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Rules v. Standards for Patent Law in the Plant Sciences

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This article argues that US patent jurisprudence as applied to the plant sciences is moving to a second stage that will be characterised by more by incremental calibration than by spectacular change. The article discusses two doctrines of patent scope that are likely to be implicated in calibrating the utility patent system for the plant sciences: enablement and experimental use. It considers how those doctrines may be refined to serve as calibration tools in the application of patent law to the plant sciences.

Introduction

Patent law jurisprudence develops in loosely definable stages within technology areas. In the plant sciences, US patent law jurisprudence has now progressed through its first stage. The Supreme Court's landmark decision in *JEM Ag Supply* (2001) has confirmed that plants are eligible for protection under the US utility patent scheme, bringing to a close an initial round of debate over the scope of the utility patent statute's eligibility provision and its relationship with the *Plant Variety Protection Act* 1970 (US) and the *Plant Patent Act* 1930 (US).

In this article, I comment briefly on the emerging, second stage of utility patent jurisprudence in the plant sciences. Whereas the first stage dealt with threshold statutory interpretation questions, the second stage will focus on calibration. That is, it will feature incremental refinements to the key patent doctrines that determine whether the patent system will foster or thwart plant sciences innovation. While second stage patent jurisprudence in the plant sciences is likely to be considered less spectacular than its forerunner, it will nonetheless provide courts with the challenge of confronting the patent system's most sensitive policy problems.

This exploration of second stage jurisprudence focuses on two doctrines of patent scope that are likely to be implicated in calibrating the utility patent system for the plant sciences: enablement and experimental use. I examine how those doctrines have been applied to date in the plant sciences, and offer some suggestions for next steps in refining those doctrines to effectuate patent system calibration. Though these suggestions have implications for the substantive content of the respective doctrines, they are directed principally at rationalising the process through which the doctrines might succeed as calibration tools.

Enablement of Transgenic Plant Inventions

A US patent document must provide a description of the patented invention that is adequate to enable a person of ordinary skill in the art to make and use the claimed invention (35 USC §112, 1st ¶). The enablement requirement seeks to ensure that patentees provide high quality teachings that correlate in scope with the scope of the potentially valuable patent rights that they receive; as such, enablement is an essential part of the quid pro quo of the patent system (*In re Wright*, 1993, at 1561). A patent claim is enabled even if ordinary artisans would need to undertake some experimentation in order to make or use a patented invention, as long as experimentation is not deemed to be 'undue' (*In re Vaeck*, 1991). Courts are to balance a number of factors when determining whether experimentation is undue for enablement purposes, including the often critical factor of predictability in the art (*In re Wands*, 1988). The Federal Circuit has identified biotechnology as one of the unpredictable arts for enablement purposes, though the court has also recognised that assessments of predictability should be revised as science advances (*In re Wright*, 1993; *Enzo Biochem, Inc v Calgene*, 1999). Relatedly, the Federal Circuit has suggested that the enablement requirement should be applied with particular vigour in 'nascent technologies' (*Chiron v Genentech*, 2004). Courts have also held that the enablement inquiry must be undertaken in view of the state of the art as it existed at the patent application filing date (*In re Goodman*, 1993).

An issued patent is presumed to comply with the enablement requirement, a consequence of the general presumption of validity accorded to all issued patents (35 USC §282). Patent challengers bear the burden of proving a failure of enablement, and must establish the relevant facts by the standard of clear and convincing evidence in order to overcome the presumption of validity (*Chiron v Genentech*, 2004, at 1252).

In a series of cases, the Court of Appeals for the Federal Circuit has applied the enablement requirement to transgenic plant inventions. In *Adang v Fischoff* (2002), an appeal from an interference proceeding in which two inventors, Adang and Fischoff, both claimed rights to the same invention, the court analysed the validity of the following interference count:

> A tomato plant which has been regenerated from a tomato plant cell transformed to comprise a full length *Bacillus thuringiensis* crystal protein gene capable of encoding a *Bacillus thuringiensis* crystal protein of about 130 kD under control of a promoter such that said gene is expressible in said plant in amounts insecticidal to Lepidopteran insects (at 1349).

Adang's patent specification included an example reporting the transformation of tobacco cells with a *Bt* gene having the characteristics called

for in the count, and a list of 94 types of plants (including tobacco and tomato) described as being capable of being transformed by *Bt* crystal protein genes.

