteristics relevant to distinctness in soybeans have included flower color, "leaf shape, growth habit,

Uniformity is highly plant-specific. Variations that are considered allowable for, say, a cross-pollinated variety may not be allowable for a self-pollinated variety. UPOV/DATA/BEI/04/8, *supra*, ¶ 3; Jutta Rasmussen, *The UPOV Convention—The Concept of Variety and the Technical Criteria of Distinctness, Uniformity and Stability*, *in* UPOV SEMINAR ON THE NATURE OF AND RATIONALE FOR THE PROTECTION OF PLANT VARIETIES UNDER THE UPOV CONVENTION, *supra* note 88, at 51.

116. UPOV TG/1/3, *supra* note 106, ¶ 6.4.1.1. The idea is that these crops exhibit little variation, so off-types are relatively easy to spot visually.

117. *Id.* ¶ 7.3.1.1 ("[E]xperience has demonstrated that, for many types of variety, when a variety has been shown to be uniform, it can also be considered to be stable."); Rasmussen, *supra* note 115, at 57.

118. *E.g.*, Joelle Lallem, *New Techniques and Equipment for Variety Testing*, *in* UPOV REGIONAL SEMINAR ON THE NATURE OF AND RATIONALE FOR THE PROTECTION OF PLANT VARIETIES UNDER THE UPOV CONVENTION 49, UPOV PUB. NO. 722(E) 49 (1993) (noting "the subjectivity of scoring characteristics such as foliage colour or plant growth habit").

119. *E.g.*, G. Nuel, C. Baril & S. Robin, *Varietal Distinctness Assisted by Molecular Markers: A Methodological Approach*, 546 ACTA HORTICULTURAE 65 (2001). The need for multiple grow-outs is the main source of expense.

120. *E.g.*, Fuchs, *supra* note 88, at 62 ("The morphological characteristics commonly used for examination have the disadvantage that most of them are more or less susceptible to environmental conditions."); V. Lombard et al., *Genetic Relationships and Fingerprinting of Rapeseed Cultivars by AFLP: Consequences for Varietal Registration*, 40 CROP SCI. 1417 (2000) (noting the difficulty of distinguishing between intrinsic characteristics and those resulting from environmental stresses, especially over a limited number of grow-out tests); *see also* Camlin (2003), *supra* note 89, at 38 (pointing out that the problem of environmental interaction is likely to worsen with the expansion of PVP regimes into new jurisdictions).

121. Camlin (2003), *supra* note 89, at 38 (mentioning larger reference collections); Lombard et al., *supra* note 120, at 1417. Camlin also observes that phenotype-centered rules of the PVP system may not cohere with rules of the utility patent system, which are not framed by phenotype (and which stand to become the principal vehicle for the products of plant biotechnology). Camlin (2003), *supra* note 89, at 37. This observation is particularly important for assessing essentially derived varieties, which we take up *infra* Part III.

122. *See* references cited *infra* note 126.

maturity, and other conventional morphological and disease resistance traits."[123] Assessing differences in these characteristics is especially difficult because most commercial soybean products "arise from hybridization between members of an elite group of genotypes, and the amount of genetic variability between these cultivars is small."[124] In addition, it has been noted that these distinctions have become more difficult to draw as the number of varieties has increased.[125]

Even more fundamentally, a failure of phenotypic data to show distinctness may demonstrate a limitation of the methodology rather than a lack of genotypic difference. Today it is well established that phenotypic comparisons using traits that were specifically selected by UPOV for DUS purposes do not necessarily provide reliable estimates of genetic distance[126] or of agronomic performance potential.[127] Varieties can be similar in their PVP characteristics and yet still represent genetically different germplasm.[128] The genetic basis of phenotypic traits is proving to be more complex than previously assumed, with some traits of interest proving to be multigenic.[129]

PVP experts have recognized these problems for at least a decade. During that same time, molecular techniques that facilitate direct assess-

123. N. Diwan & P.B. Cregan, *Automatic Sizing of Fluorescent-Labeled Single Sequence Repeat (SSR) Markers to Assay Genetic Variation in Soybean*, 95 THEORETICAL APPLIED GENETICS 723, 724 (1997).

124. *Id.*

125. *Id.*

126. Judith Burstin & Alain Charcosset, *Relationship Between Phenotypic and Marker Distances: Theoretical and Experimental Investigations*, 79 HEREDITY 477 (1997); C. Dillmann et al., *Comparison of RFLP and Morphological Distances Between Maize* Zea mays *L. Inbred Lines. Consequences for Germplasm Protection Purposes*, 95 THEORETICAL APPLIED GENETICS 92 (1997); *see also* C. Rebourg, B. Gouesnard & A. Charcosset, *Large Scale Molecular Analysis of Traditional European Maize Populations. Relationships with Morphological Variation*, 86 HEREDITY 574 (2001). These references point out that phenotypic similarity may, for example, result from convergent evolution, rather than reflecting similarity in genotype. One illustration is the difficulty that breeders have long faced in maintaining uniformity of maize inbreds based solely on phenotypic criteria.

127. Instead, agronomic utility must be assessed using other types of phenotypic data that are predictive of agronomic performance, or marker data that are either agronomically useful or that demonstrate a close genetic or pedigree relationship to varieties of demonstrated agronomic utility.

128. *E.g.*, Tanksley and McCouch, *supra* note 44, at 1063 (noting that a parent judged to be phenotypically inferior might contribute superior alleles to its progeny). Approaches to breeding that rely solely upon phenotype reduce the effectiveness and limit the potential that could otherwise be achieved by plant breeding. While breeders have developed increasingly sophisticated procedures to make selection a more efficient process (for example, breeders now document and track pedigrees, make controlled pollinations using identified parents, and conduct replicated field trials and statistical analyses to reduce as much as possible the clouding effects of the environment), these procedures are still based upon direct selection of the phenotype (including yield data) acting as the surrogate to accomplish selection on the genotype.

129. This fact also creates problems for the enforceable scope of PVP rights, as we discuss *infra* Part III (concerning EDVs).

ments of genotype have developed rapidly, leading many observers to consider whether molecular techniques could be used for DUS assessments, potentially weaning the PVP system away from reliance on phenotype.

As a technical matter, the use of molecular techniques for DUS is possible, but many questions remain about implementation. The technical literature includes numerous studies on the use of molecular marker data for DUS testing. Early marker systems such as isozymes and seed storage proteins,[130] along with various electrophoretic methods,[131] were reported to be useful for DUS testing over a decade ago. More recent studies employ RAPDs,[132] AFLPs[133] and more current systems such as SSRs[134] STMS markers,[135] and SNPs.[136] In general, the technical literature expresses en-

130. Cooke & Reeves, *supra* note 107, at 83 (noting that isozymes and markers indicating seed storage proteins appear in the UPOV DUS testing guidelines for some crops (including, e.g., wheat and maize), but only as additional characteristics whose use is limited to prescribed circumstances).

131. M.S. Camlin, *Possible Future Roles for Molecular Techniques in the Identification and Registration of New Plant Cultivars*, 546 ACTA HORTICULTURAE 289, 292 (2001) (noting that UPOV accorded electrophoretic methods a limited role in DUS guidelines for wheat and barley in 1994); Jones et al., *supra* note 107, at 183 (recommending that electrophoretic characteristics be given equal stature with morphological characteristics to allow better management of reference collections).

132. *E.g.*, David Lee et al., *DNA Profiling and Plant Variety Registration: I. The Use of Random Amplified DNA Polymorphisms to Discriminate Between Varieties of Oilseed Rape*, 17 ELECTROPHORESIS 261 (1996) (use of RAPDs for DUS testing).

133. John R. Law et al., *DNA Profiling and Plant Registration. III: The Statistical Assessment of Distinctness in Wheat Using Amplified Fragment Length Polymorphisms*, 102 EUPHYTICA 335 (1998) (advocating the use of AFLP markers for distinctness testing in wheat, though noting that further research was needed to determine whether AFLPs would work properly for uniformity testing); Lombard et al., *supra* note 120, at 1424 (advocating the use of AFLP molecular markers for DUS testing in rapeseed).

134. Cooke & Reeves, *supra* note 107, at 83 (reporting on an EU-funded project that produced a standardized set of SSR markers for wheat and tomato varieties); Diwan & Cregan, *supra* note 123, at 729–30 (reporting that the USPVPO had already begun accepting "SSR allelic profiles as supporting evidence for the uniqueness of a new cultivar"); S. Giancola et al., *Feasibility of Integration of Molecular Markers and Morphological Descriptors in a Real Case Study of a Plant Variety Protection System for Soybean*, 127 EUPHYTICA 95 (2002) (advocating the use of SSR markers ombined with morphological characters for soybeans). Systems like that described in Diwan & Cregan still rely on morphological data as well.

135. G. Corbett et al., *Identification of Potato Varieties by DNA Profiling*, 546 ACTA HORTICULTURAE 387 (2001) (advocating the use of STMS—sequence tagged microsatellite analysis—for identifying potato varieties); N. Nandakumar et al., *Molecular Fingerprinting of Hybrids and Assessment of Genetic Purity of Hybrid Seeds in Rice Using Microsatellite Markers*, 136 EUPHYTICA 257, 260 (2004) (asserting that in the commercialization of hybrid rice in India, "the molecular fingerprinting of the hybrids and their parental lines assumes utmost importance for protecting the Plant Breeders' Rights (PBR)" and advocating the use of STMS markers for the task); R.K. Singh et al., *Suitability of Mapped Sequence Tagged Microsatellite Site Markers for Establishing Distinctness, Uniformity and Stability in Aromatic Rice*, 135 EUPHYTICA 135 (2004) (STMS markers for DUS testing in Basmati rice varieties); B. Vosman et al., *Standardization and Application of Microsatellite Markers for Variety Identification in Tomato and Wheat*, 546 ACTA HORTICULTURAE 307 (2001) (cautiously supportive); *see also* UPOV Off. of the Union, *Progress Report of the Technical Committee, the Technical Working Parties and the Working Group on Biochemical and Molecular Techniques and DNA-Profiling in Particular*, ¶ 111, UPOV Doc. C/36/10 (Aug. 13, 2002) [hereinafter UPOV C/36/10] (asserting that STMS markers are the most widely used for plant variety characterization).

thusiasm about the potential uses of molecular data for DUS, but also contains an undertone of caution about implementation complexities. Among many cited obstacles are concerns over standardization,[137] the appropriate choice of molecular marker systems, and the development of detailed technical protocols for employing those systems. Some conclude that molecular data should be used only as a supplement to phenotypic data.[138] Any large-scale program to adapt existing DUS examination to the paradigm of genotype is likely to present significant administrative costs.

The policy consequences of attempting to adapt current DUS standards to the paradigm of genotype are likewise mixed. The effect of substituting molecular data for phenotypic assessments of DUS is indeterminate. There are concerns that the use of molecular data might result in a lower threshold of distinctness if molecular data reveal many new bases for distinctness that are not readily discernable from phenotypic observation.[139] However, there are also concerns that the use of molecular data might drive the threshold for uniformity higher if molecular data reveal variations that present issues about the sufficiency of uniformity (issues that would have gone undetected in a regime of phenotypic assessments).[140]

In keeping with these ambivalent consequences, major stakeholders in the PVP system have acknowledged the potential utility of molecular datasets, but have expressed great caution about incorporating them into assessments of DUS. In 1993, UPOV established a Working Group on

136. *See supra* note 97 (describing SNPs and their use in plant breeding).

137. For example, on the difficulties of standardizing marker data for uniformity assessments, see UPOV Off. of the Union, *Progress Report of the Technical Committee, the Technical Working Parties and the Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular*, ¶ 21–22, UPOV Doc. C/34/10 (July 24, 2000) [hereinafter UPOV C/34/10] (observing that different assessment methodologies will be required for different marker sets, but proceeding to report that experts expressed optimism that uniformity could be measured effectively using molecular methods); R.J. Cooke et al., *Assessment of the Uniformity of Wheat and Tomato Varieties at DNA Microsatellite Loci*, 132 EUPHYTICA 331, 339 (2003) (explaining some of the complexities in standardizing marker data to be used for DUS testing, but still expressing optimism about the idea of using such data; focusing on the uniformity criterion).

