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Originalism, J.E.M., and the Food Supply, or Will the Real Decision Maker Please Stand Up?

Malla Pollack, *American Justice School of Law*

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*495 ORIGINALISM, J.E.M., [\[FN1\]](#) AND THE FOOD SUPPLY, OR WILL THE REAL
DECISION MAKER PLEASE STAND UP?

[Malla Pollack \[FN1\]](#)

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In 2001, the United States Supreme Court decided *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc. (J.E.M.)*, holding that sexually reproduced plants are statutorily proper subject matter for full utility patents. [\[FN2\]](#) In the long shadow of *J.E.M.*, many of the speakers at the "Malthus, Mendel and Monsanto" conference [\[FN3\]](#) explained (some with great anger) that the world's food supply is at risk--not from Martians, but from the patent system-- as manipulated by Monsanto and a few other giant agribusinesses. Utility patents on basic food crops [\[FN4\]](#) have been *496 used to close down experimental farms. [\[FN5\]](#) Patented genetically engineered DNA has contaminated wild varieties. [\[FN6\]](#) When nature produces an insect or crop disease which flourishes on Monsanto's Round-Up®, [\[FN7\]](#) we will have insufficient alternatives. [\[FN8\]](#) This paper does not elaborate on these risks. Instead, it discusses the disheartening history of how we got here, so that we can take precautions against additional trips in this direction.

Additionally, and perhaps more importantly, this paper explains that many utility patents on plants, and perhaps most utility patents on biotechnology, are legally suspect for violation of [35 U.S.C. § 112, paragraph 1 \(section 112\(1\)\)](#), by allowing deposit to substitute for the statutorily-mandated enabling written description. The [section 112\(1\)](#) problem is especially intriguing be-

cause Justice Thomas's majority opinion in *J.E.M.* relied on the alleged modern ability of plant breeders to provide written descriptions sufficient for [section 112\(1\)](#) compliance. According to Thomas, earlier statements in congressional reports that plants were not proper subject matter for utility patents rested on the inconceivability of writing enabling descriptions. [\[FN9\]](#) According to *497 the Court (while invisible to Congress, patent attorneys, the Patent and Trademark Office (PTO), and the general public), plants of all kinds seemingly had been included in section 101 of the 1790 or 1793 Patent Act. [\[FN10\]](#) These utility patents did not issue until the 1980s because, only then, did science provide language sufficient to craft enabling written descriptions of such inventions. Oddly, only one year after *J.E.M.*, the United States Court of Appeals for the Federal Circuit (Federal Circuit) held in *Enzo Biochem, Inc. v. Gen-Probe, Inc.* that both the enablement and written description requirements of [section 112\(1\)](#) could be fulfilled through deposit [\[FN11\]](#)-without admitting that it was undercutting one of *J.E.M.*'s main props for constructing the fiction that Congress had legislated utility patents on plants. Thus, without any congressional action, the courts and the PTO have given a few large businesses the power to close down most independent research on basic food crops. [\[FN12\]](#) Raising the *J.E.M.*-Enzo II disconnect might prod the courts into more constraining deference to Congress.

As the Drafters of the Constitution warned the ratifying generation, the machine of representative government requires the lubrication of public accountability. [\[FN13\]](#) Ex ante, the public must know who will make a decision so that they may attempt to influence the outcome. Ex post, the public must know who made the decision, so that the public may assign praise or blame by words and ballots. The most frightening aspect of the current patent power of agribusiness is the lack of such a decision maker. No publicly accountable U.S. official(s) decided that utility patents on sexually reproduced plants were good policy. Such refusal to accept responsibility is not a necessary part of the rule of law in a republican polity, even when the legislature leaves large statutory *498 gaps for judicial explication. Canada chose not to take this course. [\[FN14\]](#)

What happened in the United States? Everyone involved made believe that the decision had

already been made by someone else--even though everyone knew to the contrary. No one, therefore, took responsibility for choosing a major change in public policy.

This paper traces the line of non-decision. [FN15] Part One traces the non-decision to grant full utility patent protection to basic food crops. Part Two traces the non-decision to grant such patents without the enabling written description required by statute for all utility patents.

I

The Decision to Grant Utility Patents

A. The Constitution

First, someone decided to include in the Constitution a congressional power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries[,]" [FN16] the Progress Clause, a.k.a. the Copyright and Patent *499 Clause (the "Clause"). [FN17] While James Madison and William Pinkney both made related proposals, neither suggested the exact words included in the Constitution. [FN18] The current text emerged from the Committee of Eleven and was accepted by the drafting convention with no one dissenting; any related discussion has been lost from the historical record. [FN19] During the ratification debates, the Clause was almost unmentioned. [FN20]

Nothing in the surviving materials demonstrates that the Drafters or Ratifiers believed that every non-obvious advance [FN21] should be patentable. On the contrary, the purpose limitation in the Clause would be unnecessary if all conceivable "exclusive right[s]" granted for "limited times" to "inventors" in their "discoveries" would necessarily "promote the progress of . . . useful *500 arts." [FN22] The Supreme Court has implied its recognition of some limiting principle by refusing to allow patents on scientific principles (such as $E=MC^2$), mathematical principles (such as the Pythagorean Theorem), and abstract intellectual processes (such as methods of making calculations) on the sole ground that the opposite rule would deprive the public of "basic

tools of scientific and technological work." [\[FN23\]](#)

However, Congress does seem to have the discretionary power to enact exclusive rights in non-obvious advances in plant breeding. While I, and other scholars, have argued that the original meaning of the Patent Clause excludes monopolies on business methods, [\[FN24\]](#) those arguments turn on the original meaning of the phrase "useful arts." I am not prepared to claim that, in 1789, farming was not considered a "useful art." [\[FN25\]](#) Early British and American patents protected farm machinery and processes. For example, the legislature of colonial Pennsylvania granted a 1717 petition to record an English patent on a novel method for refining Indian corn before shipment. [\[FN26\]](#) Colonial Maryland granted two patents for threshing machines. [\[FN27\]](#) Colonial South Carolina issued several patents for rice processing machinery and one for *501 "certain implements for the better preparing and cultivating of rice, indico [sic] and grain, planted in rows." [\[FN28\]](#) In Restoration Britain, a few patents were issued on newly-industrialized crops, though the patentees seemingly made no attempts to enforce their rights against others. Three early eighteenth century British patents involved fertilizers and another covered swine feed. [\[FN29\]](#) At this time, of course, the British government had a registration system; patent applications were granted without any inquiry into their merit. [\[FN30\]](#) These patents, therefore, may well have been invalid. Nevertheless, I cannot make a good argument that plant breeding is not a "useful art" pursuant to Article I, section 8, clause 8.

One might try to argue that plants are not the "discoveries" of "inventors." The Divinity or the big bang created them. Unfortunately, that argument would undercut all patentable subject matter. The Supreme Court was right, I believe, when it said the line between "products of nature" and "patentable inventions" regards the extent of human intervention involved in the process of change, not the line between living and non-living. [\[FN31\]](#) But recognizing that some living things may be patentable does not answer the question of whether Congress decided to make full utility patents available on basic food crops.

In sum, the Patent Clause of the Constitution seems to allow Congress to enact a patent stat-

ute providing full utility patents for non-obvious sexually reproduced plants. What I cannot locate is a determination by Congress to enact such a statute.

B. The Statutes

The next decision point is Congress's passage of the Patent Act of 1790, which is described in detail by historian Edward C. Walterscheid. [\[FN32\]](#) He points to no discussions about plants, animals, *502 or farm products. [\[FN33\]](#) This statute cabins patentable subject matter as "any useful Art, Manufacture, Engine, Machine, or Device, or any improvement therein." [\[FN34\]](#) In 1793, Congress passed a new Patent Act which set patentable subject matter at "any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter." [\[FN35\]](#) Patentable subject matter remained stable [\[FN36\]](#) until the 1952 revision, wherein it morphed into its current form, "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." [\[FN37\]](#) According to the accompanying congressional report, "process" was the judicially established meaning of the statutory word it replaced, "art." [\[FN38\]](#)

If plants are patentable subject matter, they are either "manufactures," or "compositions of matter"--enacted terms going back respectively to the Patent Acts of 1790 and 1793. Were plants within the contemplation of law makers during consideration *503 of the 1790 or 1793 Acts? No one can be sure, but the premier historian of this material, Edward C. Walterscheid, makes no mention of any such link. [\[FN39\]](#) As Walterscheid mentions, Alexander Hamilton's Report on the Subject of Manufactures, [\[FN40\]](#) submitted to the House of Representatives on December 5, 1791, recognized that some people read the Patent Clause to disallow patents for importation of technology. [\[FN41\]](#) As an alternative, Hamilton suggested a system of pecuniary rewards to support "arts, agriculture, manufactures, and commerce," including importations of technology and trained workers. [\[FN42\]](#) The inclusion of "agriculture" in the premium system is ambiguous, at best, on Hamilton's views concerning the overlap of plant breeding and utility patents. Furthermore, the Report on the Subject of Manufactures predates the inclusion of "composition of mat-

ter" in the statutory list of patentable subject matter. [\[FN43\]](#) A sentence in the report accompanying the 1836 reorganization of the patent system is similarly ambiguous. The report, discussing the United States before the War of 1812, states that "[t]he arts in this country were but little understood, and but little cultivated. Agriculture and commerce constituted our principle business." [\[FN44\]](#)

***504** Early federal legislators were aware of scientific farming. Even in the slave states, public interest in improvement in American agricultural practice was widespread in the late eighteenth and early nineteenth centuries. [\[FN45\]](#) Many leading politicians, including both George Washington and Thomas Jefferson, were actively involved in agricultural innovation on their own land. [\[FN46\]](#) Americans understood the desirability of better seed stocks. One American reaction to a 1790s epidemic of Hessian fly was a search for more resistant wheat varieties. [\[FN47\]](#)

In the twentieth century, plant breeders were given some protection by two statutory schemes distinct from utility patents, the Plant Patent Act of 1930 (PPA) [\[FN48\]](#) and the Plant Variety Protection Act of 1976 (PVPA). [\[FN49\]](#) Neither required the detailed enabling description needed to obtain a utility patent. [\[FN50\]](#) Neither gave right holders the exclusion power of utility patents. Reproducing a plant by seed (i.e., sexually) is not (and never was) a ***505** violation of a plant patent. [\[FN51\]](#) PVPA rights have two major exceptions--one allowing farmers to save seed for later planting [\[FN52\]](#) and one allowing research. [\[FN53\]](#)

