

# **Experimental Use and the Shape of Patent Rights for Plant Innovation**

**Mark D. Janis**

*Professor of Law and  
H. Blair & Joan V. White Intellectual Property Law Scholar  
University of Iowa College of Law*

## **Abstract**

In this paper I consider how the experimental use defense to patent infringement may be used to shape utility patent rights for plant-related inventions. I review a recent, controversial case, *Madey*, and argue that it is of greater interest as a symbolic expression of aspirations than as a statement of formal law. I argue that a properly-conceived experimental use doctrine would account for informal arrangements prevailing in research communities. Finally, I consider possible sources of informal research norms prevailing in plant breeding and plant biotechnology research, and consider whether they might be articulated as a set of informal research guidelines.

## Experimental Use and the Shape of Patent Rights for Plant Innovation

Mark D. Janis

With the recent surge in utility patents for plants, culminating in the Supreme Court's confirmation that plants are eligible subject matter for utility patent protection, *J.E.M. Ag Supply v. Pioneer Hi-Bred Int'l, Inc.*, 122 S.Ct. 593 (2001), it is now especially important for scholars and policymakers to consider how traditional utility patent doctrines should be adapted to fit the needs of plant breeding and plant biotechnology research. Janis & Kesan (2002a). This is part of a larger debate in patent circles about how technology-neutral general principles of patent law are incorporated into technology-specific patent law rules. (Burk & Lemley 2003). This paper considers the application of the experimental use doctrine, a defense to patent infringement, to patents on plant biotechnology.

The patent infringement provision in U.S. law speaks in absolute terms. The provision prohibits unauthorized "making" or "using" of a patented invention, without regard for whether the alleged infringement is innocent, *de minimis*, or carried out in a non-commercial setting. (35 U.S.C. §271(a)). The absolutist approach of the patent infringement provision offers social benefits: it may reinforce the innovation incentives that the patent grant is thought to provide and may facilitate market transactions in patent rights. On the other hand, it may also impose social costs: it may chill follow-on innovators, even those who are exploiting patented technology as part of a program of academic research.

When confronted with these competing considerations, the U.S. Congress and courts only rarely have departed from the absolutist structure of the U.S. patent infringement provision. Thus, where alleged infringers have claimed that their unauthorized "use" was in the course of academic experimentation, U.S. courts have only grudgingly recognized, and almost never applied, an exception to infringement liability. Courts have repeatedly characterized the experimental use defense as "truly narrow" (e.g., *Roche Prod., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984)), and Congress has declined to add any general experimental use defense to the statute. Janis (2001).

Notwithstanding the relative paucity of actual decisions involving experimental use, patent

scholars have long been intrigued by the concept, exploring its potential application across a variety of technologies (e.g., Mueller (2001), Cohen & Lemley (2001), O'Rourke (2000), Eisenberg (1989), Hantman (1985)), including plant breeding and plant biotechnology. Janis (2001). Many scholars have argued for the adoption of a robust experimental use defense, although scholarly opinion is by no means uniform. *E.g.*, Karp (1991).

Recently, the experimental use debate has expanded beyond academia, surfacing in an unusual decision of the Court of Appeals for the Federal Circuit in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002). That decision is now attracting intense scrutiny.

In *Madey*, Professor Madey owned patents on laser equipment, growing out of his research at Stanford. He moved his lab to Duke, where he used the patented equipment to conduct various research projects. After a dispute over Madey's management of the lab, Duke removed Madey as the lab's director, and he eventually resigned his tenured position. When Duke continued to operate the patented equipment at the lab, Madey sued for patent infringement, and Duke defended in part on the ground that the equipment was being used in the course of academic research, such that the use should escape patent infringement liability under the experimental use doctrine. The lower court held in favor of Duke on summary judgment; on appeal, the Federal Circuit reversed and remanded, finding that the factual issues concerning experimental use could not be resolved short of trial. Duke petitioned the Supreme Court for review.

According to *amicus curiae* briefs urging Supreme Court review, the Federal Circuit's decision on experimental use "radically departs from prior law", Assoc. of Am. Med. Colleges (2003), and frustrates the Constitutional goals of the patent system. Consumer Project on Tech. (2003). Distinguished commentators have asserted that *Madey* "[sweeps] aside almost 200 years of opinions", Eisenberg (2003), and "explodes the myth that private 'non-profit' organizations. . . may experimentally use patented technology." Wegner (2003).