138. *E.g.*, V. Lombard et al., *Genetic Distance Estimators Based on Molecular Data for Plant Registration and Protection: A Review*, 546 ACTA HORTICULTURAE 55, 62 (2001); *see also* G.P. Bernet et al., *Applicability of Molecular Markers in the Context of Protection of New Varieties of Cucumber*, 122 PLANT BREEDING 146, 151 (2003) (questioning the feasibility of using molecular markers alone for DUS testing in cucumbers and suggesting that marker data could be useful as a supplement in arranging field trials).

139. If distinctness becomes easier to establish, protection may be easier to obtain, but the scope of protection may be eroded. It may be easier for accused infringers to show that their variety is distinguishable from the protected variety, thus avoiding infringement liability. *See infra* Part III (dealing with the scope of PVP rights in the genotype era).

140. Variations in genotypic data introduced in the ordinary course of breeding would have to be managed more carefully, lest the variety be deemed not sufficiently uniform. *E.g.*, Smith, *supra* note 56, at 13.

Biochemical and Molecular Techniques (the "BMT" group) that has studied the use of molecular techniques for DUS testing.[141] At present, however, it seems clear that the BMT's work will not result in a substantial reduction in the role that phenotypic determinations play in DUS assessments. The BMT group considered three options for incorporating molecular data into DUS determinations: (1) using molecular data only as a predictor of a specific phenotypic characteristic; (2) using molecular data as the basis for calculating quantitative thresholds based on genetic distance that could be included in DUS assessments; and (3) devising a new system—e.g., one that would substitute molecular marker data for phenotypic characteristics, although the proposal envisioned that conformity as measured by the molecular characteristics would be supplemented by grow-out tests.[142] The group concluded that options (1) and (2) were acceptable, but were unable to come to consensus on option (3).[143] The seed industry has expressed both cautious support for aspects of BMT's work and resistance to it,[144] pointing out concerns about the complexity of relationships between phenotype and genotype,[145] alterations in the standards for distinctness and uniformity,[146] and the prospect of jeopardizing the scope of PVP protection,[147] and advocating a transition period should the decision be made to implement molecular data in DUS testing.[148]

141. *E.g.*, Camlin (2003), *supra* note 89, at 41.

142. UPOV C/36/10, *supra* note 135, ¶ 114 (describing the three options); Camlin (2003), *supra* note 89, at 44 (same).

143. Camlin (2003), *supra* note 89, at 44 (noting that as to Option 3, the BMT Review Group expressed concerns that "it might be possible to use a limitless number of markers to find differences between varieties" and that "differences would be found at the genetic level which were not reflected in morphological characteristics"); *cf.* UPOV Off. of the Union, *Progress Report of the Technical Committee, the Technical Working Parties and the Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular*, add. E ¶ 9, UPOV C/38/10 (Oct. 18, 2004) (agreeing that "it would be useful" to prepare a guidance document "on the planning of databases for molecular data based on different types of markers").

144. *See, e.g.*, Int'l Seed Fed'n, ISF View on Intellectual Property 4 (June 2003) [hereinafter ISF View (June 2003)], *available at* http://www.worldseed.org/pdf/ISF_View_on_Intellectual_Property.pdf ("ISF considers that DUS testing should continue to be based on phenotypic characteristics."); *see also* ASSINSEL, Position Paper on DUS Testing: Phenotype vs. Genotype (May 2000) [hereinafter ASSINSEL (2000)], *available at* http://www.worldseed.org/Position_papers/PhenotypeGenotypee.htm (same).

145. ISF View (June 2003), *supra* note 144, at 5 ("DNA marker profiles are not yet predictive of most phenotypic characteristics due to a lack of genetic linkage information or to the relatively complex genetic control of many phenotypic traits.").

146. *Id.* (referring to a "level of uniformity" that is different from the "variability in varieties which have satisfied current DUS standards").

147. In particular, ISF notes "[t]he risk of decreasing the minimum distance to an extreme" and expresses concerns over differentiating "between the concepts of distinctness and essential derivation when both of them are assessed using molecular markers" *Id.* We take up scope of protection issues in Part III.

All but absent in this debate is a recognition of the larger question: whether DUS should remain the "gold standard" for obtaining PVP rights.[149] Policymakers should recognize that (1) the DUS criteria are essentially artifacts of the paradigm of phenotype, rather than instrumental criteria well calibrated to stimulate innovation in plant breeding, and (2) the difficulties involved in incorporating genotype concepts into DUS rules reflect the shortcoming of the DUS rules, not merely the shortcomings of genotyping techniques as they are currently practiced. While first-generation PVP systems defined distinctness in terms of "important" characteristics,[150] PVP authorities quickly dispensed with the notion that "importance" required a showing of agronomic superiority, and ultimately eliminated the language from the distinctness standard to make clear that distinctness involved no inquiry into agronomic merit.[151] Current generation DUS requirements at their best can only seek to ensure that protected varieties are distinct (and uniform and stable) in their technical, phenotypic

Sentiments similar to those expressed in the 2003 ISF paper also appeared in an ASSINSEL position paper published in May 2000. Without ruling out the possibility of future DUS testing based on genotypic data, ASSINSEL concluded "that DUS testing should continue to be based on phenotypic characteristics," and offered the following rationales: (1) "It is preferable as far as possible that D, U and S can be recognized in the field"; (2) a phenotypic approach to DUS is more consistent with the 1991 UPOV definition, which refers to "expression" of the characteristics resulting from a given genotype; and (3) "ASSINSEL considers that the use of molecular markers for DUS testing could decrease the scope of protection when the goal, in fact, should be to strengthen protection." ASSINSEL (2000), *supra* note 144.

148. ISF View (June 2003), *supra* note 144, at 5; *see also* Camlin (2003), *supra* note 89, at 45 (observing that PVP authorities may need to implement transition periods or rules that combine molecular and phenotypic characteristics).

149. As Cooke and Reeves have put it,

> No attempt is being made to question whether this morphological 'Gold Standard' was, or is now, anything more than a pragmatic approach to infra-specific taxonomy adopted in the past because no other cost-effective tools were available. If the purpose of DUS testing is simply to find some way by which to declare two varieties different regardless of the biological meaning of that difference, then the current system is entirely satisfactory. If, on the other hand, PBR is a means of rewarding the outcome of a scientifically based plant breeding exercise by establishing an effective 'zone of protection' around a variety, based on relatedness and taking associations between varieties into account, then the system should be based on metrics which reflect these associations.

Cooke & Reeves, *supra* note 107, at 84.

150. *See supra* note 99 and accompanying text for the relevant language contained in 1961 UPOV Art. 6(1)(a). The initial version of the PVPA did not include the "importance" criterion, instead defining distinctness in terms of "identifiable . . . characteristics." 7 U.S.C. § 2401(a)(1) (1970) (current version at 7 U.S.C. § 2401 (2000)).

151. Greengrass (1991), *supra* note 64, at 468; *see also* IPGRI, KEY QUESTIONS FOR DECISION-MAKERS: PROTECTION OF PLANT VARIETIES UNDER THE WTO AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 14 (1999) (stating that the "importance" criterion in 1961 and 1978 UPOV did not require showing of commercial merit). Because agronomic merit varies so widely depending upon climate, economics, and other factors, UPOV authorities perceived an agronomic importance factor for distinctness to be untenable. Greengrass (1991), *supra* note 64, at 468. Phenotypic characteristics used for DUS determinations *might* be connected to agronomic merit, but the DUS criteria are not designed to guarantee agronomic merit.

sense, not in any sense of agronomic improvement.[152] If improvement was formerly the objective, then PVP systems, by elevating the DUS criteria to prominence, have long ago become unhinged from that initial objective.[153] The design of the DUS criteria virtually guarantees that PVP systems can play no more than a meager role in the improvement of plant varieties,[154] and this fact should call into question the heavy reliance on DUS requirements in existing PVP systems and the massive administrative expense of implementing those requirements, especially in European practice.[155]

PVP authorities should take greater heed of the profound lack of fit between the DUS rules and the paradigm of genotype. It is likely that the DUS criteria have outlived their usefulness. Adopted at a time when genotypic data did not exist, the DUS criteria supplied a mechanism—albeit an essentially artificial one not necessarily linked to agronomic merit—for distinguishing among plant varieties. But the criteria have outlived their

152. UPOV TG/1/3, *supra* note 106, ¶ 4.2.2. Nor is it realistic to suppose that the existing DUS scheme could simply be adapted to become a guarantor of agronomic importance. Quite to the contrary, with the extension of PVP systems to the diverse climates of the developing world, it is more unrealistic than ever to suppose that a unified notion of agronomic importance can be imposed.

153. There is a legendary 1920s-era anecdote on the divergence of phenotype and meritorious agronomic traits: a young Henry Wallace exploded the myth that certain visual characteristics of corn ears correlated with yield—and brought an end to popular "corn shows." *See* Merle T. Jenkins, *1936 Corn Improvement*, *in* USDA YEARBOOK OF AGRICULTURE 455 (1937) (explaining that in the corn show era, the ear was "regarded as a thing of beauty" and that farmers "more or less assumed that the characteristics associated with its beauty were of value from the standpoint of production . . . ."); *see also* H. A. Wallace, *What is in the Corn Judge's Mind?*, 15 J. AMER. SOC. AGRONOMY 300 (1923). Wallace would go on to master the production of hybrid corn, found the Pioneer Hi-Bred company (still the world's leading producer of hybrid corn seed), and occupy a central place in American agriculture in the twentieth century through his work as Secretary of Agriculture and Vice-President to Franklin Delano Roosevelt. *See* JOHN C. CULVER & JOHN HYDE, AMERICAN DREAMER: THE LIFE AND TIMES OF HENRY A. WALLACE (2000).

154. Notwithstanding recent claims that attribute variety improvement to the operation of PVP systems, UPOV IMPACT REPORT, *supra* note 7, § III, it would seem that the DUS requirements are likely no more capable of stimulating the development of "improved" plant varieties than the copyright laws are capable of spurring the creation of "improved" novels. Instead, the DUS requirements, at best, perform a role comparable to the originality requirement in copyright law. Consider the doctrine of originality in copyright law requires a showing that the putative author indeed did create independently the work at issue (that is, that the putative author indeed merits recognition as an "author") and that the work exhibits a trifling amount of creativity. Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., Inc., 499 U.S. 340, 345 (1991). This latter requirement is minimal; questions of the level of creativity are relevant, if at all, to considerations of scope. Accordingly, originality can serve the purpose of copyright law insofar as the purpose is to stimulate the proliferation of works, without regard to their artistic merit. Similarly, the best that can be expected of the DUS requirements is that they may stimulate the proliferation of plant varieties, without regard for the merits of those varieties. If this proliferation is independently of value—for example on the grounds that "more is better" for biodiversity purposes—then the DUS requirements may be accomplishing something, but only at substantial administrative cost. The copyright registration scheme, by contrast, expends almost nothing up front on close questions of originality. Those questions arise later in litigation, either over originality itself or over questions like scope of rights.

155. An expenditure which may increase with the availability of molecular marker data, given the complexities in incorporating that data into the DUS criteria, as we have discussed.

usefulness.[156] The paradigm of genotype calls for a different set of rules for obtaining PVP rights.

III. OBSOLESCENCE IN RULES OF SCOPE

Like the rules of PVP protection, the rules of PVP scope in first generation systems were designed around the concept of plant varieties, and thus were driven by assumptions about phenotype.[157] At the time, the concept of ownership of a variety (as opposed to ownership of an individual plant or seeds) was still new,[158] and the technical understanding required to control the genetics of a variety—by genetic recombination through basic breeding techniques—was still evolving.[159] Against this uncertain backdrop, first-generation PVP systems relied on a distinction between protected varieties and "other" varieties in order to establish PVP scope. Breeders could not reproduce the protected variety unless the PVP owner consented,[160] but breeders could use the protected variety for the purpose of creating "other" new varieties.[161]

156. Interestingly, PVP authorities have already edged away from the uniformity requirement, deeming it less important than distinctness. UPOV C/34/10, *supra* note 137, ¶ 21–22.