The court concluded that the disclosure did not enable the count. References from the technical literature, even after the filing date of Adang's application, showed that attempts to incorporate a full length *Bt* crystal protein gene into various strains of tobacco plants using *Agrobacterium*-mediated transformation failed to produce stable transformations or predictable insect toxicity – and in some instances failed even to produce viable plants. Although both Adang and Fischoff had submitted expert evidence (testimony and new experimental evidence), Fischoff's was more credible; Adang's seemed to be based on hindsight. The court upheld the Patent and Trademark Office's (PTO) conclusion that it would have required undue experimentation on the part of a worker of ordinary skill to use the Adang disclosure to produce a transgenic tomato plant within the scope of the interference count (at 1355-8).

In *Plant Genetic Systems v DeKalb Genetics* (2003), the patent-in-suit claimed a transformed 'plant cell':

> A plant cell having a heterologous DNA stably integrated into its genome; said DNA comprising a heterologous DNA fragment encoding a protein having an acetyl transferase activity which inactivates a glutamine synthetase inhibitor in said cell (at 1338).

The patent disclosed working examples involving the transformation, by *Agrobacterium*-mediated transformation, of tobacco, tomato, sugar beet and potato plants, all dicots. Yet the term 'plant cell' in claim 1 arguably covered not only dicots, but also monocots (such as DeKalb's transgenic corn varieties). Likewise, claim 1 arguably covered any transformation technique. The enablement issue was whether the disclosure would have enabled a person of ordinary skill in the art to employ any transformation technique, including *Agrobacterium*-mediated transformation, to transform any plant cells, including monocot plant cells, as of the 1987 application filing date.

The trial court concluded that the patent specification did not provide an enabling disclosure of claim 1, and the Federal Circuit upheld this judgment on appeal. The trial court relied on an earlier case, *In re Goodman* (1993), and a detailed analysis of the technical literature and expert testimony. Concerning *Goodman*, the trial court had pointed out that the facts of record there supported the proposition that a viable *Agrobacterium*-mediated transformation technique for monocots was not generally known in the art as of 1985. The trial court concluded that *Goodman* therefore supplied a starting point for the trial court's enablement analysis; the trial court could look to the literature between 1985 and 1987 to determine whether the transformation art had advanced

during that time period. The Federal Circuit approved of this methodology, rejecting the argument that the trial court had effectively shifted the burden of proof on enablement to the patentee.

As for the literature, although the technical literature had reported one transformation of corn via *Agrobacterium* in 1986, other contemporaneous literature references expressed reservations about these reports, as did the patentee's own personnel. Early 1990s work reported only limited success in transforming corn via electroporation and microprojectile bombardment, and not until 1995 did the patentee succeed in transforming corn via *Agrobacterium*. The Federal Circuit concluded that the trial court had properly considered the reports of successes in the 1990s in the enablement analysis, because they raised the inference that undue experimentation would have been required to achieve success as of 1987, the relevant date for the enablement inquiry.

In a related litigation, the enablement issue came before the Federal Circuit again. In *Monsanto v Bayer Bioscience* (2004), Monsanto (successor to DeKalb Genetics) sued Bayer (successor to Plant Genetic Systems) for a declaration that several patents relating to *Bt* technology were not infringed and/or were unenforceable. The patents claimed methods for transforming plants with a truncated *Bt* gene (and related genes and transformed plants and plant cells), with no express limitation to particular plants. Yet the patents apparently disclosed only the transformation of tobacco plants, again presenting the question of whether a claim encompassing all plants, including monocots, was enabled by a specification that disclosed only the transformation of a dicot, in view of the state of the art in 1986, the relevant application filing date.

The trial court undoubtedly would have been correct to look to earlier cases for factual support for the proposition that the disclosure in the patents did not enable the claims. But the trial court used a different strategy, concluding that the patentee Bayer was precluded even from litigating the issue, on the ground that Bayer's predecessor had litigated and lost a similar issue in the *Plant Genetic Systems* case (2003). The Federal Circuit reversed this decision. The patent disclosure at issue was not identical to the disclosure that had been in issue in the *Plant Genetic Systems* case. While Bayer was bound by the earlier finding that *Agrobacterium*-mediated transformation of monocots was not established in the art as of 1986, Bayer was still entitled to litigate the question of whether its patent disclosure supplied the missing teachings.

I have related these cases in some detail to illustrate a broader point about the character of second stage patent jurisprudence. None of these enablement decisions articulates especially bold new statements of the law. Instead, they offer insights tied closely to the particular facts of the cases. The *Monsanto* case (2004) in particular exemplifies the rather

extreme fact specificity of the enablement inquiry. Each of the cases turns on close assessments of the technical literature and credibility judgments about conflicting expert testimony.