In this essay, I offer a different interpretation of *Madey*, and consider the broader implications of experimental use for patented plant biotechnology inventions. In the first section, I argue that the text of the *Madey* opinion is largely a predictable and straightforward application of existing law on experimental use. What is potentially significant about *Madey*, I argue, is its symbolic impact on

informal arrangements among researchers. In the second and third sections, I focus on the interaction between the experimental use defense as a statement of formal law, and a notion of experimental use as expressed through informal norms of behavior that prevail in research communities. I consider possible sources of informal norms in the plant breeding and plant biotechnology research communities, and conclude if those norms can be articulated in a manner that is accessible to courts, courts could take account of those norms in constructing a meaningful experimental use doctrine for plant biotechnology that adequately balances private rights and public access.

### **I. *Madey* Reinterpreted.**

*Madey* is being portrayed as a watershed decision that expresses extreme hostility to the notion of an experimental use defense to patent infringement. In my view, that portrayal should be carefully reassessed, with attention to the context of past decisions on experimental use and the particular factual circumstances of *Madey*.

First, on the spectrum of judicial commentary concerning the experimental use doctrine, *Madey* does not, in fact, lie at the extreme. In *Embrex v. Service Engineering, Inc.*, 216 F.3d 1343 (Fed. Cir. 2000), Judge Rader's concurring opinion questioned whether any common law experimental use defense could properly be recognized in U.S. patent law at all, given the fact that experimental use required an inquiry into the alleged infringer's intent, coupled with the fact that the Supreme Court had recently confirmed the longstanding patent law proposition that intent could play no part in the patent infringement calculus. *Warner-Jenkinson Co. v. Hilton Davis Chem Co.*, 520 U.S. 17 (1997). The Federal Circuit in *Madey* could have adopted this approach, eliminating the experimental use defense altogether. Indeed, *Madey* argued that the Federal Circuit should do just that. Instead, the Federal Circuit declined, opting to preserve the defense, albeit in "very narrow form."

Second, it is not surprising that the Federal Circuit rejected the lower court's burden-shifting approach to experimental use. On appeal, *Madey* argued that the lower court had shifted to him, the patent owner, the burden of showing that the alleged infringer's activities were *not* mere

experimentation. That result would indeed have been a departure from prior law. Predictably, the Federal Circuit clarified that experimental use was an affirmative defense to be established by the experimenter, rather than placing on the patent owner the burden of showing that the alleged infringer's activity was not experimentation, hardly a controversial point.

Third – and here I depart from most recent commentators – it is not a foregone conclusion that the *Madey* decision necessarily changes the scope of the experimental use doctrine. To be sure, the Federal Circuit refused to hold that a user's non-profit *status* automatically immunized the user against infringement charges under the experimental use doctrine. Instead, the Federal Circuit insisted on examining the “character, nature, and effect” of the use in determining whether the experimental use defense applied. But experimental use cases, sparse though they are, have always operated on the basis of fact-specific inquiries rather than bright-line, formal rules. Regardless of one's views on the ultimate wisdom of the Federal Circuit's approach, it surely cannot be said to come as a surprise that the Federal Circuit applied the same fact-specific analysis of experimental use in a university setting as it would have applied to assertions of experimental use in other settings.

Nor is it entirely clear that the *Madey* court's troubling reliance on the concept of the alleged infringer's “legitimate business” actually changes the scope of the experimental use doctrine. According to the *Madey* court,

In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.

It is difficult to know what to make of this rhetoric, which the Federal Circuit extracted from a rather obscure Claims Court decision, *Pitcairn v. U.S.*, 547 F.2d 1106 (Cl.Ct. 1976). To the extent that previous cases on experimental use distinguished between commercial activity and non-commercial experimentation, perhaps the Federal Circuit intended to supplant that distinction with the “legitimate business interests” formulation. Some have criticized the court's apparent subjugation of the commercial/non-commercial distinction in *Madey*. Eisenberg (2003). However, that distinction was never very helpful as a metric for experimental use allegations anyway, because of

the ease with which inferences of commercial motivation can be drawn even in academic settings. The Federal Circuit may simply have moved from one bad standard to another, equally bad standard.