Neither the Court nor the PTO has suggested that Congress considered and decided to grant full utility patent protection to sexually reproduced plants, which include the United States' major food crops. On the contrary, the Congresspersons involved in passing the PPA and PVPA clearly indicated their belief that utility patents, section 101 patentable subject matter, did not include these food crops. Both the House and Senate reports concerning the PPA asserted that:

[t]he purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry, and thus assist in placing agriculture on a basis of economic equality with industry. . . . Today the plant

breeder has no adequate financial incentive to enter upon his work. A new variety once it has left the hands of the breeder may be reproduced in unlimited quantity by all [\[FN54\]](#)

The report accompanying the PVPA stated that the new protection was necessary because "[u]nder patent law, protection is presently limited to those varieties of plants which reproduce asexually." [\[FN55\]](#)

Yet the United States Supreme Court insists that Congress created full utility patent protection for sexually reproduced plants, including basic food crops. [\[FN56\]](#) How? By the lawyerly trick of conflating constructive intent (the words of a statute) with actual intent (*506 thinking through a problem). [\[FN57\]](#) According to the Court (while invisible to Congress, patent attorneys, the PTO, and the general public), plants of all kinds seemingly had been included in section 101 from the 1790 or 1793 Patent Act. These utility patents did not issue until the 1980s because, only then, did science provide language sufficient to craft enabling written descriptions of such inventions. [\[FN58\]](#)

C. The Courts

So how did the United States Supreme Court conclude that "any . . . manufacture . . . or composition of matter" includes sexually reproduced food crops? First, the language was read broadly because the language was perceived as being broadly worded. [\[FN59\]](#) This is troubling because the Court began with the standard axiom that "unless otherwise defined, words will be interpreted as taking their ordinary, contemporary common meaning." [\[FN60\]](#) The Court, however, did not recite any 1790, 1793, or 1952 use of "manufacture" or "composition of matter" which, even allegedly, included food crops. [\[FN61\]](#)

To check for the contemporary understanding of the terms "manufacture" and "composition of matter" as used in the 1790 and 1793 Patent Acts, I looked in the PTO's online database of all surviving patent grants. [\[FN62\]](#) Since the United States issued patents without examination under the 1793 statute (changing to examination *507 only with the 1836 statute), [\[FN63\]](#) one

would expect patents on plants during this period --if Americans did understand the words used in the statute to include plants. Nevertheless, I found none. The PTO database allows search of pre-1976 patents by only two fields: modern patent classification and patent number. [FN64] First, I searched for all utility patents in the 1790-1975 database in classification "800," locating zero matching patents. [FN65] Then I pulled all utility patent numbers from the relevant period, locating 1989 files. [FN66] Using the search result list, I opened each file in order, locating not one patent on a seed, plant, plant part, or animal.

The J.E.M. Court's theory of linguistic meaning is startling. Presumably, the J.E.M. Court meant that Americans from 1790 through 1836 would have thought that "manufacture" or "composition of matter" included plants, if they had "recognized" that these statutory terms included living things, something "discovered" by the Supreme Court in 1980. [FN67] I simply do not understand how a word can mean x in year y, if speakers of the language in year y do not use the word to mean x. Word meaning is an empirical fact, not a neo-Platonic form.

As for the allegedly all-encompassing "any," the Court has recently refused to read it as all-encompassing. The Telecommunications Act of 1996 allows the Federal Communications Commission to preempt any state and local laws or regulations that "prohibit[] the ability of any entity" to provide telecommunications *508 services. [FN68] Yet eight Justices refused to accept this wording as including utilities owned by state or local government units. [FN69] This refusal is especially interesting because state owned utilities were mentioned in the related hearings and they were expressly excluded from the coverage of another section of the 1996 Telecommunications Act. [FN70] Clearly, Congress thought about state run telecommunications services while working on the 1996 Telecommunications Act. In contrast, no one has provided this type of evidence demonstrating that the 1790, 1793, or 1952 Congress thought about utility patents on food grains. Each time Congress actively considered full utility patent protection of such societal basics, it failed to enact this level of private control.

Second, to support the claim that Congress had intended full utility patent protection for ba-

sic food crops, the Court relied on the legislative history of the 1952 Patent Act. [\[FN71\]](#) However, the Court stood the legislative history on its head. According to the Court, section 101 must be read broadly because Congress intended it to "include anything under the sun that is made by man." [\[FN72\]](#) The one sentence report paragraph reads: "A person may have invented a machine or a manufacture, which may include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled." [\[FN73\]](#)

The report says "may," not "shall." [\[FN74\]](#) The purport of the sentence is a limitation on patentability, not an extension. To paraphrase, the report states that regardless of the extent of section *509 101 patentable subject matter (even if, arguendo, it includes anything under the sun that is made by man), no alleged invention shall receive a patent grant unless it fulfills all the other complex provisions of 35 U.S.C.

Third, the Court relied on a 1999 amendment to section 119 of the Patent Act--the addition of subsection (f) allowing the use of foreign plant variety protection documents to set priority for related patents. This amendment, according to the opinion of the Court delivered by Justice Thomas, demonstrates that Congress "has even recognized the availability of utility patents for plants." [\[FN75\]](#) He seems to have overlooked section 119(f)'s language which, while granting priority, makes the prioritized filings "subject to the same conditions and requirements of this section as apply to applications for patents," i.e., requires that utility patents not be granted unless all other sections of 35 U.S.C. are met, including the section 101 limit on patentable subject matter--which Thomas is circularly construing in light of section 119(f). Furthermore, as the petitioner in J.E.M. pointed out, this amendment was part of a rushed, middle of the night, insertion into an omnibus appropriations act. The last minute additions to the bill were so enormous that no one could believe that Congresspersons read them before voting on the legislation. Therefore, this amendment provides weak support for the subjective intent of a majority of the House and Senate --or even their staffers. [\[FN76\]](#) Thomas's use of this amendment, furthermore, is incon-

sistent with his lack of interest in what the 1930 and 1970 Congresses thought about the meaning of section 101. [\[FN77\]](#)

***510** Close scrutiny of the section 119(f) argument further undermines its vitality. Section 119(f) deals with PPA "plant patents," not utility patents on plants. This section neither recognizes nor requires the existence of full utility patents on sexually reproduced plants. The plain language of the subsection allows priority. It does not purport to add anything to section 101 patentable subject matter. It does not purport to recognize the existence of any U.S. utility patents which could be supported by international breeders' rights certificates; the set may be empty. [\[FN78\]](#) Furthermore, section 119(f) does not define international breeders' rights certificates as only including plants outside the United States' PPA "plant patents," which lack the full power of U.S. utility patents. U.S. plant patents are governed by [35 U.S.C. §§ 161-64](#). However, on most matters, these specific sections merely provide, by reference, the provisions that cover U.S. utility patents. [\[FN79\]](#) Plant patent priority based on international filings, including breeders' certificates, is covered by [35 U.S.C. § 119\(f\)](#). Furthermore, some foreign countries do cover asexually produced plants (subject matter of U.S. "plant patents") with breeders' certificates. [\[FN80\]](#) [Section 119\(f\)](#) provides that these international breeders' certificates can be used to create priority for U.S. plant patents. The section is neither superfluous nor only marginally useful absent utility patents on plants. In short, the Court overlooked ***511** the cross reference between [35 U.S.C. § 161](#) and [§ 119\(f\)](#). [\[FN81\]](#)

Furthermore, [section 119\(f\)](#) was merely a technical amendment. Justice Thomas's J.E.M. opinion downplayed the importance of the 1952 move of plant patents out of section 101, a move which strongly implied that plants had never been considered inside the subject matter of utility patents. [\[FN82\]](#) Justice Thomas and the rest of the majority were "loath to interpret what was essentially a housekeeping measure as an affirmative decision by Congress to deny sexually reproduced plants patent protection under § 101." [\[FN83\]](#) They did, however, rely strongly on [section 119\(f\)](#), which was merely a "technical amendment" required to fulfill one requirement of the In-

ternational Union for the Protection of New Varieties of Plants. [\[FN84\]](#)

The enactment history of [section 119\(f\)](#) is also indicative of its unimportance. The measure first appeared in House Bill 3460, the Morehead-Schoeder Patent Reform Act of 1996. According to the accompanying report, no hearings were held on the provision. [\[FN85\]](#) The measure was described as part of the international priority system required by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Specifically, some member countries lacked plant or utility patents on plants and were entitled to priority based on breeder's certificates. [\[FN86\]](#) The report did imply that the United States had full utility patents on *512 plants. [\[FN87\]](#) The TRIPS Agreement, interestingly, does not require full utility patent protection be granted on sexually reproduced plants. [\[FN88\]](#) The same bill provision, with almost identical legislative history (including the lack of hearings), was included in the Omnibus Consolidated Appropriations Act of 1997, [\[FN89\]](#) the 21st Century Patent System Improvement Act of 1997, [\[FN90\]](#) the American Inventors Protection Act of 1999, [\[FN91\]](#) and the Intellectual Property and Communications Omnibus Reform Act of 1999. [\[FN92\]](#) [Section 119\(f\)](#) was finally passed by Congress as part of the Fiscal Year 2000 Consolidated Appropriations Act, House Bill 3194. [\[FN93\]](#) House Bill 3194 engulfed [section 119\(f\)](#) by incorporating Senate Bill 1948. No report was ever issued to accompany Senate Bill 1948. [\[FN94\]](#) The report accompanying House Bill 3194 incorporated only the text of [35 U.S.C. § 119\(f\)](#). It included no discussion of the reason for the section. It did not, therefore, include the language from earlier congressional reports implying the existence of U.S. utility patents on plants. [\[FN95\]](#)

*513 Let me be clear, I am not claiming that enacted language is not positive law absent proof that a majority of congresspersons thought through the language. Legislation becomes law when a majority of both the House and the Senate vote "yea," and the president timely signs the bill. [\[FN96\]](#) An additional, subjective intent requirement would create chaos. However, I am arguing that, when enacted language clearly has not been thought through, the courts should enforce only what the language expressly states--as opposed to using that language to imply a ma-

major change in policy by Congress. The major policy change involved here is slamming shut the research (and the seed-saving) exceptions to private control of major food crops. I find unacceptable the Supreme Court's willingness to read such a policy change into law without a clearer congressional statement; this move is even more unacceptable in situations, such as this one, where the record demonstrates that the policy change was actively considered, and, after consideration, Congress said no. Furthermore, as discussed next, the Court strongly relied on a much less meaningful nonaction allegedly supporting plant patentability.