On first glance, these cases may seem to refute the claim that the enablement doctrine could serve as an important policy instrument in shaping patent rights in the plant sciences. If policy advancement resides in the promulgation of a constellation of new, bright-line rules, then the pessimistic assessment of enablement's potential may be correct. These cases surely illustrate that enablement is not a likely platform for the development of rule-bound law.

However, we should resist the notion that policy advancement in patent law requires the articulation of new catalogues of special rules. And, we should resist the quick dismissal of the enablement doctrine as a policy tool. The very essence of what I mean by 'second stage jurisprudence' is that policy advancement can occur (1) incrementally and (2) by way of a few flexible standards rather than a multitude of intricate rules.

These observations connect to a larger jurisprudential debate between the relative merits of rules versus standards. A full consideration of this debate, even limited to its application in patent law, is beyond the scope of this article. However, a brief introduction is pertinent here. A 'rule', as understood in this debate, involves a high degree of ex ante determination of authorised (or required) conduct, leaving limited discretion to the adjudicator, while a 'standard' involves a high degree of ex post determination, leaving to the adjudicator the bulk of the task of determining authorised or required conduct and adjudicating disputed facts (Kaplow, 1992). Actual legal commands cannot be expected to organise themselves neatly into one or the other category, but it is plausible to speak of a continuum of legal commands running from rules at one extreme (constraining judicial discretion) to standards at the other (furnishing discretion) (Lee, 2002).

Whether a given legal problem calls for resolution by a rule or by a standard is a complex judgment, but one simple way to think about the problem is to consider a rough balance of costs and benefits. A rule is relatively costly to promulgate but should be relatively cheap for judges to apply (and for interested parties to apply when attempting to predict outcomes). A standard is relatively cheap to promulgate but may be costly for judges to apply (and costly for interested parties, because outcomes may be less predictable) (Kaplow, 1992: 621).

In the lexicon of rules v standards, enablement currently operates as a standard, as cases like *Adang* and *Plant Genetic Sciences* and *Monsanto* illustrate. The enablement requirement does not particularise in advance the precise level of disclosure that will be compliant; instead, it states a generalised aspiration and leaves PTO examiners and judges

broad discretion to adjudicate enablement ex post. This approach entails certain costs. As the plant sciences enablement cases illustrate, enablement is costly for litigants (and judges) to apply, requiring intensive development and evaluation of technical evidence. Outcomes in enablement cases, including those in the plant sciences, have been criticised as unpredictable (Todaro, 1994). Moreover, the fact that the enablement determination is made ex post, sometimes years after the application filing date, yet must evaluate the disclosure in view of the state of the art existing as of the application filing date, creates the potential for the error through reliance on hindsight.

These costs are significant, and these types of arguments about costs are standard fare in patent policy circles. In particular, arguments about the value of predictability in patent rights form the centrepiece of much of the Federal Circuit's recent thinking about patent scope, on issues such as claim interpretation and limits on the doctrine of equivalents.

What is routinely missing from these debates over claim scope is an analysis of the other side of the balance – that is, a recognition that the process of formulating detailed rules on enablement and other claim scope doctrines would likewise entail significant costs. At this early stage in the history of utility patents for plants, we lack sufficient information to design particularised enablement rules for plant sciences innovations. The enablement cases discussed above show that the information set necessary for designing any such rules is a complex one. In addition, given the rapid pace of technological change, and change in our understanding of the innovation process, any particularised rules would quickly become obsolete. These sorts of objections – information costs, obsolescence – are commonly offered against rule-bound law (Sunstein, 1995).

In view of these countervailing considerations, policy-makers should resist the temptation to craft (or attempt to craft) particularised, bright-line rules to govern matters of patent scope in the plant sciences. At least in this second stage of jurisprudence, policy-makers should allow doctrines like enablement to operate as flexible standards, on the ground that it is likely to be more efficient to develop the law incrementally, through case-specific judgments, than to engage in a complicated rule-making exercise.

This line of argument has its limits. I am not advocating untrammelled judicial discretion over claim scope determinations. Consider, for example, the US patent law's 'written description' requirement. The Federal Circuit has held that 35 USC §112, 1st paragraph imposes a requirement that the patent applicant provide an adequate 'written description' of the invention in addition to providing an *enabling* description of the invention (*University of Rochester v GD Searle*, 2004). I and others have criticised the court's written description jurisprudence as

essentially standardless – that is, as not even articulating a discernible standard that supplies minimal guidance for the exercise of judicial discretion (Janis, 2000). Here, the costs of unpredictability are substantial, and the cost of articulating at least a flexible standard is surely not so high as to justify the current, standardless approach.