157. Plant breeders knew—at least since the rediscovery of Mendel's laws (in 1900)—that their goal was to develop improved genotypes. However, selection for yield and other criteria such as pest or stress resistance long remained dependent upon viewing or measuring morphological attributes of plants that are grown in the field or glasshouse. In the era dominated by phenotype, genotypic selection was indirect, practiced via the plant's physical appearance or performance in the field.

158. As Cary Fowler puts it, only a few years earlier, it was considered that "[s]eed could be owned, of course, but there was no way to own or control it *as breeding material*." FOWLER (1994), *supra* note 10, at 58.

159. Only a few years previously, fundamental breeding techniques like developing inbred lines were still considered experimental, and plant breeders had their hands full simply attempting to maintain the uniformity of desirable varieties. *Id.* at 49 (observing that even after the dawn of scientific plant breeding, a number of breeders still considered "varieties" to be mysterious and changeable). Through the mid-twentieth century, when first-generation PVP scope rules were being drafted, plant breeders had very little knowledge about the genotypic basis for phenotypic traits. For example, a 1960s plant breeding text stated, with an air of resignation, that "[q]uantitative genetic effects cannot generally be ascribed with certainty to particular loci and the number of loci controlling quantitative characters cannot be determined with any degree of precision." WATKIN WILLIAMS, GENETICAL PRINCIPLES AND PLANT BREEDING 35 (1964).

Today, plant breeders are beginning to understand that productivity gains in major crops result from a complex combination of effects, from improved husbandry (adequate soil fertility, weed control, and chemical control of pests and diseases) to changes in the genetic make-up of varieties. *See* Donald N. Duvick et al., *Changes in Performance, Parentage, and Genetic Diversity of Successful Corn Hybrids, 1930–2000*, *in* CORN: ORIGIN, HISTORY, TECHNOLOGY, AND PRODUCTION 65 (C. Wayne Smith, Javier Betrán & E.C.A. Runge eds., 2004); Donald Duvick et al., *Long-term Selection in a Commercial Hybrid Maize Breeding Program*, 24 PLANT BREEDING REVIEWS 109 (2004).

160. UPOV (1961), *supra* note 4, art. 5(1) (imposing liability for the unauthorized "production, for purposes of commercial marketing, of the reproductive or vegetative propagating material, as such, of the new variety, and for the offering for sale or marketing of such material.").

161. Specifically, competitors could use the protected variety without authorization "as an initial source of variation for the purpose of creating other new varieties or for the marketing of such varieties"

Unfortunately, these rules relied upon morphological indicia for determining what made a competitor's variety something "other" than the protected variety. Some breeders who sought to compete with PVP owners used "cosmetic" breeding practices to manipulate trivial phenotypic characteristics of the PVP-protected variety, creating a competing product while still evading the scope of PVP rights.[162] Alternatively, the downstream breeder might subject a PVP-protected variety to a conventional (non-biotechnology) breeding technique such as repeated backcrossing[163] to achieve a targeted gene insertion, again creating a competing but non-infringing product.[164]

It would have been plausible to respond to these cases by liberalizing the notion of the variety as it appeared in first-generation PVP infringement provisions. For example, a court faced with a PVP dispute could have ruled as a matter of statutory construction that plants that were only trivially different from the protected variety remained the variety—that is, did not qualify as some "other" variety. But this approach would have been in tension with the rules for granting PVP protection.[165] Under those rules, a variety could be distinct from preexisting varieties for purposes of obtaining protection based on differences in commercially trivial phenotypic characteristics.[166]

except "when the repeated use of the new variety is necessary for the commercial production of another variety." *Id.* art. 5(3).

162. Barry Greengrass supplies an example: a competitor might evade PVP rights in a red-flowered ornamental by inducing the protected plant to produce a slightly less-red mutant of the protected ornamental, then propagating the mutant without authorization. *E.g.*, Greengrass (1991), *supra* note 64, at 470.

163. Backcrossing refers to breeding progeny back to one of its parents. When carried out successively, it can be effective to add a gene of interest from the progeny to the parent. POEHLMAN & SLEPER, *supra* note 48, at 47, 172–75 (explaining the technique and illustrating its use).

164. For example, to evade PVP rights in a corn inbred, a competing breeder might first identify an unprotected variety having an unimportant trait (say, silk length) that differed from the protected inbred, then use repeated backcrossing to develop a variety having the silk length of the unprotected variety but all other characteristics of the protected inbred. *See* UPOV *The Concept of Essentially Derived Varieties, Annex to Model Law on the Protection of New Varieties of Plants* 146–47, UPOV Doc. No. 842(E) (1996) (identifying this example as a "plagiaristic" breeding practice) [hereinafter UPOV, *Model Law*]; ASSINSEL, Position Paper on Essential Derivation and Dependence: Practical Information 1 (1999) [hereinafter ASSINSEL, Practical Information], *available at* http://www.worldseed.org/Positionpapers/derive.htm (referring to the problems of "cosmetic" modifications to fruit and ornamental trees through mutations, and "'conversion' by repeated backcrossing of parental lines of hybrid varieties").

165. In principle, it is not problematic to create a set of intellectual property rules under which technology may be the subject of one party's valid intellectual property protection yet infringe another party's intellectual property rights. This happens frequently in patent law, where a pioneer may own patent rights and an improver may own separate patent rights. Nonetheless, this scenario seems to have been perceived as problematic in UPOV circles at the time.

166. *See supra* notes 100–05 and accompanying text.

Plant genetic engineering—even in its early stages—manifestly enhanced the efficiency of cosmetic breeding to avoid PVP rights. Rather than relying solely on conventional techniques like backcrossing, a breeder could use plant transformation techniques to insert a gene sequence into a PVP-protected variety, effectuating a cosmetic phenotypic variation more quickly and efficiently than previous techniques allowed. As the science of plant breeding continues to progress, largely though the development of methods of experimental design, the generation and use of marker-trait association data, the reduction of time to cycle from parents to progeny, and data analysis which provides an improved ability to select more effectively upon genotype, the potential for using molecular information to avoid PVP infringement increases.

Second-generation PVP schemes have attempted to respond by liberalizing the notion of variety legislatively, through recognition of essentially derived varieties ("EDVs"). Second-generation PVP schemes prohibit the copying of protected varieties, restrict the copying of varieties that are essentially derived from protected varieties, but otherwise allow competitors to use the protected variety to create competing varieties by invoking the breeder's exemption.[167] In this Part, we analyze the adequacy of the EDV provisions as a response to obsolescence, and we consider the effect of the continued maintenance of the breeder's exemption on PVP scope in light of advancing technology.

A. *Non-Literal Copying: The Problem of Essential Derivation*

The UPOV system's most salient response to technological obsolescence was to expand the scope of PVP rights through the concept of essentially derived varieties. Though hailed as a "striking innovation"[168] that was "unique to plant breeding,"[169] the EDV provisions and the debate surrounding them bear the familiar imprint of intransigent debates in patent law over non-literal infringement[170] and in copyright law over the distinction between unauthorized derivative works and transformative fair uses.[171]

167. *See infra* Part III.B..

168. *Plant Variety Protection Act Amendments of 1993: Hearing on S. 1406 Before the Senate Comm. on Agric., Nutrition, and Forestry*, 103d Cong. 6 (1993) [hereinafter *S. 1406 Hearing*] (statement of Kenneth C. Clayton, U.S.D.A.) (asserting that the creation of the EDV concept "is the most striking innovation in the 1991 revision of the UPOV convention").

169. Plant Variety Protection Act Amendments of 1993: Hearings on H.R. 2927 Before the House Comm. on Agriculture, 103d Cong. 72 (1994) (statement of Dietrich Schmidt, President, American Seed Trade Association).

170. For a sampling of current views from patent law scholars on infringement under the doctrine of equivalents, see, for example, Michael J. Meurer & Craig Allen Nard, *Invention, Refinement and Patent Claim Scope: A New Perspective on the Doctrine of Equivalents*, 93 GEO. L.J. 1947 (2005);

The EDV provisions, first appearing in the 1991 UPOV,[172] seem to concede the inadequacy of phenotypic characteristics for establishing the scope of PVP rights,[173] and purport to interject genotype concepts into the phenotype-based rule set.[174] The concept of variety remained intact,[175] and the breeder's exemption was retained, but the provisions changed the relationship between breeders of protected initial varieties and downstream breeders of varieties derived from those initial varieties.[176] The provisions established three conditions for determining whether a downstream variety constituted an EDV of an initial variety: the alleged EDV must be (1) predominantly derived from the initial variety, (2) distinguishable from the initial variety,[177] and (3) in conformity with the initial variety in "the ex-

Joshua D. Sarnoff, *Abolishing the Doctrine of Equivalents and Claiming the Future After* Festo, 19 BERKELEY TECH. L.J. 1157 (2004); John R. Thomas, *Claim Re-Construction: The Doctrine of Equivalents in the Post-*Markman *Era*, 9 LEWIS & CLARK L. REV. 153 (2005).

171. *See, e.g.*, Pierre N. Leval, *Toward a Fair Use Standard*, 103 HARV. L. REV. 1105 (1990); Mitch Tuchman, *Judge Leval's Transformation Standard: Can It Really Distinguish Foul from Fair?*, 51 J. COPYRIGHT SOC'Y U.S.A. 101 (2003).

172. The United States followed suit in 1994, amending the PVPA to recognize the EDV concept.

173. Cooke & Reeves, *supra* note 107, at 84–85 (noting that the introduction of EDVs was an acknowledgment that morphological characteristics alone cannot adequately provide a zone of protection under the PVP scheme).

174. *E.g.*, ASSINSEL, Statement Regarding The Implementation of the New Principle of Essentially Derived Varieties in the UPOV Convention (June 5, 1992), *reprinted in S. 1406 Hearing*, *supra* note 168, at 18, 19.

> In its principle, the concept of e.d.v. deals with the genotype rather than with the phenotype. Contrary to the principle of "clear distinctness" . . . being judged on the basis of the expression of certain morphological or physiological characteristics, [the e.d.v. provision] has to do with the question whether the essence of the genotype of the initial variety (i.v.) has been taken over . . . .

175. Rosselló, *supra* note 65, at 59 (observing that the EDV concept broadens the scope of PVP rights while leaving unchanged the concept of a variety).

176. EDV proponents also hoped that the provisions would facilitate mediation between the patent and PVP regimes. For example, suppose that *A* owns a utility patent claiming a gene construct and *B* owns PVP certificate on a variety. If *B* inserted *A*'s patented gene construct into *B*'s PVP'd variety without a license from *A*, *B* was subject to liability for utility patent infringement. But the reverse scenario—where *A* inserted *A*'s patented gene construct into *B*'s PVP'd variety—might not have subjected *A* to PVP infringement liability under a first generation PVP scheme. *A*'s variety would likely have been deemed "another" variety, and *A*'s activity would have been shielded under the breeder's exemption under the UPOV (1961) provisions, even if *A*'s variety conformed to *B*'s PVP'd variety in its essential characteristics. Greengrass (1991), *supra* note 64, at 471 (noting the concern). EDV proponents speculated that in a second-generation PVP scheme that extended protection to EDVs, the prospect that *A*'s variety would be deemed an EDV of *B*'s variety would bring *A* to the table to negotiate an exchange of licenses with *B*. *Id.* We are not aware of any empirical studies seeking to assess whether EDV provisions have, in fact, stimulated any significant patent/PVP licensing activity.

177. The existing provisions unnecessarily complicate the EDV inquiry by including distinctness as an affirmative element of proof. Presumably this element is included only as a way of conveying that the EDV inquiry need only be reached when the accused variety is distinct from the protected variety. The U.S. PVPA and UPOV (1991) should be reformulated to specify that notwithstanding its distinctness from the protected variety, a variety may still qualify as an EDV if the conditions of derivation and conformity are met. Early proposals for amending the PVPA apparently would have adopted the approach that we have suggested. The American Seed Trade Association ("ASTA") had proposed language that referred to varieties that were essentially derived from "but nonetheless clearly

pression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety."[178] The provisions then expanded PVP rights to encompass EDVs, but with a caveat: an EDV falls within the scope of the PVP rights of its underlying initial variety, but not of any intervening EDVs.[179] This principle of limited dependence, in effect, imposes a fourth condition:[180] the PVP-protected variety at issue must be an initial variety—that is, it must not itself be an EDV of some preexisting variety.[181] In sum, the EDV provisions create two levels of protection.

distinguishable from" existing protected varieties. *S. 1406 Hearing*, *supra* note 168, at 14 (statement of Dietrich Schmidt, President, American Seed Trade Association).