Fourth, the J.E.M. Court relied on congressional nonaction in the face of PTO grant of full utility patents on plants since 1985, [\[FN97\]](#) an action taken by the PTO in reliance on *Diamond v. Chakrabarty*. [\[FN98\]](#) At best, congressional nonaction is ambiguous evidence; more commonly it has no probative value whatever. As the Court has repeatedly stated "to give weight to the nonaction of Congress [is] to venture into speculative unrealities." [\[FN99\]](#) *514 "As a general matter, [the Court is] reluctant to draw inferences from Congress' failure to act." [\[FN100\]](#)

If Congress re-enacts the exact language which has been interpreted by the courts, at the most, the re-enactment may imply congressional endorsement of the judicial gloss on statutory language, but only in those few situations where Congress has "prolonged and acute awareness" of that interpretation. [\[FN101\]](#) While the 1952 Patent Act re-enacted most of the earlier language of [35 U.S.C. § 101](#), no prior decision had declared plants to be within the subject matter of utility patents. The Court did not misinterpret [section 101](#) to cover "anything under the sun that is made by man" until 1980. [\[FN102\]](#) The 1952 re-enactment of "manufacture" and "composition of matter," therefore, has no probative value. The extensive reach of Chakrabarty's mistake has only slowly become visible. The Court's reliance, in J.E.M., on post-1985 congressional nonaction is inconsistent with its own nonaction jurisprudence:

There are vast differences between legislating by doing nothing and legislating by positive enactment, both in the processes by which the will of Congress is derived and stated and in the clarity and certainty of the expression of its will. And there are many reasons, other

than to indicate approval of what courts have done, why Congress may fail to take affirmative action to repudiate their misconstruction of its duly adopted laws. Among them may be the sheer pressure of other and more important business [T]here may be a strong and proper tendency to trust to the courts to correct their own errors. [\[FN103\]](#)

Finally, the Court had the facts wrong on two points important to the majority. One has already been discussed, the relationship between [section 119\(f\)](#) and PPA plant patents. The second is discussed at length in part two of this paper. The Court believed *515 that scientific advances had produced tools allowing applicants to write enabling descriptions of sexually reproduced plants, thus undoing the [section 112\(1\)](#) problem perceived by Congress when enacting the PPA in 1930 and the PVPA in 1970. The Court dismissed the legislative history statements that utility patents were not available on sexually reproduced plants as merely "illustrat[ing] . . . that . . . Congress believed that plants were not patentable under [§ 101](#), both because they were living things, and because in practice they could not meet the stringent description requirement. Yet both of these premises were disproved over time." [\[FN104\]](#) As discussed below, the record demonstrates that the PTO (not Congress) gutted [section 112\(1\)](#)'s "stringent description requirement" for biological material by approving use of specimen deposits as a replacement for [section 112\(1\)](#)'s required written description.

D. The Missed Alternative

The United States Supreme Court did not need to follow this path. Canada did not do so. Canada's statutory list of patentable subject matter almost literally matches [35 U.S.C. § 101](#). [\[FN105\]](#) Canada's highest court followed the United States Supreme Court in recognizing the patentability of engineered micro-organisms. [\[FN106\]](#) Yet the Supreme Court of Canada decided not to read "manufacture" and "composition of matter" broadly enough to include the Harvard oncomouse. [\[FN107\]](#) The Canadian Supreme Court, recognizing that the Canadian patent office (like its United States counterpart) does not have the authority to refuse patents on non-statutory grounds, [\[FN108\]](#) declined to extend patent coverage to higher life forms in the absence of clear

legislative decision--the opposite of the position taken by the United States *516 Supreme Court. Higher life forms, the Canadian court recognized, possess attributes not clearly captured by the terms "manufacture," "machine," and "composition of matter." The Canadian court recognized that a policy of rewarding or incentivizing invention in general, does not require the inclusion of higher life forms inside patentable subject matter. [\[FN109\]](#)

The United States Supreme Court could have taken the same path. The Court has repeatedly used clear statement rules [\[FN110\]](#) to pass problems back to Congress. In J.E.M., the Court insisted on choosing the widest possible reading of [section 101](#), even though this reading wiped out two congressionally-created public interest exceptions to private intellectual property control over basic food crops. The Court chose this wide reading despite the absence of any evidence that Congress had ever made a considered decision to kill the public interest exceptions it had created. The Court, nevertheless, insisted that Congress had made the choice.

The J.E.M. decision is legal formalism run amok. I prefer the Canadian Supreme Court's "common sense" in *Harvard College v. Canada*. [\[FN111\]](#)

*517 II

Eliminating the Requirement of an Enabling, Written Description

The situation is even more bizarre. For utility patents on plants, the PTO is waiving one of the basic requirements for all utility patents--an enabling written description. Congress has never authorized this lowering of the patentability requirements. This part describes the time line on this usurpation of legislative authority. While dry, this is the most important section of this Article. J.E.M. has been decided. To overturn it, Congress would have to be motivated to work against politically powerful, large business interests. However, the current situation might be ameliorated by Supreme Court [\[FN112\]](#) consideration of the PTO's usurpation of the authority to allow mass violation of [35 U.S.C. § 112](#). [\[FN113\]](#) Furthermore, such a contest should not be undermined by Chevron deference to the PTO. [\[FN114\]](#)

Since their inception, U.S. utility patents have required the patent grantee to provide a sufficiently clear, written description of the alleged invention. "Sufficiently clear" means a description which would enable a person of ordinary skill in the relevant art to practice the invention. [\[FN115\]](#) This requirement continues in the current statute, where the patent application must contain the ***518** enabling, written description. [\[FN116\]](#) While not part of the application, the 1790 Act required patent grantees to provide enabling descriptions as soon as their patents were issued. [\[FN117\]](#) Under the 1793 Act, grant of a patent was a mere ministerial act; the application was not examined for its worthiness. [\[FN118\]](#) Nevertheless, applications filed pursuant to the 1793 Act were required to contain an enabling written description and, in certain circumstances, to be accompanied by deposits. [\[FN119\]](#) The Patent Act of 1836 reinstated examination of applications prior to the issuance of a patent. [\[FN120\]](#) Applications were required to include enabling written descriptions and, in certain circumstances, deposits as well. [\[FN121\]](#) As ***519** mentioned earlier, the current Patent Act requires an application to contain an enabling, written description; according to another section of the statute, the PTO has the discretion to require a model or specimen. [\[FN122\]](#) Nothing in the current statute allows replacement of the statutorily-required written description by a deposit.

The enabling description requirement makes sure that the public obtains practical use of the invention after the patent term expires. It also allows everyone interested in the art (including competitors) to study the technology while the patent is in force and, if they wish to compete, to invent around the patent. [\[FN123\]](#) Congress has lowered this requirement for plant patents [\[FN124\]](#) and for plant variety certificates. [\[FN125\]](#) In addition to a written description, ***520** PVPA applicants must deposit in a "public repository," and periodically replenish, "a viable sample of basic seed . . . necessary for propagation of the variety." [\[FN126\]](#) Congress has made no exceptions to the enabling, written description requirement for utility patents, but the PTO has done so.

The acceptability of a deposit to fulfill the enabling description of [section 112\(1\)](#) is rooted in

a 1970 decision by the now-defunct United States Court of Customs and Patent Appeals (CCPA), [\[FN127\]](#) In re Argoudelis, [\[FN128\]](#) reversing a PTO denial of a patent application. Argoudelis did not deal with a utility patent on a plant. The case involved PTO rejection of claims for two new antibiotic compounds and a microbiological process for preparing these compounds. Since the claims involved a product and the related process which required use of a specific micro-organism, then-current PTO guidelines required deposit of the needed micro-organism in a public depository. The applicant had made this deposit, but a few days later than required by PTO practice. Before the deposit, however, the micro-organism had been available in a university. [\[FN129\]](#) On the sole ground that the allegedly enabling deposit had been made untimely, the PTO rejected the patent application.

The CCPA described the issue as dealing with the date on which the application material was required to be enabling to the public--not the acceptability of deposit material (as opposed to written words) for enablement. [\[FN130\]](#) The court recognized that the PTO had allowed deposit of microbiological material for some fifteen years. [\[FN131\]](#) The court also recognized that "because of the *521 particular area of technology involved, [the applicant could] not sufficiently disclose by written word how to obtain the micro-organism starting material from nature." [\[FN132\]](#) The court also recognized that it did not have the power to grant "a general dispensation from the requirements of [\[section\] 112](#)," similar to that legislatively granted in section 162, the Plant Patent Act. [\[FN133\]](#) Additionally, the court recognized that it was dealing with an issue of first impression. [\[FN134\]](#) Focusing on the date issue, the court held that deposit was timely and ordered the PTO to grant the patent.