To a reformer, the suggestion that the enablement doctrine be allowed to operate as a standard, and that it be left to evolve incrementally through case law, may seem too passive. But this is deceptive. It is quite possible to fashion policy initiatives proactively in a standards-driven environment. For example, there are several ways in which the enablement standard, as applied to plant sciences inventions, might be enriched without converting it into a bright-line rule:

(1) develop a better understanding of the qualities of the 'person of ordinary skill' in the plant biotechnology art;
(2) develop a better fact base for assessing whether particular endeavours within the plant sciences are 'predictable';
(3) continue to develop a fact base for assessing 'undue' experimentation.

One mechanism that might be considered for implementing these suggestions is the process of developing examination guidelines at the US Patent and Trademark Office. The process of formulating examination guidelines for enablement in plant biotechnology might yield benefits even apart from the substantive content of any such guidelines. The guidelines drafting exercise could serve as a forum in which researchers can inform the PTO about relevant facts within the plant sciences industry. In addition, because guidelines are less formal than legislation or even regulations, guidelines may in theory be formulated more rapidly, and may thus prove to be a good mechanism by which the PTO can respond to rapid shifts in the technological landscape. Similarly, because guidelines need not be permanent, they can provide a good forum for policy experimentation. Mistakes can be more readily addressed, and hypothetical illustrations can be explored and analysed. There is some evidence that examination guidelines can operate constructively in the patent system, and can inform judicial decisions as well as PTO practice (for example, *In re Brana*, 1995; *Enzo Biochem, Inc v Gen-Probe, Inc*, 2002; 2001 Utility Examination Guidelines).

Examination guidelines also present significant potential downsides. Because they do not have the force of law, they are inherently less capable of reducing uncertainty costs than is a binding set of legal commands. In addition, a guidelines drafting exercise always carries the risk of devolving into an exercise in formalism (for example, Pila, 2003). An effort to develop bright-line rules in the guise of guidelines would be as counterproductive as an effort to develop bright-line legislation for enablement.

Experimental Use in Plant Sciences Research

The patent infringement provision in US law speaks in absolute terms. The provision prohibits unauthorised 'making' or 'using' of a patented invention, without regard for whether the alleged infringement is innocent, *de minimis*, or undertaken in an arguably non-commercial setting (35 USC §271(a)). The absolutist approach of the patent infringement provision offers some social benefits: it may reinforce the innovation incentives that the patent grant is thought to provide, and may facilitate market transactions in patent rights by eliminating a source of uncertainty over enforcement. On the other hand, the absolutist approach also imposes social costs: it may chill follow-on innovators, even those who are exploiting the patented technology for purposes of academic research.

When confronted with these competing considerations, the US Congress and courts only rarely have departed from the absolutist structure of the US patent infringement provision. Where alleged infringers have claimed that their unauthorised 'use' of a patented invention was in the course of experimentation, US courts have only grudgingly recognised, and almost never applied, an exception to infringement liability, characterising the experimental use exception as 'truly narrow' (*Madey v Duke University*; *Roche v Bolar*). Congress has crafted a statutory exemption that is limited to experimentation 'solely for purposes reasonably related to' the development of data for submission to the FDA (35 USC §271(e)(1)). The US Supreme Court has held that the §271(e)(1) exemption applies to 'the use of patented compounds in preclinical studies ... as long as there is a reasonable basis for believing that the experiments will produce' the type of data that would be relevant for an eventual FDA submission (*Merck KgaA v Integra Lifesciences I, Ltd*, 2005).

Patent scholars have long been intrigued by the experimental use doctrine, and have exhaustively explored its policy implications (for example, Strandburg, 2004; Mueller, 2001; Cohen & Lemley, 2001; O'Rourke, 2000; Karp, 1991; Eisenberg, 1989; Hantman, 1985). But despite numerous calls for the creation of a regime of formalised experimental use rules (including some recent debate about whether to expand the existing §271(e)(1) exemption to cover plants), the US Congress has declined, to date, to implement experimental use legislation. By contrast, in Europe, a generic experimental use exception has been codified in many national patent statutes and, in Germany, a particularised experimental use exception directed at shielding experimental plant breeding from patent liability has been incorporated into the patent statute (Deustcher Bundestag).

The basic policy arguments underlying the experimental use doctrine are well understood. A robust experimental use exception is thought to

lower the cost to researchers of conducting follow-on research, but it also is thought to reduce patent royalties (by shielding research uses from liability) and shorten the effective patent term (by reducing the costs to researchers of designing around). The net effect on incentives to invest in innovation is not clear and, even if it were, it is not clear that actual researcher behaviour would approach the rational instrumentalism that this simple cost/benefits analysis might imply. Accordingly, the way forward for the application of the experimental use doctrine in modern US patent law, and particularly in patent law concerning the plant sciences, is not clear.