178. UPOV (1991), *supra* note 6, art. 14(5)(b); *accord* 7 U.S.C. § 2401(a)(3) (2000). The relevant language, as it appears in the U.S. PVPA, defines an EDV as a variety that

> (i) is predominantly derived from another variety (referred to in this paragraph as the "initial variety") or from a variety that is predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety;
> (ii) is clearly distinguishable from the initial variety; and
> (iii) except for differences that result from the act of derivation, conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

Id. § 2401(a)(3)(A). In addition to these express references to characteristics resulting from the genotype, the definition proceeds to provide an open-ended list of breeding methodologies that might result in the creation of an EDV:

> 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.

Id. § 2401(a)(3)(B); *see also* UPOV (1991), *supra* note 6, art. 14(5)(c).

179. UPOV (1991), *supra* note 6, art. 14(5)(a)(i); *accord* 7 U.S.C. § 2541(c)(1) (infringement liability shall extend not only to proscribed acts undertaken with protected varieties, but shall also apply equally to such acts undertaken with "any variety that is essentially derived from a protected variety, unless the protected variety is an essentially derived variety . . . .").

180. Some have characterized the inquiry into EDV status (involving conditions (1)–(3)) as a "technical" question, and the inquiry into dependence (involving condition (4)) as a "juridical" question. ASSINSEL, Practical Information, *supra* note 164, at 1. We doubt that the inquiries separate so neatly in practice. The determination of EDV status involves policy judgments, *see infra* notes 205–09 and accompanying text, and the juridical question of dependence may require resort to technical facts if there is a contest over whether the protected variety enjoys initial variety status.

181. *See* ISF View (June 2003), *supra* note 144, at 11. For example, consider varieties *A*, *A**, and *A***, where A is an initial variety, *A** is essentially derived from *A*, and *A*** is essentially derived from *A**. PVP rights in variety *A* extend to both *A** and *A***, because both are EDVs of *A*, and *A* is an initial variety. However, any PVP rights in *A** would not extend to *A***, because even though *A*** is an EDV of *A**, *A** is itself an EDV of a preexisting variety (*A*). *See* UPOV, *EDV Guidelines*, *reprinted in* INTELLECTUAL PROPERTY RIGHTS: PROTECTION OF PLANT MATERIALS app. 2, at 165–66 (P. Stephen Baensiger, Roger A. Kleese & Robert F. Barnes eds., 1993) (supplying multiple examples of the application of the dependency concept). That is, a cascade of derivation does not have the legal consequence of creating a cascade of dependence.

For views on the operation of the EDV rules in cases where the act of derivation occurs before the initial variety achieves PVP protection, see Int'l Seed Fed'n, Position Paper on Essential Derivation from a Not-yet Protected Variety and Dependency (June 2005), *available at* http://www.worldseed.org/Position_papers/ED&Dependency.htm (asserting that the initial variety owner should be entitled to provisional remedies for certain acts of derivation preceding the grant of PVP rights to the initial variety).

For a PVP-protected variety that is also an initial variety, PVP rights extend to the protected variety and to all EDVs, whether they are the immediate progeny of the protected variety or EDVs from subsequent generations. For a PVP protected variety that is not an initial variety (because it is the EDV of some preexisting variety), PVP rights extend only to the protected variety.

There are encouraging lessons to be drawn from the implementation of the EDV concept in existing PVP systems. For example, the industry is developing an infrastructure for alternative dispute resolution to support EDV determinations[182] and is articulating norms of conduct for breeding in specific crops.[183]

However, on the whole, the EDV concept as implemented so far has proven disappointing. First, while the EDV rules provide a platform for the use of molecular information in PVP scope determinations, that information is employed within a formalistic legal framework that requires inquiries that are so technologically complex that they present the risk of overwhelming, or at least masking, important underlying policy judgments. The troublesome conformity criterion illustrates this point.[184] Second, the EDV provisions operate on a well-intentioned, but flawed premise: that genotype concepts can be superimposed on rule structures that were designed on a foundation of phenotype. Experience with EDV provisions so far suggests that EDVs may bring about a modest inculcation of genotype data into PVP systems, but are not likely to serve as a springboard for reconceptualizing the overall model for PVP systems.

182. Int'l Seed Fed'n, *Procedure Rules for Dispute Settlement for the Trade in Seeds for Sowing Purposes and for the Management of Intellectual Property: Mediation, Conciliation, Arbitration* (July 2006), *available at* http://www.worldseed.org/pdf/DisputeSettlement_2006.pdf; Int'l Seed Fed'n, *Regulation for the Arbitration of Disputes Concerning Essential Derivation (RED)* (2005) [hereinafter *RED*], *available at* www.worldseed.org/pdf/EDV%20Arbitration%20Rules.pdf; Int'l Seed Fed'n, *Explanatory Notes: Regulation for the Arbitration of Disputes Concerning Essential Derivation (RED)* (2005), *available at* www.worldseed.org/pdf/Explanatory%20notes%20RED.pdf (noting that the RED and the Explanatory Notes were "drafted as a *Lex specialis*" of the general arbitration rules).

183. Int'l Seed Fed'n, *Guidelines for the Handling of a Dispute on EDV in Lettuce* (May 2002) [hereinafter *EDV Guidelines for Lettuce*], *available at* http://www.worldseed.org/Position_papers/guidelines%20EDV%20Lettuce.htm; Int'l Seed Fed'n, *Principles of a Code of Conduct in Essentially Derived Varieties of Perennial Ryegrass* (May 2002) [hereinafter *EDV Code of Conduct for Ryegrass*], *available at* http://www.worldseed.org/position_papers/code_conduct.htm; *see also* ISF View (June 2003), *supra* note 144 at 12 n.5 (reporting work towards the development of consensus genetic thresholds for maize, tomato, and oilseed rape).

184. *See infra* Part III.A.1.

1. Concerns About Conformity

Although the EDV provisions set out three conditions for EDV status (derivation, distinctness, and conformity),[185] it appears that future EDV disputes will turn primarily on the conformity condition.[186] Under the ISF's *Regulation for the Arbitration of Disputes Concerning Essential Derivation* ("*RED*"), if a PVP owner shows that an alleged EDV exhibits conformity with the protected variety, a prima facie case of essential derivation is established and the burden shifts to the alleged EDV breeder to rebut,[187] typically by showing that the alleged EDV fails the "derivation" condition (i.e., that it was not "predominantly derived from" the protected variety),[188] or alternatively by attacking the initial variety status of the protected variety.[189] The only reported litigation on EDVs, *Astee Flowers*,[190] also seems to center around a showing of conformity.[191]

185. *See supra* notes 177–78 and accompanying text.

186. This approach may help obviate concerns about defining the relationship between distinctness and conformity. *See* ISF View, *supra* note 144, at13–14 (expressing the concern). Distinctness is a measure of the *existence* of difference, under a rule that provides that if there is a difference in even one essential characteristic, distinctness is shown. Conformity for EDVs is a measure of the *extent* of similarity. If a variety Y differs in one essential characteristic of ten from a variety Z but is identical in the remaining nine, it is quite possible that variety Y is distinct from variety Z but is still in conformity with variety Z. In practice, the relationship is likely to be even more complicated, because the characteristics used for determining distinctness need not be the same characteristics used for determining conformity. *See* UPOV C/34/10, *supra* note 137, ¶ 29 ("reconfirm[ing]" that the assessment of EDVs—which effectively means the assessment of conformity—would not be restricted to the characteristics used for distinctness).

187. *RED*, *supra* note 182, art. 6.1; *see also EDV Code of Conduct for Ryegrass*, *supra* note 183, ¶ 4; *EDV Guidelines for Lettuce*, *supra* note 183, ¶ 5.

188. According to the ISF, the downstream breeder is in the best position to access its own breeding books or other evidence refuting predominant derivation, justifying the burden shift. *Explanatory Notes*, *supra* note 182, at 1 (asserting that predominant derivation is "difficult or impossible" for the PVP owner to prove); UPOV, *EDV Guidelines*, *supra* note 181, at 163–64 (downstream breeder in a "uniquely strong position to provide evidence" on derivation); *see also* M. Heckenberger, M. Bohn & A.E. Melchinger, *Identification of Essentially Derived Varieties Obtained from Biparental Crosses of Homozygous Lines: I. Simple Sequence Repeat Data from Maize Inbreds*, 45 CROP. SCI. 1120, 1120 (2005) [hereinafter Heckenberger I (2005)] (pedigree data will usually not be available to the PVP holder who wants to evaluate a suspected EDV).

189. That is, by arguing that the protected variety is itself an EDV of some prior variety.

190. Astee Flowers B.V./Danziger Flower Farm, KG 02/1014, 18 Oct. 2002 (Neth.) (provisional judgment), *abstracted in* PLANT VARIETY PROTECTION (UPOV, Geneva, Switz.), Dec. 2002, at 7.

191. *Id.* Notably, neither the *RED* nor the *Astee Flowers* decision places any significance in the distinctness criterion. In practice, the conformity requirement may well overlap with the derivation requirement. Direct evidence of derivation in intellectual property disputes is notoriously difficult to obtain. Plant breeding records for the accused variety might supply direct evidence that the protected variety was in the accused variety's lineage, but if the records are unreliable or nonexistent, courts may need to decide whether circumstantial evidence of derivation suffices. In copyright law, evidence creating an inference of the defendant's probable access to the protected material, plus substantial similarity between the accused and protected material, suffices for a circumstantial showing of copying. *See supra* note 23 (discussing copyright principles). In the EDV provisions, the existing requirement for conformity would seem to duplicate any substantial similarity requirement. A court might reasonably conclude from this that the derivation requirement in the EDV provision is satisfied merely by a show-

Most observers expect that the conformity assessment will rest on a quantitative inquiry. Under this approach, reflected in the *RED*[192] and other documents, the PVP owner is expected to provide conformity data demonstrating that the alleged EDV exceeds a predetermined, crop-specific threshold that reflects the initial variety's contribution to the alleged EDVs genome.[193] The threshold may be a single value—demarcating a fixed boundary between a "red" zone of presumptive EDV status and a "green" zone[194]—or it may be a range of values, defining a red zone above the upper end of the range, a green zone below the lower end, and an "orange" zone within the range where conformity is a matter of reasonable debate and must be resolved by further investigation.[195]

While the focus on a quantitative basis for assessing conformity might provide a natural entry point for molecular marker data[196] and may even provide a short-term solution to obsolescence problems, we have serious reservations about whether the EDV framework (and conformity in particular) provides a viable long-term solution for adapting PVP protection to the realities of the era of genotype. We base this assessment on a number of considerations. First, the technical literature reveals not only the lack of consensus in establishing threshold values for specified crops,[197] but also

ing that the propagating material of the protected variety was distributed widely enough to make it probable that the defendant had access to it. We suspect that this showing would be straightforward in many cases. The EDV provisions should be amended to clarify that circumstantial evidence of access suffices to show derivation.

192. *RED, supra* note 182, art. 2(e) (defining "EDV Threshold").

193. *Id.* art. 3. Where no predetermined threshold exists and the parties have not agreed to a threshold, the arbitral panel has discretion to decide what showing, if any, suffices to shift the burden to the downstream breeder. *Id.* art. 6.2.

194. *See, e.g., EDV Code of Conduct for Ryegrass, supra* note 183, ¶ 3 (establishing a single threshold); *EDV Guidelines for Lettuce, supra* note 183, ¶ 4 (same).

195. ASSINSEL, Practical Information, *supra* note 164, at 3–4 (proposing a three-zone hierarchy); *see also Explanatory Notes, supra* note 182, at 2 n.1 (reporting that maize growers have agreed to accept a three-zone hierarchy).