In 2002 the issue reached the Federal Circuit in Enzo Biochem, Inc. v. Gen-Probe, Inc. [\[FN135\]](#) Enzo involved patent claims "directed toward nucleic acid probes that selectively hybridize to the genetic material of the bacteria that causes gonorrhoea." [\[FN136\]](#) In Enzo I, a split panel held the patent invalid for failure to fulfill the written description requirement of [section 112\(1\)](#). The majority explained Argoudelis and other deposit cases as holding that deposits may

fulfill the enablement requirement of [section 112\(1\)](#). "Written description," however, was deemed a separate requirement which could not be met by deposits. The panel had two overlapping reasons. Most basic, the "statutory mandate" requires a "written description." [\[FN137\]](#) Second, policy dictates that "[t]he disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim[;]" [\[FN138\]](#) "to require the public to go to a public depository and perform experiments to identify an invention is not consistent with the statutory requirement to describe one's invention in the *522 specifications." [\[FN139\]](#) While the panel did not mention the problem, in many instances using the deposit material to understand the patent would be infringement. [\[FN140\]](#) The panel, however, rapidly vacated its first opinion and issued a contrary decision, Enzo II. [\[FN141\]](#)

In Enzo II, the Federal Circuit panel continued to recognize that deposit had begun as a method of fulfilling the enablement requirement, [\[FN142\]](#) but added this key paragraph changing its conclusion as to whether a deposit can fulfill the separate "written description" requirement of [section 112\(1\)](#):

Enzo asserts that the claimed sequences are inherently described by reference to deposits of three sequences that are within the scope of its claims. Whether reference to a deposit of a nucleotide sequence may adequately describe that sequence is an issue of first impression in this court. In light of the history of biological deposits for patent purposes, the goals of the patent law, and the practical difficulties of describing unique biological materials in a written description, we hold that reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of [§ 112, P 1](#). [\[FN143\]](#)

Notice that the Federal Circuit does not claim any statutory authority for its change of course. The Enzo II opinion assumes the patentability of inventions incapable of written description and, to preserve their patentability, guts the statutory requirement of a description in writing. This

move is especially disingenuous in light of the Supreme Court's explication in J.E.M. that plants now may obtain utility patents because they are describable in writing-- shrugging off Congress's earlier statements that plants were not patentable as grounded on the belief that plant inventions could not be described in writing. Enzo I and *523 Enzo II were decided after J.E.M., but neither discusses the Supreme Court's reliance on written descriptions in J.E.M. [FN144] The public interest was betrayed by the Federal Circuit's announcement of the non-existence of a limit on patentability shortly after the Supreme Court relied heavily on the existence of that specific limit; as long as the Federal Circuit retains this posture it continues to disserve the public. [FN145]

What both the Argoudelis and Enzo II courts declined to recognize is that Congress has never decided that deposit is acceptable as a replacement for a [section 112\(1\)](#) written description. [FN146] This lack of congressional action undermines the acceptability of deposit for any requirement of [section 112\(1\)](#). The statute said in 1970, and still says, a "written description" with listed qualities. When Congress created quasi-patent protection for asexually reproduced plants and sexually reproduced plants, it enacted lesser "description" requirements than [section 112\(1\)](#). In Argoudelis the applicant wanted a weaker deposit requirement. The PTO only wanted a deposit made earlier, in accordance with its own rules. Neither party had any reason to argue that the PTO lacked the power to weaken Congress's statutes by substituting a deposit (which would only be available at one or a limited set of locations and interactive inspection of which might constitute infringement) for a written description (which could be consulted more easily and perusal of which would not constitute infringement).

To a believer in separation of powers, Enzo II is more disturbing. After noticing at least part of the statutory problem with deposit, the panel blithely opted to ignore statutory language to increase ease of patentability. Enzo II does not even deign to reply to Enzo I's practical critiques of the availability of deposits to the members of the public wishing to visualize the claimed invention.

*524 While not fully explained in Enzo I, the public availability difference between a written

description and a deposit has become even more important in practice since the CCPA decided *In re Argoudelis* in 1970. First, one can now obtain full text patents (with drawings) from any computer linked to the Internet. [FN147] Second, deposits underlying utility patents on seeds are not always accessible to the anonymous public before the patent has expired. As the J.E.M. majority recognized, the PTO's regulations require that once a utility patent is issued, the depository must provide samples of the deposit material to the public upon request (presumably for a fee). [FN148] However, the same regulations allow the patent holder to require written notification from the depository of each such sample, including the name and address of the requestor, and the date the sample was requested. [FN149] If the seed or plant part deposited is claimed in the utility patent, making any "use" of the deposited material inside the United States would be patent infringement. [FN150] Perhaps accepting such a shipment outside the United States (inside a jurisdiction where the seed or plant part was not protected under a national patent) would not be infringement, but a contrary argument could be made. [FN151] At least inside the United States, therefore, a requestor *525 would have no legal way of learning the science "disclosed" by the deposit without infringing--quite a chill on acquiring knowledge, especially since the putative plaintiff has timely notice of a requestor's probable infringement, his name, and his address - -notice, furthermore, creating a writing that might be used in court as evidence of his action.

Argoudelis and its immediate progeny did not involve this level of de facto secrecy; the courts relied on public availability of these deposits as soon as the patent issued. [FN152] The deposited material's use (by itself) did not appear to be infringement. [FN153] The current regulation allowing the depositor to contract for information on each sample was not yet in place. [FN154] The current limitation on access during the pendency of the patent right is a major *526 change in policy. Without meaningful public access to the deposit, the patent holder can delay (for years) others' access to information about scientific advances, information that might fuel other discoveries. This PTO maneuver resembles the notorious refusal of William Thornton, the first United States Superintendent of Patents, to allow public access to granted patents, despite the contrary, written opinion of the Attorney General. [FN155]

Additionally, written specifications are enabling in fact as long as any copy of the document is available (hopefully forever). The PTO regulations require maintenance of biotechnology patent deposits for only a limited time, albeit definitely beyond the patent term. [\[FN156\]](#)

In 1990, Congress did take up the issue of deposits for biotechnology patents, but did not grant the PTO the authority to substitute deposit for a [section 112\(1\)](#) written description. House Bill 5982 would have amended [section 112\(1\)](#) by adding: "With respect to an invention involving biological material, the Commissioner may accept a deposit of biological material to satisfy any requirement of this section if made accessible under such conditions as the Commissioner may require." [\[FN157\]](#) The bill would also have limited patentable subject matter by excluding human beings, [\[FN158\]](#) and created an experimental use exception to patent infringement. [\[FN159\]](#) House Bill 5982, however, never became law.

***527** The report accompanying House Bill 5982 refers to a statement and related letter from Donald J. Quigg, then Assistant Secretary of the Commerce Department and Commissioner of Patents and Trademarks. [\[FN160\]](#) Commissioner Quigg disliked any weakening of patent-holders' power, [\[FN161\]](#) perceived that the PTO had already prevented patents on human beings, [\[FN162\]](#) and believed that the PTO already had the power to use deposits to satisfy [section 112\(1\)](#). [\[FN163\]](#)

Commissioner Quigg overstated his agency's power. Seeing that the patent act requires the PTO to issue a patent whenever statutory requirements have been satisfied, Commissioner Quigg is simply wrong about the PTO's ability to block patents on human beings. [\[FN164\]](#) He is similarly wrong about the PTO's power to modify [section 112\(1\)](#).

The PTO's rule-making authority is created by [35 U.S.C. § 2](#): [\[FN165\]](#)

The United States Patent and Trademark Office . . .

(b)(2) may establish regulations, not inconsistent with law, which --

*528 (A) shall govern the conduct of proceedings in the Office;

(B) shall be made in accordance with section 553 of title 5;

(C) shall facilitate and expedite the processing of patent applications, particularly those which can be filed, stored, processed, searched, and retrieved electronically, subject to the provisions of section 122 relating to the confidential status of applications;

(D) may govern the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office, and may require them, before being recognized as representatives of applicants or other persons, to show that they are of good moral character and reputation and are possessed of the necessary qualifications to render to applicants or other persons valuable service, advice, and assistance in the presentation or prosecution of their applications or other business before the Office;

(E) shall recognize the public interest in continuing to safeguard broad access to the United States patent system through the reduced fee structure for small entities under section 41(h)(1) of this title; and

(F) provide for the development of a performance-based process that includes quantitative and qualitative measures and standards for evaluating cost-effectiveness and is consistent with the principles of impartiality and competitiveness [\[FN166\]](#)

The PTO did follow Administrative Procedure Act procedures to promulgate rules regarding biological deposits for [section 112\(1\)](#) use. The addressed comments dealt with the details of the rules, not with the PTO's power to dilute [section 112\(1\)](#). [\[FN167\]](#)

As I read [35 U.S.C. § 2\(b\)\(2\)](#), the PTO lacks the authority, for two independent reasons, to use deposit in lieu of the written, enabling description required by [section 112\(1\)](#) (though the PTO is allowed to require deposits and models to supplement enabling written descriptions). [\[FN168\]](#) First, the PTO may promulgate only regulations "not inconsistent with law." [\[FN169\]](#)

[Section 112\(1\)](#) is law. [\[FN170\]](#) Second, the PTO may promulgate regulations only in the listed categories. These categories do not include the requirements *529 for patentability, as opposed to "the conduct of proceedings in the Office." [\[FN171\]](#) Commissioner Quigg lists several cases that allegedly allow the use of deposits for [section 112\(1\)](#) purposes. [\[FN172\]](#) They all rely on Argoudelis, which, as discussed above, does not address the core issue. Argoudelis furthermore, dealt with a deposit of material needed to practice a claimed process. The res deposited was a starting point, not a claimed product. Commissioner Quigg's cases simply expand a decision that was never made. The PTO's depository rule-making assumed a power the PTO did not have.

The PTO has issued full utility patents on sexually reproduced plants. The Court in J.E.M. sets the figure at 1800. [\[FN173\]](#) How many of these do not meet the enabling written description requirement of [section 112\(1\)](#), absent improper reliance on deposit? Seemingly quite a few utility patents on plants are at risk. Perhaps most biotechnology patents are vulnerable.

The legal test for enablement is that the written description must enable a person of ordinary skill in the art to practice the invention without undue experimentation. [\[FN174\]](#) If one can only *530 reproduce the transgenic organism by biological reproduction of the deposited material, the written description is not enabling on its own (something that the majority of the Supreme Court did not recognize in J.E.M.). [\[FN175\]](#)

My own research supports the claim that seemingly quite a few utility patents on plants are vulnerable to [section 112\(1\)](#) challenge. To check the incidence of problematic patents, I ran a *531 search in the PTO's files for all patents in class 800/295. [\[FN176\]](#) The search engine presented 407. [\[FN177\]](#) I then used the search result list to jump into the full text of each patent. In each, I searched for the term "deposit." I located 180 utility patents which, to my scientifically untrained eyes, seemed to depend on a deposit of biological material to satisfy [section 112\(1\)](#). [\[FN178\]](#) A large number of these inserted a reference to a deposit in the claim language to serve as part of the definition of the claimed invention, as contrasted to referencing a deposit only in the written description for purposes of disclosure. [\[FN179\]](#) While admitting my lack of scientific

***532** training, without access to the referenced deposits, such references in the written description appear not to be enabling, even to persons of high skill in the relevant art. Sun Devil Lettuce, for example, was created through a six-year selective breeding process, which started in year one with "a hand pollinated cross of PAG 02-23, an individual plant selection from the commercial variety Raider, available from Genecorp seed, and Van Pire also available from Genecorp Seed." [\[FN180\]](#)

More expert opinion than mine, the opinion of Dr. Ignacio Chapela, supports the claim that all or almost all biotechnology patents may be vulnerable to [section 112\(1\)](#) challenge. [\[FN181\]](#) This assertion should not be over-read. Not all utility patents on ***533** plants are "biotechnology" patents in this sense. Many plant utility patents involve controlled crosses of existing parent lines; the parent lines may or may not themselves have been created by direct gene manipulation. [\[FN182\]](#) Dr. Chapela explains that genetically modified plants are created by repeated attempts to insert foreign genes into a subject. Most such attempts fail. Transgenic plant lines are created by biologically multiplying the occasional successes. Such creations cannot be reliably duplicated by repeating the insertion process. Neither the process nor the exact genetic modification obtained can be reduced to a written explication. [\[FN183\]](#) Dr. Chapela's knowledgeable representation severely undercuts the legal sufficiency of written descriptions of biotechnology patents.