The debate over the experimental use exception resembles the debate over application of other claim scope doctrines, such as enablement. Like enablement, experimental use appears to be operating more like a standard than a rule. Experimental use appears to be characterised by largely ex post evaluations of conduct, except that whereas ex post evaluations in enablement are undertaken by judges in contested litigation, ex post evaluations of experimental use in the plant sciences (and in many other areas) apparently are being undertaken informally, by parties operating in the shadow of potential litigation.

Perhaps predictably, many suggestions for reforming experimental use are directed at attempting to transform experimental use into a formalised hierarchy of rules. Many of these reform arguments focus on the need to create a sharply defined safe harbour for follow-on researchers, reducing the costs imposed on them by the threat of patent litigation. However, for many of the same reasons that I offered in connection with enablement, the costs of attempting to formulate a code of rules for experimental use might swamp any savings realised.

This brings us again to the question of whether accepting experimental use as a standard, as contrasted with a rule, is tantamount to remaining passive while the doctrine merely runs its course in the various technology areas in which it is important, including the plant sciences. The answer, again, is no. Here, as with enablement, efforts could be directed towards reducing the cost of the information necessary to make correct decisions, rather than being directed towards formulating new rules.

One strategy for reducing information costs connected with the experimental use exception is to develop a better understanding of the informal research norms and practices in biotechnology. Patent scholars have noted the potential benefits of such an approach in biotechnology patenting generally (Eisenberg, 1989; and Rai, 1999). In other writings, I have advocated for such an approach to the experimental use doctrine in plant biotechnology patenting (Janis, 2001).

Even a casual analysis of anecdotal information suggests that there exists a repository of sources that might enrich the application of the experimental use doctrine in the plant sciences. For example, the literature contains references to a past era of public sector plant breeding research characterised as a 'collegial system of exchange' of germplasm among researchers, and contrasts the old norm to modern practices, which are said to be dominated by widespread claims of exclusive rights (Zohrabian, 2003).

The old norm of free sharing deserves close study. In actual operation, did research colleagues share germplasm freely without any limitations? Was there an implicit requirement that the recipient give credit? Was there 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 decision-makers.

Anecdotal information about current practices is also obviously of great relevance, and may likewise yield a rich and complex array of results. For example, 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 US (for example, US Pat No 4,945,050, Method for transporting substances into living cells and tissues and apparatus therefor; see generally Finer et al 1999). Another major transformation technology particularly effective in dicots, *Agrobacterium*-mediated transformation, is subject to many claims of patent protection (for example, US Pat No 6,051,757, Regeneration of Plants Containing Genetically Engineered T-DNA) and, as we have seen, has played a central role in enablement cases in the plant biotechnology area.

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 behaviour. However, anecdotal evidence might well be informative about the patentees' licensing practices on patented plant transformation equipment and techniques, and researchers' behaviour in response to those practices.

Recent reports about a new transformation technique may give an indication of the complexity of modern norms of research behaviour in the plant biotechnology area. A group of researchers 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, as we have seen in the enablement cases, 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 this brief example that using the proposed approach will not result in a set of pristine rules for applying the experimental use exception. That, of course, is part of the very premise on which this approach is based: it trades off uncertainty for accuracy, and seeks to avoid the costly proposition of legislating deeply on experimental use.

Conclusion

Surprisingly, despite over two centuries of experience with the utility patent system, through multiple cycles of rapid technological progress, we still know relatively little about how to calibrate a patent system to accommodate a new technology area. We know that traditional patent doctrines, such as enablement and experimental use, are important and, in the emerging second stage patent jurisprudence in the plant sciences, we have a few examples of how those doctrines may apply. We do not yet know enough, however, to craft detailed, bright-line rules that precisely designate ex ante the level of disclosure that will be required to enable a transgenic plant invention, or the scope of experimentation that will be

allowable in a plant biotechnology research setting. Rather than expending effort attempting to transform enablement and experimental use into rule-bound doctrines, we should allow both doctrines to continue to operate as flexible standards, and expend effort enriching the information base on which courts and the PTO can draw in applying those doctrines. This bottom-up approach to the doctrines of enablement and experimental use may prove most productive as the jurisprudence of patent rights for plants continues to mature.

Note

* A prior version of this article appears as a chapter in Jay P Kesan (ed), *Agricultural Biotechnology and Intellectual Property: Seeds of Change* (Oxford – (ABI) (forthcoming 2007).

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