196. For a representative expression of enthusiasm, see, for example, R. Bernardo & A.L. Kahler, *North American Study on Essential Derivation in Maize: Inbreds Developed Without and with Selection from F2 Populations*, 102 THEORETICAL APPLIED GENETICS 986 (2001) (asserting that "[m]olecular markers have been generally accepted as a means for determining essential derivation"); *see also* Cooke & Reeves, *supra* note 107, at 85 (describing a prospective EU-funded data gathering project that will attempt to generate data on genetic distances for use in clarifying the EDV concept). Some have recommended the use of marker data for assessing EDVs in vegetatively propagated crop, where genetic profiles would be expected to have high degrees of relatedness due to the nature of asexual reproduction. *See* J. Ibanez & F.A. van Eeuwijk, *Microsatellite Profiles as a Basis for Intellectual Property Protection in Grape*, 603 ACTA HORTICULTURAE 41 (2003) (STMS markers); Ben Vosman et al., *The Establishment of "Essential Derivation" Among Rose Varieties, Using AFLP*, 109 THEORETICAL APPLIED GENETICS 1718, 1725 (2004) (recommends the use of markers for EDVs in rose mutants and argues for a 0.95 threshold).

197. Heckenberger I (2005), *supra* note 188, at 1120 (observing that EDV provisions do not define genetic thresholds, and that plant breeders have not developed a consensus on appropriate thresholds for specific crops); *see also* M. Heckenberger et al., *Identification of Essentially Derived Varieties Ob-*

questions about the normative desirability of establishing a fixed relatedness threshold for a given crop that would apply to the breeding of all traits into that crop, irrespective of whether those traits are single-gene discrete traits or multi-gene, quantitatively inherited traits.[198] Even if the concept of crop-specific threshold values were deemed acceptable, there remain the manifest technical difficulties in establishing and implementing threshold values, including difficulties concerning measurement standards and methods,[199] choice of technological tools and standards for using those tools,[200] and choice of overarching methodological frameworks for employing those measurement techniques and marker sets.[201] While it would be naive to

tained from Biparental Crosses of Homozygous Lines: II. Morphological Distances and Heterosis in Comparison with Simple Sequence Repeat and Amplified Fragment Length Polymorphism Data in Maize, 45 CROP. SCI. 1132, 1132 (2005) (reiterating these conclusions); ASSINSEL, Practical Information, *supra* note 164, at 4 (also noting that industry standards on genetic thresholds would not bind courts).

198. W. Lesser & M.A. Mutschler, *Balancing Investment Incentives and Social Benefits when Protecting Plant Varieties: Implementing Initial Variety Systems*, 44 CROP. SCI. 1113, 1117–19 (2004). Lesser & Mutschler propose that for discrete traits, if the downstream variety contains the trait, it should be deemed prima facie essentially derived from *all* ancestors containing that trait. *Id.* at 1119. That is, for such traits, Lesser & Mutschler would apparently eliminate the conformity assessment and would expand the principle of dependence beyond the initial variety to intervening varieties.

For complex traits, Lesser & Mutschler suggest using the existing EDV framework, but using a relatively low relatedness threshold to account for the fact that "complex, multigene improvements by definition involve more genetic differences than simple, single gene ones." *Id.*

The Lesser & Mutschler proposal focuses on fine tuning PVP incentives, but, like the existing EDV scheme, it could entail complex technical judgments and substantial administrative costs. We take Lesser & Mutschler to be arguing principally that the existing EDV scheme is unworkable, a proposition that we take seriously.

199. Int'l Seed Fed'n, Issues to be Addressed by Technical Experts to Define Molecular Marker Sets for Establishing Thresholds for ISF EDV Arbitration (2005), *available at* http://www.worldseed.org/pdf/Technical% 20rules%20EDV%20threshold.pdf (posing numerous questions concerning choices of sampling techniques, appropriate marker systems, statistical methods for measuring genetic distances, and other protocols). The ISF's regulation governing arbitration of EDV disputes confusingly provides that "each molecular method" used in EDV arbitration must "conform" to the ISF *Issues* paper. *RED, supra* note 182, art. 3(3). Since that paper merely presents questions, "conforming" to it is rather an odd requirement.

200. *E.g.*, Martin Heckenberger et al., *Variation of DNA Fingerprints Among Accessions Within Maize Inbred Lines and Implications for Identification of Essentially Derived Varieties: II. Genetic and Technical Sources of Variation in AFLP Data and Comparison with SSR Data*, 12 MOLECULAR BREEDING 97, 104–05 (2003) (recommending that AFLPs and SSRs be used as complements; otherwise breeders might "select for genetic diversity at some SSR markers to avoid an EDV, while maintaining a high degree of relatedness in other genomic regions"); *see also* Lombard et al., *supra* note 138, at 62 (advocating the use of markers, but only when combined with morphological data, to develop genetic distance estimators; suggesting that this might be achieved "by searching for molecular markers linked to the variation of morphological traits (QTL) or involved in the expression of these characters (EST)"); Ibanez & van Eeuwijk, *supra* note 196 (assessing the use of STMSs for grape characterization, with the objective of using such protocols to show infringement or EDVs).

201. For example, Heckenberger et al. advocate the use of SSR markers to set genetic thresholds for assessing EDVs by revealing pedigree relationships, in contrast with the methodology employed in the *EDV Code of Conduct for Ryegrass*, where EDV thresholds would be based on percentiles of the distribution of genetic distance values in a reference set of germplasm. Heckenberger I (2005), *supra* note 188, at 1130 (asserting that the choice of elite varieties for a reference set may involve too much

suggest that these problems could be avoided altogether in a newly designed genotype-centered intellectual property regime, they are critical in a regime like PVP, which requires the elucidation of precise boundary lines to define the scope of the protected subject matter.[202] There is some evidence that the scale and complexity of the project to use EDVs to delineate PVP scope is becoming apparent in the plant breeding community as initial enthusiasm about EDV provisions is giving way to more sober reflection about the costs and challenges that EDVs entail[203] and to more searching questions about the incentive effects of EDVs.[204]

The technical complexity of the conformity inquiry, and the intransigence of the technical issues bound up in implementing that inquiry, suggest that EDVs will be costly to administer. But these factors also present a second, more subtle problem: the enterprise of wading through the technicalities of conformity may become an end in itself, lending false objectivity to what is actually a subjective value judgment[205]—a "'gentleman['s] agreement' between breeders and [government] authorities" rather than a "statistical question[]."[206]

The debate over EDVs for maize illustrates the subjectivity concern. One pertinent article advances arguments for minimum threshold values of 90%, reasoning that major corn breeding firms all started with materials from the same public breeding programs, so that there is already a high

subjective judgment). Hybrid crops pose additional challenges. *See Explanatory Notes*, *supra* note 182, at 3 (pointing out that derivation is not practiced directly from a hybrid, but rather from the hybrid's parents, and suggesting that the EDV assessment must be adjusted accordingly to focus on derivation from the hybrid's parents).

202. By contrast, as we suggest *infra* Part IV, in a regime that focuses on acts of misappropriation, a complex inquiry like conformity would be less important.

203. van Eeuwijk & Baril, *supra* note 110, at 51 (arguing that "[i]n the early days of the essential derivation concept it was believed that genetic similarities as calculated from marker information could straightforwardly be interpreted as estimators of pedigree relations," but suggesting that this initial enthusiasm was unfounded despite the emergence of various proposed genetic distance methodologies, and concluding that "it still seems that approaching essential derivation via genetic relatedness creates prohibitive complications").

204. For example, Lesser & Mutschler point out that because the EDV rules provide only for limited dependence—that is, no cascading of dependence, such that any given variety is only deemed dependent on an initial variety, not any intervening varieties—EDV rules might not provide satisfactory incentives where the breeding enterprise involves "pyramiding"—breeding new varieties that add traits to the initial variety. Lesser & Mutschler, *supra* note 198, at 1117. Applied to this scenario, EDV rules might overcompensate initial variety developers while undercompensating breeders of intervening varieties. Lesser & Mutschler also express concerns that EDV rules might systematically undercompensate breeders who are enhancing germplasm (i.e., moving a discrete trait from a wild variety to a finished variety). *Id.*

205. UPOV, *EDV Guidelines*, *supra* note 181, at 161 (the conformity condition of the EDV analysis "primarily calls for a value judgment").

206. Lombard et al., *supra* note 138, at 61.

level of background relatedness.[207] Regardless of the weight to be attributed to this argument, the choice of 90% as the precise quantitative standard was not apparently based on any quantitative calculations, but instead on a value judgment: the paper simply concluded that 90% "seems appropriate."[208] Others have called for 70–80% relatedness thresholds.[209]

If, as we suggest is the case, EDV determinations are ultimately driven by subjective judgments, we question the wisdom of a system that requires those judgments to be buried beneath a blizzard of intricate quantitative assessments that can only be undertaken at considerable cost. In our view, this approach has it backwards; a better model would make explicit the governing subjective factors, and would allow parties to resort to quantitative evidence as one type of evidence that assists in establishing the existence or non-existence of those subjective factors.

2. Continued Predominance of Phenotype

Although the EDV rules appear on the surface to provide a mechanism for adapting phenotype-bound scope rules to the genotyping era, the *Astee Flowers* decision suggests that phenotypic characteristics will continue to drive the scope analysis. Danziger owned Community plant variety rights in a variety called "Million Stars,"[210] and its competitor Astee introduced a variety called "Blancanieves," which Danziger alleged was an EDV of Million Stars.[211] In litigation, both parties offered molecular marker evidence. Danziger's tests showed a difference in markers of 5 out of 214, or 2.3%; Astee's tests showed a difference of 12 out of 133, or 9%. Astee had also procured expert statements detailing phenotypic differences between the disputed varieties and questioning the methodology used in Danziger's marker tests.

In summary proceedings, the court ruled that Danziger had failed to make a plausible case for the existence of an EDV.[212] The court found it significant that both parties' genetic tests showed that "the genotype of

207. A. Forrest Troyer & Torbert R. Rocheford, *Germplasm Ownership: Related Corn Inbreds*, 42 CROP SCI. 3, 9 (2002) (also arguing that royalties payable for EDVs should extend only for five years).

208. *Id.*

209. Bernardo & Kahler, *supra* note 196, at 988 (calling for a 70–80% relatedness threshold for maize).

210. A Gypsophila, known commonly as "baby's breath."

211. Danziger distributed letters to the trade alleging that Blancanieves was a mutant of Million Stars. In response, Astee initiated summary proceedings in the Netherlands, seeking various orders in connection with the letters, and Danziger counterclaimed for infringement, thus placing the merits of the EDV allegation in issue. Astee Flowers B.V./Danziger Flower Farm, KG 02/1014, ¶¶ 1–2, 18 Oct. 2002 (Neth.).

212. *Id.* ¶ 4.12.

Blancanieves differs from that of Million Stars,"[213] but the court did not elaborate on the point. That is, the court did not accept any particular quantitative threshold value as defining a forbidden "red zone," a judgment that might have taken the court into the intricacies of the genotyping evidence.

Instead of the anticipated quantitative assessment focusing on conformity, the court's impressions of the phenotypic evidence seemed to drive the conclusion.[214] The court accepted that "the phenotype of Blancanieves differs from that of Million Stars regarding a number of points including plant height, branching, length of the flower stem and diameter of the flower" and considered it relevant that "Blancanieves was found to have no stamens while Million Stars did have stamens."[215] Provisionally, the court ruled that the identified phenotypic characteristics were "essential characteristics, resulting from the hereditary material of Blancanieves and which are not present in Million Stars."[216] Thus, where phenotypic characteristics are used to establish conformity and thus to trigger a presumption of EDV status,[217] genotype evidence may well be relegated to a role (if any) as a potential source of rebuttal evidence on derivation.[218] The EDV exercise may collapse back to predominantly phenotypic comparisons.

We think that the effort to continue to work out guidelines for employing or accounting for molecular techniques in EDV adjudication is a hard path. We applaud these efforts as a short-term fix, but we think that ultimately it will be determined that a genotype-centered EDV concept, even if it could be designed, would still be incompatible with the regime of phenotype-centered rules.

B. *The Breeder's Exemption and the Erosion of Natural Lead Time*

The consequence of extending PVP protection in second-generation PVP systems to EDVs was necessarily to narrow the range of downstream breeding activities allowed under the breeder's exemption.[219] But the policy commitment to the breeder's exemption remained, and the 1991 UPOV

213. *Id.* ¶ 4.11.