***534** In short, the PTO (with Federal Circuit acquiescence) has modified the written description requirement to permit the grant of otherwise illegitimate utility patents on plants. This modification lacks statutory authority. The J.E.M. opinion implies that the Court would have decided differently if it had known of this PTO modification. Opponents of full utility patents on plants should aggressively litigate [section 112\(1\)](#) issues. [\[FN184\]](#)

Conclusion

Congress never decided to allow private entities the power to block experimentation on food crops; Congress never decided to allow full utility patents on sexually reproduced plants. The courts and the PTO have illegitimately bypassed representative government to create and enforce

such private power. The PTO has made this private power even more onerous by allowing such patents to issue even when the applications do not fulfill the statutory requirement of a full, enabling, written description. The substituted deposit, furthermore, is much less publicly accessible than a written description. Both the courts and the PTO, however, have hidden behind mythical decisions by Congress.

What can we do? We can raise the [section 112\(1\)](#) deposit issue in court suits. We can pressure Congress to pass legislation disavowing its mythical former decisions. Congress might take the sensible course of allowing deposit to substitute for an enabling written description only on res where the United States has a treaty obligation to allow full utility patent protection (i.e., yes for microorganisms, no for other plants and animals). [\[FN185\]](#) Hopefully, the Malthus, Mendel, and Monsanto Conference will help raise support for such actions.

[\[FN1\]](#). Visiting Associate Professor, University of Oregon School of Law, 2003-04; Visiting Associate Professor, University of Idaho School of Law, 2004- 05. My thanks for generous comments on earlier drafts from the participants and audience at the "Malthus, Mendel and Monsanto" conference, Keith Aoki, Louis Altman, Ignacio Chapela, Gene Quinn, and Edward C. Walterscheid. All errors are solely the responsibility of the author.

[\[FN1\]](#). [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 \(2001\)](#).

[\[FN2\]](#). [Id. at 145](#).

[\[FN3\]](#). Held by the Wayne Morse Center for Law and Politics at the University of Oregon School of Law, April 16, 2004 [hereinafter "MMM Conference"].

[\[FN4\]](#). A rule against patenting "plants," "seeds," or other listed subject matter might prove impractical to enforce due to the ability of patent attorneys and patent agents to draft claims to bypass such limits. See Mark D. Janis, [Sustainable Agriculture, Patent Rights, and Plant Innovation, 9 Ind. J. Global Legal Stud. 91, 96-103 \(2001\)](#) (discussing this problem and illustrating it

with decisions of the European Patent Office). The flexibility of patent drafting helped defeat the unpatentability of computer programs in the United States. Compare [Gottschalk v. Benson, 409 U.S. 63, 71-72 \(1972\)](#) (holding that the formula for converting format of numbers is not patentable subject matter) with [In re Alappat, 33 F.3d 1526, 1545 \(Fed. Cir. 1994\)](#) (en banc) (holding as patentable claims to software which were drawn in relationship to a general purpose computer); accord Janis, *supra* at 101-02 (comparing gradual U.S. acceptance of patentability of computer software with current European Union issues regarding theoretical unpatentability of plant varieties). Additionally, if a country allows patents on modified genes but not on plants or plant parts, what happens when someone plants a seed containing the modified gene? The Supreme Court of Canada recently held that the planter infringes the patent on the gene. See *Schmeiser v. Monsanto Canada, Inc.*, [2004] S.C.R. 34, 58-59.

[\[FN5\]](#). See Steven Jones, Remarks in Panel on "The Production of Agricultural Knowledge and Access to Seed Germplasm," MMM Conference, *supra* note 3.

[\[FN6\]](#). See Steven Brush, Remarks in Panel on "Global Food Supply Concentration, Erosion, Traditional Knowledge, and Crisis," MMM Conference, *supra* note 3; see also Margaret Mellon & Jane Rissler, *Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply* (Union of Concerned Scientists 2004), available at http://www.ucsusa.org/documents/seedreport_fullreport.pdf.

[\[FN7\]](#). "Super weeds" resistant to Round-Up®, which require use of herbicides similar to Agent Orange, have already invaded the great plains of Canada and the United States. See Percy Schmeiser, Remarks on "David v. Goliath: Foreign Enforcement of U.S. Patent Law and the Might of Monsanto," MMM Conference, *supra* note 3.

[\[FN8\]](#). Stock piles of diversity to cope with future possible crises are dwindling in both plant and animal populations. Only three major breeding flocks of food turkeys exist, and their DNA is almost identical. Five firms (two of which share a joint venture) control the global seed industry.

See William Hoffman, Remarks in Panel on "The Global Food Supply: Concentration, Erosion, Traditional Knowledge, and Crisis," MMM Conference, *supra* note 3.

[FN9]. [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 134 \(2001\)](#). "[I]n 1930 Congress believed that plants were not patentable under [§ 101](#) ... because in practice they could not meet the stringent description requirement. Yet th[is] premise[] w[as] disproved over time." *Id.* (emphasis in original). Referring to PPA legislative history, Justice Thomas opined that "[w]hatever Congress may have believed about the state of patent law and the science of plant breeding in 1930, plants have always had the potential to fall within the general subject matter of [§ 101](#)" *Id.* at 135 (emphasis in original). Justice Thomas then reasoned with regard to the PVPA that "[t]he relevant statements in the legislative history reveal nothing more than the limited view of plant breeding taken by some Members of Congress who believed that patent protection was unavailable for sexually reproduced plants." *Id.* at 41.

[FN10]. See [J.E.M., 534 U.S. at 135](#). The Court also rejected Petitioner's argument that "the PVPA altered the subject-matter coverage of [§ 101](#) by implication." [Id. at 141-42](#).

[FN11]. [Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956 \(Fed. Cir. 2002\)](#).

[FN12]. See *id.*, discussed *infra* text accompanying notes 131-51.

[FN13]. "But one of the weightiest objections to a plurality in the Executive, and which lies as much against the last as the first plan, is, that it tends to conceal faults and destroy responsibility. Responsibility is of two kinds to censure and to punishment." The Federalist No. 70, 4 (Alexander Hamilton) (arguing in favor of a unitary executive), available at <http://thomas.loc.gov/home/histdox/fedpapers.html> (last visited Sept. 15, 2004).

[FN14]. See *Harvard Coll. v. Canada (Commissioner of Patents)*, [2002] S.C.R. 45 (refusing to order Commissioner of Patents to grant patent on the oncomouse, "[t]he patentability of higher life forms is a highly contentious matter raising serious practical, ethical and environmental con-

cerns not contemplated by the [Canadian Patent] Act If a special legislative scheme was needed to protect plant varieties, a subset of higher life forms, a similar scheme may also be required to deal with patenting higher life forms in general.").

[FN15]. The fact of "non-decision" has been noticed by many others. Bagley describes the United States' system as "patent first, ask questions later," and points out that Congress's inaction is a de facto delegation of power over patentable subject matter to inventors' patent attorneys and patent agents. See Margo A. Bagley, [Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law](#), 45 *Wm. & Mary L. Rev.* 469, 474-78 (2003). Nor is patent the only area of law in which Congress routinely ducks decision making. See, e.g., Scott Baker & Kimberly D. Krawiec, [The Penalty Default Canon](#), 72 *Geo. Wash. L. Rev.* 663 (2004) (arguing that, when a statutory hole constitutes an attempt by Congress to shift decision-making responsibility, courts should void the relevant statute as an unconstitutional delegation of power); Mark Seidenfeld, [Pyrrhic Political Penalties: Why the Public Would Lose Under the 'Penalty Default Canon'](#), 72 *Geo. Wash. L. Rev.* 724 (2004) (agreeing that Congress ducks decision making, but arguing that the penalty suggested by Baker and Krawiec would be counter-productive); see also Baker & Krawiec, *supra*, at 6-7, 73-86 (listing other theories on construction of incomplete statutes).

[FN16]. [U.S. Const. art. I, § 8, cl. 8.](#)

[FN17]. See Malla Pollack, [What is Congress Supposed to Promote? Defining "Progress" in Article I, Section 8, Clause 8 of the United States Constitution, or Introducing the Progress Clause](#), 80 *Neb. L. Rev.* 754, 755 n.1 (2001) (discussing Clause's various titles).

[FN18]. James Madison, *Notes of Debates in the Federal Convention of 1787*, at 477-79 (1966) (listing suggestions for congressional powers).

[FN19]. See, e.g., Malla Pollack, [Purveyance and Power, or Over-Priced Free Lunch: The Intellectual Property Clause as an Ally of the Takings Clause in the Public's Control of Government](#), 30 *Sw. U. L. Rev.* 1, 99-106 (2000) (reviewing available information about the drafting conven-

tion's handling of the clause).

[FN20]. See [id. at 106-116](#) (discussing ratification); see also Edward C. Walterscheid, To Promote the Progress of Useful Arts: American Patent Law and Administration, 1787-1836, at 55-59 (1998) (discussing scantiness of ratification material); Malla Pollack, The [Multiple Unconstitutionality of Business Method Patents: Common Sense, Congressional Consideration, and Constitutional History](#), 28 *Rutgers Computer & Tech. L.J.* 61, 81-120 (2002) [hereinafter Multiple Unconstitutionality] (discussing ratification record and concluding that it supports the exclusion of business methods from patentable subject matter).

[FN21]. For the purposes of this paper, I accept the Supreme Court's conclusion that the "discoveries" of "inventors" are limited to those advances which are not obvious to a person of ordinary skill in the relevant art. See [Graham v. John Deere Co.](#), 383 U.S. 1, 9 (1966) (holding that these constitutional words require that patents be granted only to advances which would not be obvious to persons of ordinary skill in the relevant art). But see Edward C. Walterscheid, The Hotchkiss Unobviousness Standard: Early Judicial Activism in the Patent Law, (forthcoming), (draft copy on file with author) (concluding that the non-obviousness standard for a patentable invention is required by the constitutional phrase 'promote the progress of ... useful arts,' but reading Graham as not recognizing the standard's constitutional basis). As discussed at length elsewhere, my empirical research demonstrates that the 1789 American meaning of "progress" was "physical movement," so that "promote the progress of science and useful arts" means "promote the distribution of knowledge and new technology throughout the population." See Pollack, *supra* note 17, *passim* (explaining data supporting this conclusion).