The Federal Circuit's instructions to the lower court on remand may also be illuminating. The Federal Circuit averred that the lower court's focus

should not be on the non-profit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.

Courts may well find this formulation to be entirely unhelpful. A university's "legitimate business" presumably *includes* "strictly philosophical inquiry," in addition to other activities where commercial motivation is more direct. Perhaps, then, the Federal Circuit merely meant to restate the general principle that non-profit status was not outcome-determinative, and that courts would need to engage in fact-specific inquiries in order to evaluate experimental use claims. If the "legitimate business" formulation means only this, it does not meaningfully alter the existing law on experimental use.

Finally, it is worth noting that *Madey* is factually peculiar in at least two important respects. First, Duke is a privately-funded institution. Public universities in the U.S. may not need the protection of an experimental use defense, because they may be immune from liability anyway under Eleventh Amendment sovereign immunity, at least under current law. Bohannon (2002). Second, *Madey* does not present the factual scenario that most concerns scholars. In *Madey*, there was no indication that the patent owner (an apparently disgruntled ex-faculty member) entered the litigation with such vastly superior litigation resources as to be able to bludgeon the university into submission by aggressive litigation tactics. Thus, one potential policy rationale for a vigorous experimental use defense – avoiding the chilling effect on legitimate research that may occur when a well-financed patent owner sues a university – is missing from the *Madey* case. *Madey* does not mandate that courts in the future adopt a monolithic approach to experimental use regardless of the fact situation, and it will be interesting to see how courts react when applying *Madey* to a fact pattern in which the equities may seem more tilted towards the university.

## **II. Experimental Use Law v. Experimental Use Norms.**

*Madey* is the latest installment in a rather unsatisfying line of experimental use caselaw. In two centuries of U.S. patent law, only a few courts have discussed the experimental use doctrine in depth, and those discussions have not been especially illuminating. Certainly, courts have not articulated any precise test for distinguishing between experimental use and infringing use.

Perhaps this inability to formalize experimental use into a refined legal doctrine suggests that experimental use is impoverished conceptually, but there are several other plausible explanations. The amount of recoverable damages in patent infringement cases in research settings may frequently be too low to justify litigation. Patent owners may have widely believed that pressing litigation on the experimental use doctrine might have resulted in a definitive court ruling broadly immunizing researchers from liability. Similarly, universities may have believed that the risk of creating adverse precedent (e.g., a ruling that no experimental use defense would be recognized at all) was sufficiently great to induce early settlement.

If these suppositions are correct, then it seems quite possible that the scope of the experimental use doctrine has been defined predominantly by informal arrangements, rather than by formal legal rules. There are important implications here for agricultural biotechnology policymakers, and, indeed, for intellectual property policymakers more generally. The exercise of creating an appropriate safe harbor for experimentation, free of patent infringement liability, is more subtle and complex than merely crafting formal legal rules on experimental use. Instead, the exercise must account for the interaction between formal legal doctrine on experimental use and established or evolving norms of behavior in the affected research communities.

In such an exercise, formal law may have a fundamentally different role than serving as a vessel for a package of binding obligations that are actually enforced against the involved parties. Instead, formal law may merely serve the function of expressing aspirations, Sunstein (1996); its importance may lie in its symbolic impact on the norms with which it interacts. Thus, in assessing *Madey*, while there is some value in parsing the text of the opinion to understand what *Madey* actually says, it is more important to ask the difficult question about what *Madey* signals, and whether those signals undermine or reinforce existing norms systems in various research communities. Walsh et al. appear to have drawn a similar conclusion. Walsh, et al. (2003).

This is a daunting exercise, especially for intellectual property scholars, who might otherwise take for granted the preeminence of formal law. Fortunately, the problem of accounting for informal norms is not entirely foreign to intellectual property policy. For example, Professor Rai has examined the operation of research norms in basic biotechnology research and their interaction with selected patent law doctrines. Rai (1999). Professor Eisenberg has studied the experimental use doctrine specifically, looking to the philosophy of science literature to identify rationales that might illuminate that doctrine. Eisenberg (1989).