214. Danziger had argued, apparently as a matter of law, that phenotypic differences were irrelevant to the EDV determination. *Id.* ¶ 4.10. This position would be difficult to square with the language of the EDV provisions, *supra* note 178, which calls for conformity "in the *expression* of the essential characteristics that result from the genotype . . . ." (emphasis supplied).

215. *Astee Flowers*, KG 02/1014, ¶ 4.11.

216. *Id.*

217. ISF View (June 2003), *supra* note 144, at 12 (assessment of the conformity requirement "could be based on reliable phenotypic characteristics").

218. *Id.*

219. *E.g.*, HELFER, *supra* note 3, at 16 (asserting that the implementation of EDVs has had the effect of narrowing the breeder's exemption and expanding the rights of first-generation breeders).

language amplified the importance of the exemption by housing it in an article separate from the infringement provisions.[220] The 1991 UPOV Diplomatic Conference "strongly reaffirmed" the breeder's exemption[221] and insisted that the incorporation of EDVs did not undermine the exemption.[222] As recently as 1999, the leading industry group remained officially of the view that the breeder's exemption is "essential for continued progress from plant breeding."[223]

Implicitly, at least, the breeder's exemption in both first and second generation PVP systems has always attempted to accommodate twin competing aspirations. First, reflecting the inherently cumulative nature of plant breeding, the breeder's exemption signifies a desire to provide downstream breeders with access to existing PVP-protected germplasm in order to breed new varieties. According to UPOV, the existence of the breeder's exemption "optimizes variety improvement by ensuring that germplasm sources remain accessible to all the community of breeders" while it also "helps to ensure that the genetic basis for plant improvement is broadened and is actively conserved, thereby ensuring an overall approach to plant breeding which is sustainable and productive in the long term."[224]

Second, the breeder's exemption, taken in concert with the infringement provisions and the provisions establishing the term of PVP protection, aspires to provide innovation incentives to breeders by offering the promise of a commercially meaningful scope and period of exclusivity. In theory, these provisions would incorporate a set of expectations about the commercial realities of plant breeding, including considerations of the *de facto*

220. UPOV (1991), *supra* note 6, art. 15(1)(iii).

221. Greengrass (1991), *supra* note 64, at 471.

222. *E.g.*, FOOD & AGRIC. ORG. OF THE UNITED NATIONS, MULTILATERAL NEGOTIATIONS ON AGRICULTURE: A RESOURCE MANUAL § 5.2.4 (2000), *available at* http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/003/x7355e/x7355e05.htm (observing that the breeder's exemption under UPOV 1991 does not apply to the breeding of essentially derived varieties, but noting that "the free availability under the 1978 Convention of the underlying genetic resource embodied in a protected plant variety for the purpose of breeding is reaffirmed in the 1991 Convention").

223. ASSINSEL, Practical Information, *supra* note 164, at 1.

224. UPOV, The UPOV System of Plant Variety Protection, http://www.upov.int/en/about/upov_system.htm (last visited Apr. 29, 2007) (discussing Article 15 of the 1991 UPOV); *see also* UPOV, Statement on the Breeder's Exemption (Dec. 6, 2004), http://www.upov.int/en/about/pdf/breeders_exemption.pdf (official explanation dated December 6, 2004, concerning the breeder's exemption, the explanation being "intended to clarify that the authorization of the breeder for the use of protected varieties for breeding purposes is required neither under the 1978 Act nor under the 1991 Act"); ISF View (June 2003), *supra* note 144, at 8–9 ("The objective of the breeder's exception is to give access to PVPed genetic resources that are commercially available allowing their use for further breeding.").

Perhaps the continued veneration of the breeder's exemption should not come as a surprise. Jim Chen has pointed out that the breeder's exemption seems to have grown from "a romantic vision of innovation" in which individual plant breeders freely exchanged germplasm with the objective of developing improved varieties "for the good of agriculture." Chen, *supra* note 3, at 138.

commercial lifetime of protected variety,[225] which in turn includes considerations of natural lead time—the time it takes for downstream breeders to use the protected variety to develop competing varieties—enjoyed by a PVP owner.[226]

Despite the longstanding expressions of faith in the breeder's exemption, it has never been clear that the coupling of a robust immunity for competing breeders with PVP-style infringement provisions is effective to achieve either the access or incentive aspirations. Moreover, the technological shift from phenotype-driven to genotype-driven breeding practices, along with other legal changes, presents a risk of compromising the effectiveness of PVP systems, particularly as applied to the cereal crops.

As to the access aspiration, the breeder's exemption has always been premised on the assumption that downstream breeders would have access to PVP-protected seed, but nothing in the PVP rules guarantees that access. There is no requirement that a PVP owner deposit seed in an accessible depository, nor is there any rule analogous to utility patent law's "enablement" requirement.[227] It has simply been assumed that a PVP owner would commercialize the PVP-protected variety, and downstream breeders could access the variety through usual commercial channels.

Whether that assumption is warranted depends upon the individual proclivities of PVP owners. The assumption has become especially questionable, however, in second-generation PVP systems extending PVP protection to hybrids. Because the PVP owner is not obliged to provide an "enabling" teaching of the hybrid, the owner need not release the parental lines of the hybrid. Even if the PVP'd hybrid is commercially released, such that a competing breeder may access it and attempt to breed a distinct

225. As Koo et al. point out, relevant considerations include the size of the seed market for a particular crop, the commercial success of the particular variety, and varietal obsolescence (biological or planned). Koo et al., *supra* note 13, at 4–6. Regulatory delays experienced by both the original and downstream breeders also are relevant. On the outcomes of such calculations for particular crops, see, for example, *Proposed Amendments to the Plant Variety Protection Act: Hearing Before the House Comm. on Agric.*, 101st Cong. 9 (1990) (statement of Owen J. Newlin, Senior Vice-President, Pioneer Hi-Bred Int'l, Inc.) ("A new variety has a useful life of about 6 years."); RICHARD J. PATTERSON, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE, OFFICE OF TECHNOLOGY ASSESSMENT CONTRACTOR DOCUMENTS, PART 3, at 27–28 (1988) (asserting that in the late 1980s, the commercial life of a typical corn hybrid variety was 6–8 years, with exceptional varieties remaining commercially viable for 10–20 years, and some inbred lines having a much longer commercial life); *id.* at 36 (asserting that expected cultivar lifespans for wheat grown during the mid- to late-twentieth century were about 5–9 years).

226. *Cf.* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989) (outlining the key elements of a policy analysis of the experimental use exception in utility patent law).

227. *See* Janis & Kesan (2002), *supra* note 3, at 747–48; *see also* Chen, *supra* note 3, at 139–54 (analyzing the access question in detail).

hybrid variety from it, this is likely to be less efficient than accessing the parent line and breeding a distinct parent line from it.[228] Recognition of this problem has prompted some calls for reform.[229]

In our view, however, the greater threat—perhaps the most serious threat to PVP systems in the area of grain crops—is the threat that new genomics technologies will allow downstream breeders, operating under the breeder's exemption, to so erode the *de facto* lead time provided by the PVP system that any PVP incentives will be seriously diminished. When first-generation PVP systems were created, notwithstanding the breeder's exemption, PVP owners enjoyed a *de facto* exclusivity period because it took downstream breeders time—perhaps ten years—to breed a finished variety out of the protected variety.[230] That is, the breeder's exemption, understood in its contemporary technical context, amounted to a judgment about the appropriate amount of inherent lead time that PVP owners would enjoy against others who would undertake breeding activities with the protected variety under the exemption.

Second-generation PVP systems have retained the breeder's exemption, but the co-deployment of genomics techniques with breeding techniques such as doubled haploids (a practice which reduces recombination and dramatically increases the speed with which new inbred lines or varieties can be created) and more widespread use of off-season nurseries (allowing multiple generations of plants per year) significantly alters the balance between PVP owners and downstream breeders. Genomics techniques and new breeding strategies will facilitate access to germplasm that was previously protected by the biology of hybrids, and also will reduce significantly the time it takes to breed new varieties, thus substantially reducing the *de facto* lead time that the PVP owner would have enjoyed in a pre-genomics age.[231] For example, by employing a marker-assisted selec-

228. ISF View (June 2003), *supra* note 144, at 8–9.

229. Richard L. McConnell, *Developing Genetic Resources for the Future: The Long Look*, 7 BIO-SCIENCE L. REV. 57, 59 (2004) (suggesting that UPOV be amended to provide "assured access to seed deposits for all varieties").

230. It was understood that "[t]he breeder may often spend years creating a breeding program to develop a new variety." *Proposed Amendments to the Plant Variety Protection Act: Hearing Before the Subcomm. on Dept. Operations, Research, and Foreign Agric. of the House Comm. on Agric.*, 101st Cong. 30 (1990) (statement of Jerome J. Peterson, President, American Seed Trade Association); H.R. REP. NO. 96-1115, at 4 (1980); *see also* BUTLER & MARION, *supra* note 39, at 5 (estimating that "[n]ew varieties can take 10–12 years, and sometimes as long as 20 years, to develop").

231. Heckenberger I (2005), *supra* note 188, at 1120 ("The advent of new methods such as genetic engineering and marker-assisted backcrossing, however, has provided the basis to undermine the breeder's exemption in its original intention."); William Kingston, Repairing Incentives to Invest in Plant Breeding (unpublished manuscript, on file with authors) (same); *see also* Reichman, *supra* note 1, at 2452 (noting the problem in general that "today's innovators often lack the natural lead time that

tion technique that uses "a large number of molecular markers that cover the plant's entire genome," a downstream breeder can identify which individual PVP-protected plants "contain the largest contribution of genetic material from the recurrent recipient line," allowing the breeder to introduce a new desired allele in fewer generations of breeding.[232] Also emerging are new "reverse breeding" techniques in which the downstream breeder employs molecular marker and transgenic technologies (and other techniques) to recreate the performance of existing varieties using less recombination and segregation than conventional techniques use, but still enough recombination of parental lines to provide an argument against EDV status.[233]

Recognizing these concerns, some in the plant breeding industry now advocate the development of phased-in, crop-specific breeder's exemptions.[234] For example, Rick McConnell has recommended a phased-in breeder's exemption for maize that would (1) establish a first phase of ten years from the PVP application filing date during which no breeder's exemption would apply, and (2) establish a second phase, from the end of the first phase through PVP expiration, in which breeders could operate under the exemption if they complied with recording requirements.[235]

enabled innovators in the past to secure a place in the market and to recoup their costs of research and development").

232. CULLIS, *supra* note 95, at 163; *see also* Smith, *supra* note 56, at 13–14. Developments in the study of complex (quantitatively inherited) traits, particularly the mapping of quantitative trait loci ("QTLs") have greatly enhanced the breeding process. Tanksley & McCouch, *supra* note 44, at 1065 ("Often a substantial portion of the genetic variation of a population can be explained by a few QTLs of moderately large effects."). QTLs can be identified and marker-assisted selection can be used to remove undesirable alleles that are in the vicinity of the QTL. Smith, *supra* note 56, at 13. For a literature review, see Trudy F.C. Mackay, *The Genetic Architecture of Quantitative Traits*, 35 ANN. REV. GENETICS 303 (2001); *see also* CULLIS, *supra* note 95, at 152–60 (detailed technical discussion and example).

The view that molecular-enhanced breeding techniques will offer more rapid progress than conventional breeding is widely held, but does have its detractors. *See, e.g.*, Major M. Goodman, *Plant Breeding Requirements for Applied Molecular Biology*, 44 CROP. SCI. 1913 (2004) (asserting that "[p]lant breeding is unlikely to be radically altered by genetic engineering despite progress in genomics" because it will still take over a decade on average to incorporate a new gene into a commercially successful cultivar).

233. Smith, *supra* note 56, at 16. Generally, as plant genetic sequences become better characterized through the use of genomics techniques, researchers are using those sequences (or induced mutations to them) to predict phenotypic characteristics—an exercise in "reverse" genetics. For a relevant review, see Steven Henikoff & Luca Comai, *Single-Nucleotide Mutations for Plant Functional Genomics*, 54 ANN. REV. PLANT BIOLOGY 375 (2003).