[FN22]. The Supreme Court declined to enforce the Clause's purpose limitation in [Eldred v. Ashcroft](#), 537 U.S. 186 (2003). However, the Court expressly pointed out the petitioners' decision not to argue that the purpose limitation had independent power. See [id. at 211](#) ("[P]etitioners do not argue that the Clause's preamble is an independently enforceable limit on Congress's power."). I read Eldred's holding as limited to approving Congress's power to grant retrospective

extensions of copyright and patent terms. See [id. at 218](#) ("For the several reasons stated, we find no Copyright Clause impediment to the CTEA's extension of existing copyrights.").

[\[FN23\]](#). [Gottschalk v. Benson, 409 U.S. 63, 67 \(1972\)](#); accord [Diamond v. Diehr, 450 U.S. 175, 185 \(1981\)](#); [Parker v. Flook, 437 U.S. 584, 589-90 \(1978\)](#).

[\[FN24\]](#). See, e.g., John R. Thomas, The [Patenting of the Liberal Professions, 40 B.C. L. Rev. 1139, 1169-75 \(1999\)](#); Multiple Unconstitutionality, *supra* note 20, at 86-91. But see [State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1375 \(Fed. Cir. 1998\)](#) (laying "to rest" the "ill-conceived" business method exception to patentable subject matter).

[\[FN25\]](#). One of the unincorporated suggestions made to the Drafting Convention expressly supported agriculture, a congressional power "[t]o establish public institutions, rewards and immunities for the promotion of agriculture, commerce, trades, and manufactures." II The Records of the Federal Convention of 1787, at 181-82 (Max Farrand ed., 1937).

[\[FN26\]](#). See Bruce W. Bugbee, *Genesis of American Patent and Copyright Law* 72 (1967) (quoting patent as protecting "Cleansing, curing & Refining of Indian Corn Growing in the Plantations, fitter [sic] for Shipping & Transportation, in a manner not before found out and Practised.").

[\[FN27\]](#). See *id.* at 73-74 (asserting that colonial Maryland issued only two known patents, an Oct. 18, 1770 grant to John Clayton for a threshing machine and a Nov. 2, 1770 grant to Isaac Perkins for another threshing machine).

[\[FN28\]](#). See *id.* at 76-82. One of the petitions sent to Congress by inventors (before a patent statute was enacted) involved farm machinery. See Walterscheid, *supra* note 20, at 107 (listing petition by Leonard Harbaugh for rights over "machines which he has invented for threshing, reaping").

[\[FN29\]](#). See Christine MacLeod, *Inventing the Industrial Revolution: The English Patent Sys-*

tem, 1660-1800, at 98 n.4 (1988).

[FN30]. See *id.* at 2 n.4 (British had registration system until late nineteenth century).

[FN31]. "Congress ... recognized[,] the ... distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions." *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980) (discussing congressional reports accompanying the PPA).

[FN32]. See Walterscheid, *supra* note 20, at 109-143.

[FN33]. The first suggested bill covered both patents and copyrights, H.R. 10, 1st Cong. (1789), reprinted in Walterscheid, *supra* note 20, at 433. Patentable subject matter was defined as "any new art, manufacture, engine, machine, invention or device, or any improvement upon, or in some art, manufacture, engine, machine, invention or device." H.R. 10 § 3, reprinted in Walterscheid, *supra* note 20, at 435. Congress then turned to separate acts respectively for copyrights and patents. Under the first separate Patent Bill, H.R. 41, 1st Cong. (1790), patentable subject matter included "any new art, manufacture, engine, machine, invention or device, or any improvement upon, or in some art, manufacture, engine, machine, invention or device." H.R. 41, 1st Cong. § 1 (1790), reprinted in Walterscheid, *supra* note 20, at 445. In the March 10, 1790 version of H.R. 41, patentable subject matter is edited to read, "any useful art, manufacture, engine, machine, or device; or any improvement upon, or in some art, manufacture, engine, machine, invention or device." H.R. 41, 1st Cong. § 1 (1790), reprinted in Walterscheid, *supra* note 20, at 455.

[FN34]. Patent Act of 1790, 1 Stat. 109, ch. 7, § 1 (1790), reprinted in Walterscheid, *supra* note 20, at 463. An amendment was suggested in February 1791 which probably read "any new and useful art, machine, or composition of matter." Walterscheid could not locate an official version of H.R. 121, 1st Cong. (1791), but suggests this language is located in Thomas Jefferson's papers. See Walterscheid, *supra* note 20, at 469. The next suggested iteration of patentable subject

matter is H.R. 166, 2nd Cong. (1792) which included "any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement." H.R. 166, 2nd Cong. (1792), reprinted in Walterscheid, *supra* note 20, at 493.

[\[FN35\]](#). 1 Stat. 318 § 1 (1793), reprinted in Walterscheid, *supra* note 20, at 479.

[\[FN36\]](#). The Patent Act of 1836, 5 Stat. 117 § 6, retained the earlier limits on patentable subject matter, "any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement [of the same]." Reprinted in Walterscheid, *supra* note 20, at 497, 499.

[\[FN37\]](#). [35 U.S.C. § 101 \(2004\)](#).

[\[FN38\]](#). [S. Rep. No. 82-1979, at 5 \(1952\)](#), reprinted in 1952 U.S.C.C.A.N. 2394, 2398-99.

[\[FN39\]](#). See Walterscheid, *supra* note 20, at 23-24. In e-mail correspondence, Walterscheid advised me that his concentrated study of the historical record had unearthed no evidence that the Drafters, the ratifying generation, or the members of early sessions of Congress believed that plants, or other living matter, were patentable subject matter. E-mail from Edward C. Walterscheid, to Malla Pollack, Visiting Professor, Univ. of Ore. School of Law (May 1, 2004) (on file with author).

[\[FN40\]](#). See Alexander Hamilton, Report on the Subject of Manufactures (1791), reprinted in 4 The Works of Alexander Hamilton in Twelve Volumes, at 70-198 (Henry Cabot Lodge ed., Fed. Ed. 1904).

[\[FN41\]](#). See Walterscheid, *supra* note 20, at 148-49 (discussing Hamilton, *supra* note 40, at 156).

[\[FN42\]](#). See Walterscheid, *supra* note 20, at 149 (discussing Hamilton, *supra* note 40, at 195-97).

[\[FN43\]](#). One early patent holder, the hero (or villain) of several early patent cases did want patentable subject matter to include plants, but he was never empowered to enact statutes.

The discovery of an unknown plant and its uses. Here the plant will be secured, and all the

uses that are specified by the patentee The discovery of new uses of a known plant. Here the new uses will be secured, subject to the prior right of the discoverer of the plant, during the patent term.

Walterscheid, *supra* note 20, at 317 (quoting Oliver Evans writing as P.N.I. Elisha, Patent Right Oppression Exposed; Or, Knavery Detected (1813)).

[FN44]. See 1836 Senate Committee Report, reprinted in 18 J. Pat. Off. Soc'y 853, 859 (1936), available at <http://heinonline.org/HOL/Page?handlein.journals/jpatos/B&size=2&rot=0&collection=journals&id=1133>.

[FN45]. See A. Glenn Crothers, Agricultural Improvement and Technological Innovation in a Slave Society: The Case of Early National Northern Virginia, 75 Agric. Hist. 135, 135 (2001).

[FN46]. See *id.* at 140, 142, 148, 158, 160 (mentioning specific innovations tried by Jefferson and Washington).

[FN47]. See *id.* at 145-46, 151 (mentioning suggested varieties).

[FN48]. See Act of May 23, 1930, 46 Stat. 376 (codified as amended at [35 U.S.C. §§ 161-164 \(1954\)](#)). Several earlier, but unenacted, bills would have provided utility patent protection for some types of plants. See Mark D. Janis & Jay P. Kesan, [U.S. Plant Variety Protection: Sound and Fury ... ?](#), 39 *Houston L. Rev.* 727, 733-37 (2002) (mentioning five such bills between 1892 and 1930). Another such bill was considered in the 1960s. See *id.* at 737- 39.

[FN49]. Pub. L. No. 91-577 (1970) (codified as amended at [7 U.S.C. §§ 2321-2583 \(1994\)](#)).

[FN50]. Compare [35 U.S.C. § 112](#), P1 (2000), for utility patents:

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

rying out his invention;

with [35 U.S.C. § 162 \(2000\)](#), for plant patents: "No plant patent shall be declared invalid for noncompliance with [section 112](#) of this title if the description is as complete as is reasonably possible"; with [7 U.S.C. § 2422\(2\) \(2000\)](#), referring to the PVPA:

A description of the variety setting forth its distinctiveness, uniformity, and stability and a description of the genealogy and breeding procedure, when known. The Secretary [of Agriculture] may require amplification, including the submission of adequate photographs or drawings or plant specimens, if the description is not adequate or as complete as reasonably possible

[FN51]. See [35 U.S.C. § 163](#) (providing "the right to exclude others from asexually reproducing the plant") (emphasis added); see also [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 151 \(2001\)](#) (Breyer, J., dissenting) (recognizing that PPA does not give "an exclusive right to reproduce the plant sexually, i.e., the right to reproduce it through seeds.").

[FN52]. [7 U.S.C. § 2543 \(2000\)](#).

[FN53]. [7 U.S.C. § 2544 \(2000\)](#) ("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."); see also [7 U.S.C. § 2541\(e\) \(2000\)](#) ("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."). Accord [J.E.M., 534 U.S. at 129 n.1](#) ("Most notably, the PVPA provides exemptions for research and for farmers to save seed from their crops for replanting.").

[FN54]. H.R. Rep. No. 71-1129 (1930); S. Rep. No. 71-315 (1930).

[FN55]. [H.R. Rep. No. 91-1605 \(1970\)](#), reprinted in 1970 U.S.C.C.A.N. 5082-83.

[FN56]. See [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 138 \(2001\)](#).