These scholars have taken on the ambitious task of identifying some overarching norms that are common to the research enterprise generally. My task here is different and to some extent more pragmatic. I am interested in elucidating prevailing norms in plant breeding and plant biotechnology research, norms that may differ from those in other disciplines, even other disciplines of biotechnology. As I have argued elsewhere, rather than insisting on a generic concept of experimental use, courts should be open to the possibility that research norms differ among research communities, and that the extent of allowable experimental use may differ accordingly. Janis (2001). In the next section, I offer some ideas on sources of research norms in plant biotechnology research and forms in which those norms might be articulated.

### **III. Articulating Norms of Experimental Use for Plant Biotechnology Research.**

In the preceding sections, I have argued that we should not leave it entirely to courts (or, indeed, to Congress) to create detailed, formal rules on the experimental use doctrine for particular technologies. The current approach of U.S. law – which gives formal rules a relatively modest role, relying on a common law experimental use defense that is little more than a vague and generic statement of aspirations – is actually desirable, especially if courts can draw upon informal research norms to when applying the defense to particular fact situations, such as plant breeding and plant biotechnology research. This approach might also have the benefit of sidestepping difficult questions about prohibitions in the TRIPs agreement against patent rules that discriminate by technology area, and about limitations in the TRIPs agreement concerning exceptions to the



exclusive patent rights. Dinwoodie & Dreyfuss (2003). However, this leaves the hard task of identifying sources of research norms, and articulating them in an accessible way.

How might that task be carried out in the plant biotechnology research community? One potential source of relevant norms that should be approached only with great caution is the U.S. Plant Variety Protection Act (PVPA). The PVPA contains an entire constellation of exceptions and exemptions that might be argued to reflect collectively a vision of allowable experimental use. For example, the PVPA includes a safe harbor provision shielding from liability any act done privately and for noncommercial purposes. 7 U.S.C. §2461(e). In addition, the PVPA includes an express experimental use exemption, exempting from infringement “[t]he use and reproduction of a protected variety for plant breeding or other bona fide research.” 7 U.S.C. §2544. Further, while the PVPA prohibits the use of a protected variety in “producing” a hybrid or different variety, it allows the use of a protected variety in “developing” a hybrid or different variety. 7 U.S.C. §2541(a)(4). The legislative history explains that the use of a protected inbred line to cross it with another inbred to produce a commercial hybrid constitutes “producing” and thus is prohibited, while the use of a protected inbred line to develop, through breeding, a novel inbred line is “developing,” and is thus protected experimentation. U.S. Congress (1970).

It would be a mistake for a court to look to these provisions and assume that they can be engrafted *in toto* onto the utility patent law as an expression of prevailing norms in the plant breeding community. The PVPA strikes a fundamentally different balance than does the utility patent law. The PVPA extracts only subpatentable innovation and limited disclosure to the public, and in exchange grants relatively weak private rights, whereas the utility patent regime extracts higher quality innovation and more rigorous disclosure to the public, and in exchange grants relatively strong private rights. The extensive PVPA exemptions are essential to the legislative deal on the public/private balance within the PVPA, but the exemptions do not necessarily reflect a broad consensus on the scope of experimentation that should be tolerated under any other intellectual property regime. The Federal Circuit may have recognized this principle in connection with a related issue (refusing to engraft the PVPA’s “saved seed” exemption onto the utility patent law). *Monsanto Co. v. McFarling*, 302 F.3d 1291 (Fed. Cir. 2002). In addition, the PVPA exemptions have not been

interpreted in any reported decision of which I am aware. Janis & Kesan (2000b).

Turning to other potential sources, it seems inevitable that anecdotal evidence will largely drive this exercise. Here, my sense as a relative outsider is that there is a rich history to be tapped. The literature certainly contains many references to a fondly remembered past time period characterized by a “collegial system of exchange” of germplasm among researchers, followed by a modern period in which the system of collegial exchange has eroded, replaced by widespread claims of exclusive rights. Zohrabian (2003).