234. McConnell, *supra* note 229, at 59–60 (describing the second phase as allowing "organised and recorded access for breeding"); News Release, Am. Seed Trade Ass'n, Position Statement on Intellectual Property Rights for the Seed Industry ¶ 10(d)(iii) (July 15, 2004), *available at* http://www.amseed.com/ newsDetail.asp?id=97 (advocating revisions to the breeder's exemption to include a predetermined period, varying by crop, during which the exemption would be unavailable).

235. McConnell, *supra* note 229, at 60; *see also* Michael A. Kock, Susann Porzig & Eva Willnegger, *The Legal Protection of Plant-Biotechnological Inventions and Plant Varieties in Light of the EC*

Proposals of this sort have the merit of addressing directly the diminution of lead time by conferring an absolute exclusivity period on PVP owners. But they operate on the premise that the existing model of infringement provisions coupled with exemptions can be refined sufficiently to achieve the goals of the PVP system. As with EDVs, we wonder whether there is an easier path that is not so deeply wedded to existing PVP models. We turn to that discussion next.

IV. SYSTEMIC RESPONSES TO OBSOLESCENCE

In PVP systems, the response to dramatic technological change has been incremental. As we have seen, PVP systems have retained their basic orientation around the concept of variety and their preference for the DUS criteria as rules of protection, but have attempted to adapt their rules of scope by extending PVP scope to essentially derived varieties. The results have been mixed.

We expect that efforts to fine tune PVP protection through refinements to existing PVP concepts will continue, and we applaud those efforts. But this blinkered approach to reform comes at a cost, the cost of assuming that the existing model of PVP protection—the model we have described as a modified copyright model with exemptions—should remain the operative model. Reform efforts that take the existing model as a starting point will prove more satisfactory as long-term responses to obsolescence if they proceed with an understanding of the costs and benefits of alternative models that do not necessarily organize themselves around concepts like variety, DUS, and the breeder's exemption.

In the field of plant variety protection, a debate about fundamental models—copyright-like property rights model vs. other models—would be new. But it finds ample precedent in intellectual property policy more generally. A powerful debate in contemporary copyright law asks whether collections of data are best protected through a copyright (property rights) model, or a *sui generis* data protection regime that relies on unfair competition principles.[236] Similar tensions can be found in the law of trade secrets[237] and trademarks.[238]

Biopatent Directive, 37 INT'L REV. INTELL. PROP. & COMPETITION L. 135, 145 (2006) (endorsing McConnell's suggested reforms to the breeder's exemption and also suggesting "a limitation of the breeders' exemption for hybrid parental lines that are coincidentally present in the seeds"). Another commentator would apparently eliminate the breeder's exemption but impose a compulsory licensing regime. Kingston, *supra* note 231, at 3.

236. The literature is large. Representative samples include J.H. Reichman & Pamela Samuelson, *Intellectual Property Rights in Data?*, 50 VAND. L. REV. 51 (1997); J. H. Reichman & Paul F. Uhlir, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellec-*

In this Part, we outline an unfair competition model for plant varieties and show how it can serve as a counterpoint to the existing PVP model. Our model is not a legislative proposal, but rather a vehicle for provoking a discussion of the fundamental assumptions underlying existing PVP systems. We hope that such a discussion generates a more robust systemic response to obsolescence.

A. Unfair Competition as an Alternative Model

Our model starts from the premise that plants need not be conceptualized as varieties for purposes of constructing an effective intellectual property regime, but rather can be conceptualized as datasets.[239] If plants may be understood as datasets, then it may be illuminating to conceive of plant dataset protection as *one form* of plant intellectual property that may be viable in an era of genotyping—a form that would coexist with other important forms of protection, such as utility patents.

We conceive of plant dataset protection as a model that draws from principles of unfair competition. There are several reasons for choosing this orientation. First, it serves our main purpose—providing a model that presents important contrasts when juxtaposed against existing PVP models. Second, such a model has intuitive appeal even apart from its use as a good discussion model: it might actually work. Wendy Gordon has argued that an unfair competition model may be attractive in cases where high development costs and low copying costs lead to market failure, and the market failure might be averted by providing the original innovator with legal rights that emulate lead time.[240] While it may be easy to argue that those conditions may be found in many industries, we think they apply to plant breeding, and we find the invocation of artificial lead time especially compelling in view of the capacity for new genomics technologies to erode lead time.[241]

tual Property Environment, 66 LAW & CONTEMP. PROBS. 315 (2003); J.H. Reichman, *Database Protection in a Global Economy*, 2002 REVUE INTERNATIONALE DE DROIT ECONOMIQUE 455.

237. Where the law oscillates between a pure property approach to trade secret, emphasizing the delineation of exclusive rights, and a tort approach, emphasizing the nature of trade secret misappropriation and its harms.

238. *See, e.g.*, David S. Welkowitz, *The Supreme Court and Trademark Law in the New Millennium*, 30 WM. MITCHELL L. REV. 1659, 1687–90 (2004) (explaining shifts in Supreme Court trademark jurisprudence between an intellectual property view and an unfair competition view of trademarks).

239. *See supra* Part II.A.3 for a discussion of the point.

240. Wendy J. Gordon, *Asymmetric Market Failure and Prisoner's Dilemma in Intellectual Property*, 17 U. DAYTON L. REV. 853, 863–65 (1992); Reichman & Samuelson, *supra* note 236, at 141.

241. *See supra* Part III.B (discussing the breeder's exemption).

1. Core Unfair Competition Principles

The concept of unfair competition is well established in intellectual property theory,[242] even though the precise contours of specific unfair competition causes of action tend to resist careful delineation. Unfair competition has long existed as part of the international landscape of intellectual property law, enshrined, for example, in Paris Convention Article 10*bis*.[243] For purposes of exploring our model, we offer four core principles that characterize unfair competition regimes:

(1) Unfair competition is relational—that is, it reflects a relationship between contesting parties rather than directly reflecting rights against the rest of the world.[244]

(2) Unfair competition regimes usually rely heavily on case-by-case adjudication.[245] Determinations are *ex post*, rendered through formal adjudication, or, in theory, through alternative dispute resolution mechanisms or even informal codes of conduct.

(3) Unfair competition law does not divide neatly into rules of protection and rules of enforceable scope. In an unfair competition regime, eligible subject matter is typically defined loosely, and criteria of protection, if any, are typically not elaborated in detail, in contrast to the highly-

242. *E.g.*, ANSELM KAMPERMAN SANDERS, UNFAIR COMPETITION LAW: THE PROTECTION OF INTELLECTUAL AND INDUSTRIAL CREATIVITY (1997); CHRISTOPHER WADLOW, THE LAW OF PASSING-OFF 31–40 (2d ed. 1995) (law of unfair competition in British common law); WIPO, PROTECTION AGAINST UNFAIR COMPETITION (1994) (discussing, *inter alia*, the unfair competition action as understood in civil law jurisdictions). In the U.S., much of the debate has focused on whether unfair competition principles should be given recognition through a free-standing common law misappropriation cause of action. A sampling of important works includes Wendy J. Gordon, *On Owning Information: Intellectual Property and the Restitutionary Impulse*, 78 VA. L. REV. 149 (1992); Dennis S. Karjala, *Misappropriation as a Third Intellectual Property Paradigm*, 94 COLUM. L. REV. 2594 (1994); Richard A. Posner, *Misappropriation: A Dirge*, 40 HOUS. L. REV. 621 (2003); J.H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 VAND. L. REV. 1743 (2000); and numerous other works by Professor Reichman; *see also* Wendy J. Gordon, *Of Harms and Benefits: Torts, Restitution, and Intellectual Property*, 21 J. LEGAL STUD. 449 (1992), *reprinted in* 34 MCGEORGE L. REV. 541 (2003); Leo J. Raskind, *The Misappropriation Doctrine as a Competitive Norm of Intellectual Property Law*, 75 MINN. L. REV. 875 (1991).

243. Paris Convention for the Protection of Industrial Property art. 10bis(1), Mar. 20, 1883, as revised at Stockholm, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305, amended, Sept. 28, 1979 (binding Paris Convention countries to provide "effective protection against unfair competition"); *id.* art. 10bis(2) (defining an act of unfair competition as "[a]ny act of competition contrary to honest practices in industrial or commercial matters"). On the stature of Article 10bis in U.S. law, see, for example, William E. Denham IV, Comment, *No More than Lanham, No Less than Paris?: A Federal Law of Unfair Competition*, 36 TEX. INT'L L.J. 795 (2001); Patricia V. Norton, Note, *The Effect of Article 10bis of the Paris Convention on American Unfair Competition Law*, 68 FORDHAM L. REV. 225 (1999).

244. SANDERS, *supra* note 242, at 78.

245. *Id.* at 82.

elaborated, formal rules of protection that characterize property rights systems.

(4) Unfair competition law rarely employs sharply drawn infringement provisions coupled with specific exemptions. Instead, unfair competition rules strive to provide "guidance for determining the equity" of defendant's behavior.[246] Liability generally depends on the competitive harm to the plaintiff that results from the defendant's acts.[247]

While unfair competition principles in U.S. law are routinely discussed in connection with the free-standing, common law tort of misappropriation, more germane illustrations for our purposes may be found among legislative proposals for *sui generis* protection of databases, described below.

2. Database Protection Legislation as an Illustration

Legislative proposals for database protection show how unfair competition principles may be embodied in a statutory intellectual property scheme.[248] The most recently debated proposal to date[249] incorporates a number of rules that might be adapted for use in a plant dataset unfair competition regime. In the legislative proposal, protectable subject matter (a "database") is defined primarily by function, rather than by formal qualities.[250] The proposal eschews any elaborate scheme of rules of protection, instead simply calling for a showing that the database was "generated, gathered, or maintained through a substantial expenditure of financial re-

246. *Id.* at 86; *see also id.* at 82 (stating that the "relationship between the parties involved and the behaviour of a defendant are the decisive factors" in determining whether plaintiff can invoke unfair competition); Reichman, *supra* note 1, at 2476 (noting that in a typical unfair competition model "there are no well-defined objects of protection," and "no sure standards of eligibility").

247. Competitive harm may be measured in many ways. For example, it may be understood as a theory of unjust enrichment.

248. For a summary of the U.S. legislative debate, see, for example, Jonathan Band, *The Database Debate in the 108th US Congress: The Saga Continues*, 27 EUR. INTELL. PROP. REV. 205 (2005). In Europe, database protection is gradually becoming established after its introduction in the mid-1990s. For current commentary, see, for example, Mark J. Davison & P. Bernt Hugenholtz, *Football Fixtures, Horseraces and Spin Offs: The ECJ Domesticates the Database Right*, 27 EUR. INTELL. PROP. REV. 113 (2005).

249. Data Collections of Information Misappropriation Act, H.R. 3261, 108th Cong. (2004) (as reported in House). We point to this legislation for its illustrative value, not for the purpose of defending this particular legislation. We leave to others the broader debate over the merits of data protection schemes.

250. *Id.* § 2(4)(A) (stating that "the term 'database' means a collection of a large number of discrete items of information" brought together so that they can be accessed). Presumably, a molecular dataset characterizing a particular plant would qualify as a "database" under this provision, such that plants could quite literally constitute protectable databases under the legislation. That, however, is not our proposal.

sources or time,"[251]—a sweat-of-the-brow theory rather than a novelty or distinctness theory. Liability is allocated based on whether defendant has inflicted an injury on the plaintiff and on whether withholding liability would undermine the system's incentives.[252] The legislation offers remedies not limited to monetary relief, but extending to injunctive relief as well.[253] Because it involves no formal grant of property rights, the legislation imposes no term limitation but does provide a two-year statute of limitations.[254]

B. *The Unfair Competition Model Applied to Plant Datasets*

Our unfair competition model, as applied to plant datasets, can best be understood when juxtaposed against existing PVP models. The major substantive differences between the existing PVP schemes and a proposed unfair competition scheme would be three, relating to (1) the object of protection, (2) the criteria for establishing protection, and (3) the scope of protection.

Unfair competition regimes do not rely on precise *ex ante* delineation of protected subject matter. Accordingly, the rule set in a plant unfair competition regime would not need to be shackled to a concept of a plant "variety," with the ambiguities that it entails. An unfair competition model could be oriented around plant datasets or, more particularly, commercial value built up in plant datasets.