[FN57]. Someone who believes that law is merely politics with different rhetoric might see a

strong tie between the outcome and the opinion's authorship by Justice Thomas, who worked for Monsanto from 1977-79, according to the biography posted on the Supreme Court's own website. See The Justices of the Supreme Court 2, at <http://www.supremecourtus.gov/about/biographiescurrent.pdf> (last visited Sept. 15, 2004).

[FN58]. See [J.E.M., 534 U.S. at 134](#) ("[I]n 1930 Congress believed that plants were not patentable under [§ 101](#) ... because in practice they could not meet the stringent description requirement. Yet th[is] premise[] w[as] disproved over time.") (emphasis in original); [id. at 135](#) (referring to PPA legislative history, "[w]hatever Congress may have believed about the state of patent law and the science of plant breeding in 1930, plants have always had the potential to fall within the general subject matter of [§ 101](#)") (emphasis in original); [id. at 141](#) (referring to PVPA "[t]he relevant statements in the legislative history reveal nothing more than the limited view of plant breeding taken by some Members of Congress who believed that patent protection was unavailable for sexually reproduced plants.")

[FN59]. See [Diamond v. Chakrabarty, 447 U.S. 303, 308 \(1980\)](#).

[FN60]. See *id.* (quoting [Perrin v. United States, 444 U.S. 37, 42 \(1979\)](#)).

[FN61]. See *id.*; see also [J.E.M., 534 U.S. at 130-31](#).

[FN62]. See Patent Full-Text Database Contents, at <http://www.uspto.gov/patft/help/contents.htm> (last visited Sept. 15, 2004).

[FN63]. Compare The Patent Act of 1793, ch. 11, 1 Stat. 318 (1793), reprinted in Walterscheid, *supra* note 20, at 479, with Act of July 4, 1836, ch. 357, 5 Stat. 117 (1836), reprinted in Walterscheid, *supra* note 20, at 497.

[FN64]. See <http://patft.uspto.gov/netahtml/search-adv.htm> (last visited Sept. 15, 2004).

[FN65]. Search on file with author. According to the PTO, class 800, subclass 295 is the classification used when the claimed invention is a "plant, seedling, plant seed, or plant part." USPTO

Classification Definitions at 800- 11 (Dec. 2000 ed.), available at <http://www.uspto.gov>. According to the PTO's database information, "Patent Full-Text Database Contents," <http://www.uspto.gov/patft/help/contents.htm>, utility patents issued between 1790 and 1975 included four number runs: X1-X11,280; 1-3,930,270; RX1-RX125; RE1-RE29, 094. The first available patent of each of the last three runs was issued in August 1836. Since patents are issued in numerical order, the three runs were not relevant. I then did a patent number search for all patent numbers starting with X. This search located the 1989 records discussed in the text; these patents were issued between July 31, 1790 ([Patent No. X1](#), to Samuel Hopkins, July 31, 1790 for a method of making potash) and July 1836 ([Patent No. X9,900](#), to Winslow, on July 2, 1836, for a crate). The highest X patent number result (X11,280) was an empty file.

[\[FN66\]](#). See search on file with author.

[\[FN67\]](#). See [Diamond v. Chakrabarty](#), 447 U.S. 303 (1980).

[\[FN68\]](#). Telecommunications Act of 1996, [47 U.S.C. § 253\(a\) \(2000\)](#).

[\[FN69\]](#). See [Nixon v. Mo. Mun. League](#), 124 S. Ct. 1555, 1560-61 (2004).

[\[FN70\]](#). See [id. at 1567](#) (Stevens, J., dissenting).

[\[FN71\]](#). Interestingly, the use of legislative history in *Chakrabarty* was accepted in *J.E.M.* by both Justices Thomas and Scalia, justices who usually insist on the incompetence of this type of evidence. See, e.g., [Carter v. U.S.](#), 530 U.S. 255, 270-72 (2000) (denigrating use of legislative history in statutory construction); [Vt. Agency of Natural Res. v. U.S. ex rel. Stevens](#), 529 U.S. 765, 783 n.12 (2000); see also [Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.](#), 124 S. Ct. 1756, 1763 (2004) (recognizing that "not all members of this Court agree" on the statutory construction method of "delv[ing] into legislative history.") But see, e.g., [BedRoc Ltd., LLC v. United States](#), 124 S. Ct. 1587, 1598 (2004) (Stevens, J., dissenting) (castigating the rest of the Court as "deliberately uninformed, and hence unconstrained," because justices refused to follow

clear direction in congressional report).

[FN72]. [Chakrabarty, 447 U.S. at 309.](#)

[FN73]. [S. Rep. 82-1979 \(1952\)](#), reprinted in 1952 U.S.C.C.A.N. 2399.

[FN74]. The Court has based decisions on the difference between the permissive "may," and the commanding "shall." See [Anderson v. Yungkau, 329 U.S. 482, 485 \(1947\)](#) ("And when the same Rule uses both 'may' and 'shall', the normal inference is that each is used in its usual sense --the one act being permissive, the other mandatory.")(citations omitted).

[FN75]. See [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 145 \(2001\)](#), referring to [35 U.S.C. § 119\(f\)](#) which reads:

Applications for plant breeder's rights filed in a WTO member country (or in a foreign UP-OV Contracting Party) shall have the same effect for the purpose of the right of priority under subsections (a) through (c) of this section as applications for patents, subject to the same conditions and requirements of this section as apply to applications for patents.

[FN76]. Reply Brief for Petitioners at 7-8, [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., No. 99-1996, 2001 WL 811687 \(U.S. July 16, 2001\)](#).

[FN77]. See [J.E.M., 534 U.S. at 135](#) (referring to PPA legislative history, "[w]hatever Congress may have believed about the state of patent law and the science of plant breeding in 1930, plants have always had the potential to fall within the general subject matter of [§ 101](#)") (emphasis in original); [id. at 141](#) (referring to PVPA, "[t]he relevant statements in the legislative history reveal nothing more than the limited view of plant breeding taken by some members of Congress who believed that patent protection was unavailable for sexually reproduced plants.")

[FN78]. The Supreme Court has recognized empty classes of potentially trademark-worthy res. See [Wal-Mart Stores, Inc. v. Samara Bros., Inc., 529 U.S. 205, 211 \(2000\)](#):

Nothing in [§ 2](#), however, demands the conclusion that every category of mark necessarily in-

cludes some marks "by which the goods of the applicant may be distinguished from the goods of others" without secondary meaning --that in every category some marks are inherently distinctive. Indeed, with respect to at least one category of mark --colors --we have held that no mark can ever be inherently distinctive.

(emphasis and internal quotations in original; citations omitted).

[FN79]. "The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided." [35 U.S.C. § 161](#) P2 (2000).

[FN80]. I base this conclusion on the reservation which accompanied the United States' ratification of the 1991 version of the International Union for the Protection of New Varieties of Plants ("UPOV"), UPOV Notification No. 69, available at http://www.wipo.int/edocs/notdocs/en/upov/treaty_upov_69.html?printable=true (last visited March 21, 2004) ("Pursuant to Article 35(2), the United States will continue to provide protection for asexually reproduced varieties by an industrial property title other than a breeder's right and will not, therefore, apply the terms of the Convention to those varieties."). This version of the UPOV entered into force in the United States on Feb. 22, 1999. See *id.*

[FN81]. See [J.E.M., 534 U.S. at 144](#) ("Crucially, [§ 119\(f\)](#) is part of the general provisions of [Title 35](#), not the specific chapter of the PPA ...")(emphasis added). But see [Jones v. R.R. Donnelley & Sons Co., 124 S. Ct. 1836, 1842 \(2004\)](#) ("We hesitate to place too much significance on the location of a statute in the United States Code.").

[FN82]. The J.E.M. dissent concluded that all plants had been removed from the utility patent statutes by passage of the PPA in 1930, prior to the 1952 move of the plant patent act into its own corner of [Title 35](#). See [J.E.M., 534 U.S. at 147-53](#) (Breyer, J., dissenting).

[FN83]. See [J.E.M., 534 U.S. at 138](#).

[FN84]. S. [Rep. No. 105-42, at *43, 1997 WL 394243](#) ("In addition, Title VI makes some mis-

cellaneous and technical changes ... that provide an international right of priority for plant breeder's rights."); see also H.R. [Rep. No. 106-287, pt. I, at *66, 1999 WL 569140](#) ("Generally, Title VII consists of seven largely-unrelated provisions that make needed clarifying and technical changes to the Patent Act."); H.R. Conf. [Rep. No. 106-464, at * 145, 1999 WL 1095089](#) ("Subtitle H consists of seven largely-unrelated provisions that make clarifying and technical changes to the Patent Act.").

[FN85]. See H.R. [Rep. No. 104-784, *30, 1996 WL 938260](#) ("With the exception of the title containing miscellaneous provisions [including [section 119\(f\)](#)], each title consists of an independent bill that was the subject of comprehensive hearings").

[FN86]. See id. at *81-82.

[FN87]. See id. at *82.

Because [section 119](#) presently addresses only patents and inventors' certificates, applicants from those countries [which only have breeder's certificates for plants] are technically unable to base a priority claim on a foreign application for a plant breeder's right when seeking plant patent or utility protection for a plant variety in this country.

Id. Furthermore, seeking a utility patent does not imply that one will be granted. The amendment dealt only with priority, not with patentability.

[FN88]. Members may also exclude from patentability: ... (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof

Trade Related Aspects of Intellectual Property Rights (TRIPS), art. 27, § 3(b).

[FN89]. See [S. Rep. No. 105-42](#), supra note 84, at *59, *112.

[FN90]. See H.R. [Rep. No. 105-39, at *28, *29, 1997 WL 136374](#).

[FN91]. See [H.R. Rep. No. 106-287, pt. I, at *28, *66-67, 1999 WL 569140](#).

[FN92]. See H.R. Conf. [Rep. 106-464, at *146, 1999 WL 1095089](#).

[FN93]. H.R. 3194 (Division B), [Pub. L. 106-113](#) (Nov. 29, 1999). The Brief of the United States misleadingly cites to Conf. Rep. 106-464 as if it accompanied the bill which enacted [§ 119\(f\)](#). See Brief of the United States as Amicus Curiae Supporting Respondent at *19-20, [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., No. 99-1996, 2001 WL 689516](#) (characterizing Rep. 464 as "the Conference Report that accompanied new [Section 119\(f\)](#)").

[FN94]. See Bill Summary and Status report on both bills available at <http://www.thomas.loc.gov> (last visited March 20, 2004).