The old norm of free sharing deserves close study, even if it no longer is the prevailing norm. In actual operation, did research colleagues share germplasm freely without any limitations? With an implicit requirement that the recipient give credit? With an implicit requirement that the recipient participate in reciprocal exchange? Was it expected that the recipient might use the material in a commercial breeding program? In a breeding program that would produce varieties that would be distributed freely to growers, who might in turn develop commercial varieties from them or otherwise benefit commercially? These questions are important to the exercise of developing information that will be useful in patent policy circles. Acknowledging the existence of a “collegial sharing” regime is one thing; developing an understanding of the complex refinements and limitations on that collegiality is quite another, and it is the latter, more challenging exercise that could provide relevant information for modern decisionmakers.

Of course, anecdotal information about current practices is obviously of great relevance. In this regard, it is important to note that just as the past practice of “free” exchange may not have been quite absolutely free, the modern practice of claiming exclusive rights is also more complex (less absolute) than the label might indicate. Consider the example of plant transformation methodologies, “enabling” technologies for the production of transgenic plants. Particle-mediated (“gene gun”) transformation, one major transformation technology particularly suited for the production of genetically-modified corn and other monocots, is subject to patent protection in the U.S. *E.g.*, U.S. Pat. No. 4,945,050 (Method for transporting substances into living cells and tissues and apparatus therefor); *see generally* Finer, J.J., et al. (1999). Another major transformation technology particularly effective in dicots, *Agrobacterium*-mediated transformation, is subject to

many claims of patent protection. *E.g.*, U.S. Pat. No. 6,051,757 (Regeneration of Plants Containing Genetically Engineered T-DNA).

One might draw the conclusion that these examples reflect the modern “exclusive rights” norm in action, but this analysis is again too simplistic to be useful in crafting policy on the experimental use doctrine. Intellectual property rights are not self-enforcing, so a researcher’s decision to acquire intellectual property rights tells us relatively little about norms of enforcement behavior. However, anecdotal evidence about the patentees’ licensing practices on patented plant transformation equipment and techniques, and researchers’ behavior in response to those practices, might well be informative.

Current reports about a new transformation technique may give an indication of the complexity of modern norms of research behavior in the plant biotechnology area. A group of researchers recently reported a new *Agrobacterium*-mediated transformation technique that is heralded as a breakthrough technology in that it appears to be a highly effective transformation technique for corn, which has long been considered recalcitrant to *Agrobacterium*-mediated transformation. Frame et al. (2002). Reportedly, the group will make the technique freely available to researchers. Fitzgerald (2003). The group had successfully transformed maize using *Agrobacterium*-mediated transformation relying on a proprietary vector, but decided that licensing the proprietary vector “for use on a broader scale was prohibitive.” Accordingly, the group turned to a public domain vector system, which proved to have other advantages as well.

Perhaps this describes an exceptional practice, or perhaps it illustrates that the modern norm of exclusive rights is more nuanced, and that experimental use doctrine should take account of that nuance.

It will be evident from these brief comments that the exercise that I have described is not likely to produce a pristine set of rules that precisely delimit the scope of allowable experimentation with patented plant biotechnology inventions. The exercise that I have described is also essentially reactive, in which the jurisprudence of experimental use evolves as a reaction to existing norms of behavior.

I have previously suggested an approach that is more proactive. This approach envisions that

a group of interested parties acting through public or quasi-public institutions formulate a set of informal breeder's guidelines that would express a consensus understanding of prevailing practices and could provide a resource to courts looking to judge whether a researcher's behavior should be deemed "experimental use." Janis (2001). The guidelines would not purport to have binding effect on the parties that formulate them, and of course would not bind courts. There are analogs in other areas of intellectual property – for example, the educational fair use guidelines appearing in the legislative history of the 1976 Copyright Act. The practical impediments to this ambitious and systematic articulation of extant norms might be substantial, but both owners of patented plant biotechnology and researchers who seek access to that technology may actually find that they are better off with a guidelines approach that assists courts in striking a subtle and appropriate balance between private rights and public access for plant breeding research.