Unfair competition regimes also do not require robust criteria for establishing protection. Phenotype-driven rules like the DUS criteria would take on a very different role—if any role at all—in a plant unfair competition regime.[255] As we have seen, as currently applied, the DUS criteria have become so enmeshed in their own technicalities that their normative basis has either been minimized or lost.[256] In a plant unfair competition regime, a remedy would be made available where the plant breeder can satisfy functional criteria reflecting the commercial value of the plant mo-

251. *Id.* § 3(a)(1).

252. *Id.* § 3(a) (imposing liability for making available to others "a quantitatively substantial part of the information" in another's qualifying database, without authorization, where "(2) the unauthorized making available in commerce occurs in a time sensitive manner and inflicts injury on the database or a product or service offering access to multiple databases; and (3) the ability of other parties to free ride on the efforts of the plaintiff would so reduce the incentive to produce or make available the database or the product or service that its existence or quality would be substantially threatened").

253. *Id.* § 7.

254. *Id.* § 8.

255. That is, our model does not presuppose that phenotypic comparisons must be discarded in all circumstances, but it does consign them to a lesser role.

256. *See supra* Part II.B.

lecular dataset at issue. Value might be measured by evidence of a substantial expenditure of financial resources or time or by direct (*ex post*) assessments of agronomic value. The DUS criteria might still be employed, but only as proxies for commercial value, not as dispositive indicia of protectability.[257] Overall costs associated with securing protection are shifted *ex post*, to litigation.

Finally, in an unfair competition regime, the scope of protection would not depend on the identification of formal boundary lines coupled with exemptions. Under an unfair competition regime, the scope of rights inquiry, embracing inquiries like the identification of EDVs and the application of the breeder's exemption, would collapse into a single inquiry focused on assessing whether a defendant's alleged unfair competition via the unauthorized exploitation of plaintiff's plant dataset was likely to cause competitive harm to plaintiff.[258]

In some respects, this is already beginning to occur. For example, the EDV concept already has unfair competition overtones—the goal of the EDV provisions is both "to promote continued investment" in plant breeding and "to discourage unfair or parasitical activities without discouraging 'improvement breeding.'"[259] And Jim Chen has advocated an interpretation of the breeder's exemption that would allow courts to consider whether the party invoking the exemption had "clean hands," asserting that the inclusion of the phrase "bona fide research" in the language of the breeder's exemption provides a basis for holding that "surreptitious acts" cannot be shielded.[260]

Under an unfair competition model, current efforts to implement EDV provisions by creating codes of conduct for specific crops would still be relevant. But they would be redirected towards establishing standards of fair commercial breeding practice—true codes of conduct, that is. Instead of making EDV thresholds ends in themselves, such codes would recognize

257. There are important institutional consequences. For example, under the proposed scheme, substantive pre-grant examination for compliance with DUS criteria would not invariably be required. PVP offices could instead focus on facilitating the development of codes of conduct for breeding specified crops, for example.

258. In addition to redressing competitive harms—with the goal of balancing *ex ante* innovation incentives with reasonable access to innovative products—an unfair competition model also can be effective in meeting other goals that we ordinarily associate with economic functions of trademarks: securing reputation of germplasm owners by enjoining imitators who will not observe the same quality standards; indirectly encouraging private sector investment in germplasm development by providing assurance that imitators will be kept off the market; and encouraging breeders to maintain consistent quality, thereby building up goodwill. *See, e.g.*, DINWOODIE & JANIS, *supra* note 67, ch. 1 (discussing the economic functions of trademarks).

259. UPOV, *Model Law*, *supra* note 164, at 149.

260. Chen, *supra* note 3, at 134–35.

that the objective is to articulate standards of allowable research behavior, where thresholds are only modest instrumental tools for accomplishing the task.

Two other contrasts are noteworthy. First, unfair competition regimes typically do not rely on fixed terms of protection; rather, they depend upon statutes of limitation for taking action against competitors. Additionally, other factors, such as the commercial obsolescence of the plant, would also be limiting, because it would affect the extent to which a defendant's activity caused cognizable commercial harm to a plaintiff, thus serving as a practical term limitation on plaintiff's ability to get a remedy.

Second, unfair competition regimes are amenable to a range of flexible remedial options. Limited injunctive relief should be among the options.[261] Remedies could be designed around crop-specific exclusivity periods reflecting commercial realities, around an arbitrary exclusivity period during which unauthorized breeding is deemed prima facie to cause competitive harm, or around other models. The design of an appropriate menu of remedial options could build on current debates over the proper scope of the breeder's exemption.[262]

C. *Certainty and* Ex Post *Determinations*

Beyond threshold concerns such as the resistance in the U.S. to robust notions of unfair competition at common law,[263] and the obvious fact that entrenched interests may express the usual reluctance to depart from the status quo,[264] unfair competition models typically trade away certainty.

261. The idea of building in exclusivity periods is not foreign to unfair competition law. *E.g.*, SANDERS, *supra* note 242, at 200 (citing, among others, the example of "springboard injunctions" in British cases involving breach of confidentiality). We disagree with suggestions to convert plant variety protection into effectively a compulsory licensing regime, where only a damages remedy would be available. *See* Kingston, *supra* note 231, at 4. Like Kingston, we see a role for a new model of protection as a response to obsolescence. However, Kingston's model strives to fine tune *ex ante* incentives for innovative breeders by charging downstream breeders an up front, one-time compulsory licensing payment. *Id.* The payment would be calculated not by the level of innovation embodied in any given variety, but based upon a more complex accounting of the innovative breeder's total investment in R&D. *Id.* at 7–8. We are wary about the accounting measures, which seem to us to present the danger of the Enronning of plant intellectual property protection. Moreover, our unfair competition model operates differently: it seeks to redress competitive harm and thereby indirectly affect *ex ante* incentives, leaving to other regimes, like utility patents, the chief work of establishing incentives.

262. *See supra* Part III.B for a discussion.

263. *E.g.*, Dastar Corp. v. Twentieth Century Fox Film Corp., 539 U.S. 23, 29 (2003) (asserting that Lanham Act § 43(a) is not a comprehensive unfair competition cause of action); *cf.* Joseph P. Bauer, *A Federal Law of Unfair Competition: What Should be the Reach of Section 43(a) of the Lanham Act?*, 31 UCLA L. REV. 671 (1984).

264. Public choice theory would predict that plant breeders, who would inevitably be small players in the utility patent system, may perceive that system to be less responsive to their needs, and might therefore prefer a plant-specific regime in which breeders would have great political clout. But this is an

This is a serious problem in areas where there is perceived to be a strong need for the *ex ante* allocation of rights to provide third-party notice and to hold down transaction costs.

We think that the certainty concern about a plant unfair competition model should be taken seriously.[265] There are, however, a number of considerations that mitigate what might otherwise be a knee-jerk reaction against unfair competition.

First, certainty should be assessed in view of the blend of all intellectual property regimes available to protect plant innovation. In most jurisdictions, plant variety protection does not exist in isolation; it is part of a complex of intellectual property rights that may be brought to bear on plant innovation. A regime in which much innovation is protected by utility patent, where an unfair competition regime operates at the margins of the utility patent scheme, might provide adequate certainty even if an unfair competition regime positioned as the sole or predominant form of intellectual property protection would not. In a jurisdiction offering unfair competition protection as the *sole* form of plant intellectual property protection, certainty concerns cannot so readily be brushed aside.

Second, the certainty virtues of existing PVP systems are easily overstated. Existing DUS criteria do not lend themselves to sharp line-drawing, a condition likely to become exacerbated with the advance of genotyping. EDV determinations are unpredictable and are made *ex post*.[266] The very concept of variety is intrinsically ambiguous.

Related to the certainty concern is another: unfair competition models rely predominantly on *ex post* determinations, so that administering such a model requires a highly sophisticated judiciary.[267] While we do not take this concern lightly, we question whether the judicial sophistication required to decide a plant unfair competition matter would exceed very greatly that required to decide an intricate PVP matter. There may be another, more constructive message here, and further debate over an unfair

argument for a plant-specific regime that is viable over the long term, not necessarily an argument for the retention of the existing PVP model.

265. Though we do note an irony: uncertainty is especially corrosive in a property rights model like PVP, which purports to provide a clear *ex ante* allocation of rights. Unfair competition lacks such pretensions towards certainty, as a matter of design.

266. Lesser & Mutschler, *supra* note 198, at 1116 (arguing that because the dependency determination will always be uncertain and will be made only when the downstream breeder has arrived at a finished variety, EDVs may have a chilling effect on downstream breeders). In addition to private costs, there may be social costs—e.g., costs of downstream breeders routinely relying on unprotected varieties even if those are less promising agronomically, and social costs entailed in cosmetic breeding practices. *Id.*

267. Reichman, *supra* note 1, at 2476 (noting that the unfair competition action "characteristically proceeds on a hit-or-miss basis that varies with the outlook of single judges").

competition model may be useful for amplifying that message: that regardless of whether unfair competition or PVP models emerge as the best future model, those models might best be implemented with an eye towards an alternative dispute resolution mechanism—a uniform dispute resolution policy for plants, as it were.[268] That, however, is an argument for development elsewhere.

CONCLUSION

The UPOV treaty will soon reach its 50th anniversary. There are reasons to celebrate this milestone. When it was created, the PVP system was an intellectual property innovation, providing plant breeders with a modest form of intellectual property protection at a time when it was unclear whether utility patent systems would be open to them. The UPOV organization created by the treaty has become the preeminent world forum for the discussion of plant-related intellectual property. PVP systems are recognized in the TRIPS agreement, as an alternative intellectual property regime in countries where utility patent protection for plants may be politically infeasible in the short term. Additionally, the plant breeding industry has invested significantly in implementing UPOV systems, and in developing innovative institutional frameworks, such as the framework for facilitating alternative dispute resolution in EDV disputes.The coming semi-centennial of the UPOV treaty should also provide the occasion for constructive reexamination of the core assumptions and design features of PVP systems. When the UPOV treaty was drafted, the chemical structure of DNA had only recently been elucidated. The biotechnology industry had not yet been born. Plant molecular techniques in widespread use today, and the hardware and software platforms for implementing them, had not been invented. Key judicial decisions on the patent eligibility of living subject matter had not yet been rendered. Just as any intellectual property system should be reexamined in view towards accommodating rapid technological and legal change, PVP systems should have the benefit of a comprehensive review that is not hampered by the *a priori* conclusion that basic elements of the existing system must be retained without change.

In this Article, we have sought to provide a foundation for a modern debate about the fundamentals of the PVP model by juxtaposing existing

268. Experience with the design of another international alternative dispute resolution mechanism for intellectual property—the Uniform Domain Name Dispute Resolution Policy—may prove instructive. For relevant commentary, see Laurence R. Helfer & Graeme B. Dinwoodie, *Designing Non-National Systems: The Case of the Uniform Domain Name Dispute Resolution Policy*, 43 WM. & MARY L. REV. 141 (2001).

phenotype-driven PVP rules against technical literature reflecting genotype-driven orientation of contemporary plant breeding research. We have sought to raise questions about the incompatibilities between the two. To demonstrate that the best way forward for resolving these incompatibilities need not take the form of further adaptations to the existing PVP model, we have sketched out an alternative model, based on unfair competition principles. The unfair competition model is intended to provide a starting point for debate. At the end of that debate, it may be determined that an unfair competition model provides a useful substantive framework for incorporating successful aspects of existing PVP systems into a more adaptable, blended intellectual property regime. We have suggested that a blend of PVP principles in an unfair competition model may prove especially attractive in countries where meaningful utility patent for biotechnological subject matter is also available, and the blended PVP/unfair competition regime can serve as an important adjunct.

We believe that PVP systems and institutions will continue to prove to be receptive to constructive debate about systemic changes. If not, the consequences for the plant breeding community (and, indeed, for global food and fiber production) could be unfortunate, because the threat of technological obsolescence of the PVP model is serious. The broader legal implications—that *sui generis* intellectual property regimes tend to become locked in to technological models, and that their supporting institutions tend to become impervious to large-scale reform—would also be revelatory for future intellectual property policymakers.