#### **IV. Conclusion.**

It remains to be seen whether the experimental use defense to patent infringement will emerge as a significant force in shaping U.S. patent rights, either across technologies or specifically within plant breeding and plant biotechnology. The answer will depend in part on the future course of the *Madey* litigation. Perhaps, though, the answer will also depend in greater part on the evolution of informal arrangements among researchers and the exercise of articulating informal norms upon which courts might draw in deciding whether experimental activity should proceed free of patent infringement liability claims.

## References

### **(1). Cases, Statutes, Legislative History, Patents.**

*Embrex v. Service Engineering, Inc.*, 216 F.3d 1343 (Fed. Cir. 2000).

*J.E.M. Ag Supply v. Pioneer Hi-Bred Int'l, Inc.*, 122 S.Ct. 593 (2001).

*Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002).

*Monsanto Co. v. McFarling*, 302 F.3d 1291 (Fed. Cir. 2002).

*Roche Prod., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984)

U.S. Pat. No. 4,945,050 (Method for transporting substances into living cells and tissues and apparatus therefor).

U.S. Pat. No. 6,051,757 (Regeneration of Plants Containing Genetically Engineered T-DNA)

7 U.S.C. §2541(a)(4).

7 U.S.C. §2544.

7 U.S.C. §2461(e).

35 U.S.C. §271(a).

U.S. Congress, House Report No. 91-1605, p. 11 (1970).

**(2). Scholarly Articles and Briefs.**

Association of American Medical Colleges et al., *Amicus Curiae* Brief, Duke Univ. v. Madey, No. 02-1007 (U.S. Supreme Court), Jan. 2003, p. 4.

Bohannon, Christina, *Beyond Abrogation of Sovereign Immunity: State Waivers, Private Contracts, and Federal Incentives*, 77 N.Y.U. L. REV. 273 (2002).

Burk, Dan & Lemley, Mark, *Policy Levers in Patent Law*, – VA. L. REV. – (forthcoming 2003).

Cohen, Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 29 (2001).

Consumer Project on Technology, *Amicus Curiae* Brief, Duke Univ. v. Madey, No. 02-1007 (U.S. Supreme Court), Jan. 2003, p. 4.

Dinwoodie, Graeme B. & Dreyfuss, Rochelle Cooper, *WTO Dispute Resolution and the Preservation of the Public Domain of Science Under International Law*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME (Duke Law School, April 2003).

Eisenberg, Rebecca, *Patent Swords and Shields*, 299 SCIENCE 1018, 1019 (2003).

Eisenberg, Rebecca S., *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989).

*Janis/Experimental Use*

Finer, J.J., et al., *Particle Bombardment Mediated Transformation*, in HAMMOND, J., ET AL., EDS. PLANT BIOTECHNOLOGY: NEW PRODUCTS AND APPLICATIONS 59 (1999).

Fitzgerald, Anne, *Scientists free others to transform corn*, DES MOINES REGISTER M1 (March 9, 2003).

Frame, Bronwyn R., et al., *Agrobacterium-Mediated Transformation of Maize Embryos Using a Standard Binary Vector System*, 129 PLANT PHYS. 13 (2002).

Hantman, Ronald D., *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. OFF. SOC'Y 617 (1985).

Janis, Mark D., *Sustainable Agriculture, Patent Rights, and Plant Innovation*, 9 IND. J. GLOBAL LEG. STUD. 91, 105 (2001).

[Janis & Kesan 2002a]. Janis, Mark D. & Kesan, Jay P., *Intellectual Property Protection for Plant Innovation: Unresolved Issues After J.E.M. v. Pioneer*, 20 NAT. BIOTECH. 1161 (2002).

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

Karp, Jordan P., *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991).

Mueller, Janice M., *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001).

O'Rourke, Maureen, *Toward A Fair Use Doctrine in Patent Law*, 100 COLUM. L. REV. 1177 (2000).

*Janis/Experimental Use*

Rai, Arti Kaur, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999).

Sunstein, Cass R., *Social Norms and Social Rules*, 96 COLUM. L. REV. 903 (1996).

Walsh, John P. et al., *Working Through the Patent Problem*, 299 SCIENCE 1021 (2003).

Zohrabian, Arminch, et al., *Valuing Pre-Commercial Genetic Resources: A Maximum Entropy Approach*, 85 AM. J. AG. ECON.429 (May 2003).