[FN95]. See H.R. Rep. No. 106-479 (available in Cong. Rec. daily version of Nov. 17, 1999 at H12230-12609). The text of S.1948 was incorporated by reference into Division B of this report. See Cong. Rec. of Nov. 17, 1999 at H.12239.

[FN96]. [U.S. Const. art. I, § 7, cl. 3](#).

[FN97]. See [In re Hibbard, 227 U.S.P.Q. \(BNA\) 443 \(1985\)](#) (reversing examiner's rejection of an utility patent application on a plant for absence of statutory subject matter).

[FN98]. See [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 144-45 \(2001\)](#).

[T]he PTO has assigned utility patents for plants for at least 16 years and there has been no indication from either Congress or agencies with expertise that such coverage is inconsistent with the PVPA or the PPA [In reliance on Chakrabarty, the PTO has issued] some 1,800 utility patents for plants.

Id.

[FN99]. See [FTC v. Dean Foods Co., 384 U.S. 597, 610 n.11 \(1996\)](#) (quoting [Helvering v. Hal-](#)

[lock, 309 U.S. 106, 120 \(1940\)](#) (internal quotation marks omitted); see also [id. at 609-10](#) (discussing list of cases supporting nonprobative value of congressional nonaction). But see [Dep't of Navy v. Egan, 484 U.S. 518, 536-37 \(1988\)](#) (White, J., dissenting) (objecting to majority's reliance on congressional non-action).

[FN100]. [Brecht v. Abrahamson, 507 U.S. 619, 632 \(1993\)](#) (internal quotation marks and citations omitted).

[FN101]. See [Lorillard v. Pons, 434 U.S. 575, 580-81 \(1978\)](#); see also [Lindahl v. Office of Pers. Mgmt., 470 U.S. 768, 802-06, & n.3 \(1985\)](#) (White, J., dissenting); see also [Toucey v. New York Life Ins., 314 U.S. 118, 140- 41 \(1941\)](#) (limiting importance of congressional nonaction to circumstances where Congress should be expected to act, such as those where a provision has "been the subject of comprehensive legislative re-examination.").

[FN102]. See [Diamond v. Chakrabarty, 447 U.S. 303, 309 \(1980\)](#) (internal quotation marks omitted).

[FN103]. [Cleveland v. United States, 329 U.S. 14, 22-23 \(1946\)](#) (Rutledge, J., concurring) (footnotes and internal citations omitted).

[FN104]. [J.E.M., 534 U.S. at 134](#) (discussing the 1930 Congress and the PPA); see [id. at 141-42](#) (making similar statements about the 1970 Congress and the PVPA).

[FN105]. R.S.C., ch. P-4, [§ 2 \(1985\) \(Can.\)](#) ("Any art, process, machine, manufacture, or composition of matter").

[FN106]. [Harvard Coll. v. Canada \(Commissioner of Patents\), \[2002\] S.C.R. 45](#) ("Micro-organisms produced en masse as chemical compounds are produced and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics. The same could not be said for plants and animals.").

[FN107]. [Id.](#)

[FN108]. *Id.* at 3 ("Section 40 of the Patent Act does not give the Commissioner any discretion to refuse a patent on the basis of public policy considerations independent of any express provision in the Act."). See also [35 U.S.C. § 102](#) ("A person shall be entitled to a patent unless--....").

[FN109]. See *id.* at P 184 ("[T]he central objects of the Act are 'to advance research and development and to encourage broader economic activity,'" which does not imply that all inventions are patentable.).

[FN110]. See, e.g., [Nixon v. Mo. Mun. League, 124 S. Ct. 1555, 1559 \(2004\)](#) (referring to clear statement rule of [Gregory v. Aschroft, 501 U.S. 452 \(1992\)](#), requiring a clear statement from Congress before courts will read a federal statute to "constrain[] traditional state authority to order its government."); *id.* at 1566 (Scalia, J., concurring) (asserting that statute at issue "simply does not provide the clear statement which would be required by Gregory").

[FN111]. See *Harvard Coll. v. Canada*, [2002] S.C.R. 45, P 199 ("The distinction between lower and higher life forms, though not explicit in the Act, nonetheless is defensible on the basis of the common sense differences between the two."). Unfortunately, after the conference which generated this paper, the Supreme Court of Canada held that a farmer had infringed Monsanto's patent on a gene by planting seed which produced canola plants containing the claimed gene. *Percy Schmeiser v. Monsanto Canada, Inc.*, [2004] S.C.R. 34. Since the farmer had not gained additional profit from his harvest by taking advantage of the plants' resistance to Round-Up®, no damages were allowable. Because Monsanto's Canadian patent on Round-Up® had expired before these plants had been grown, and because Canadian law does not recognize patents on seeds or canola plants themselves, this decision raises many additional issues beyond those addressed in this Article.

[FN112]. As discussed *infra*, the Federal Circuit has already approved this usurpation. See [Enzo Biochem, Inc. v. Gen-Probe Inc. \(Enzo II\), 323 F.3d 956 \(Fed. Cir. 2002\)](#).

[FN113]. The petitioners in *J.E.M.* did not raise any issue except lack of [§ 101](#) patentable subject

matter. See [J.E.M., 534 U.S. at 131](#) ("Petitioners do not allege that Pioneer's patents are invalid for failure to meet the requirements for a utility patent.").

[FN114]. See [Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843-44 \(1984\)](#) (requiring judicial deference to agency interpretation of statutes and related regulations when Congress has entrusted an agency with implementation of the statutory material at issue, unless Congress has clearly spoken to the exact issue). I base this conclusion on the non-inclusion of standards of patentability within the PTO's rule making authority, see *infra* text accompanying note 165, and the statute's clear requirement that the specification contain an enabling "written description" (i.e., a writing which both describes and enables) [35 U.S.C. § 112, P 1](#).

[FN115]. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same

[35 U.S.C. § 112, P 1](#). Federal Circuit case law recognizes three separate requirements imposed by [§ 112, P 1](#), called in short-hand "written description," "enablement," and "best mode." See [Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 921 \(Fed. Cir. 2004\)](#). The Federal Circuit might consider my argument to involve both "written description" and "enablement."

[FN116]. [35 U.S.C. § 112, P 1](#).

[FN117]. And be it further enacted, that the Grantee or Grantees of each Patent shall, at the time of granting the same, deliver to the Secretary of State a Specification in Writing, containing a description, accompanied with drafts or models, and explanations and models (if the nature of the invention or discovery will admit of a Model) of the thing or things by him or them invented or discovered, and described as aforesaid in the said Patents, which Specification shall be so particular, and said Models so exact, as ... to enable a Workman or other person skilled in the Art or

Manufacture whereof it is a branch or wherewith it may be nearest connected, to make, construct, or use the same ... which Specification shall be filed in the Office of the said Secretary

Patent Act of 1790, 1 Stat. 109, reprinted in Walterscheid, supra note 20, at 465.

[FN118]. See Patent Act of 1793 § 1, 1 Stat. 318, reprinted in Walterscheid, supra note 20, at 479-80.

[FN119]. And be it further enacted, that every inventor, before he can receive a patent ... shall deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear, and exact terms as to ... enable any person skilled in the art or science of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same [A]nd he shall accompany the whole with drawings and written references, where the nature of the case admits of drawings, or with specimens of the ingredients, and of the composition of matter, sufficient in quantity for the purpose of experiment, where the invention is of a composition of matter; which ... shall be filed in the office of the Secretary of State And such inventor shall, moreover, deliver a model of his machine, provided the Secretary shall deem such model to be necessary.

Patent Act of 1793 § 3, 1 Stat. 318, reprinted in Walterscheid, supra note 20, at 480-81.

[FN120]. Patent Act of 1836 § 7, 5 Stat. 117, reprinted in Walterscheid, supra note 20, at 497, 500 ("[T]he Commissioner shall make, or cause to be made, an examination of the alleged new invention or discovery ... [and if the application fulfils statutory requirements] it shall be his duty to issue a patent therefor.").

[FN121]. But before any inventor shall receive a patent for any such new invention or discovery, he shall deliver a written description of his invention or discovery, and the manner and process of making, constructing, using and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the

same He shall, furthermore, accompany the whole with a drawing or drawings, and written references, where the nature of the case admits of drawings, or with specimens of ingredients, and of composition of matter, sufficient in quantity for the purpose of experiment, where the invention or discovery is of a composition of matter ... and he shall moreover furnish a model of his invention, in all cases which admit of a representation by a model

Id. at § 6, reprinted in Walterscheid, *supra* note 20, at 499-500.

[FN122]. "The Director may require the applicant to furnish a model of convenient size to exhibit advantageously the several parts of his invention. When the invention relates to a composition of matter, the Director may require the applicant to furnish specimens or ingredients for the purpose of inspection or experiment." [35 U.S.C. § 114](#).

[FN123]. The "written description" requirement serves a teaching function as a "quid pro quo" in which the public is given "meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time." [Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 922 \(Fed. Cir. 2004\)](#) (quoting [Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 970 \(Fed. Cir. 2002\)](#)). This policy basis for the written description requirement was noted by the J.E.M. majority. [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 \(2001\)](#).

[FN124]. [35 U.S.C. § 162 \(2000\)](#) ("No plant patent shall be declared invalid for noncompliance with [section 112](#) of this title if the description is as complete as is reasonably possible.").

[FN125]. See [7 U.S.C. § 2422\(2\) \(2000\)](#).

A description of the variety setting forth its distinctiveness, uniformity, and stability and a description of the genealogy and breeding procedure, when known. The Secretary may require amplification, including the submission of adequate photographs or drawings or plant specimens, if the description is not adequate or as complete as is reasonably possible, and submission of records or proof of ownership or of allegations made in the application. An applicant may add to or correct the description at any time, before the certificate is issued, upon

a showing acceptable to the Secretary that the revised description is retroactively accurate. Courts shall protect others from any injustice which would result. The Secretary may accept records of the breeder and of any official seed certifying agency in this country as evidence of stability where applicable.

[\[FN126\]](#). [7 U.S.C. § 2422\(4\)](#).

[\[FN127\]](#). The CCPA has been replaced by the Court of Appeals for the Federal Circuit. See Federal Courts Improvement Act of 1982, [Pub. L. No. 97-164](#), Title I (creating the Court of Appeals for the Federal Circuit).

[\[FN128\]](#). [434 F.2d 1390 \(1970\)](#), [168 U.S.P.Q. \(BNA\) 99, 58 C.C.P.A. 769](#).

[\[FN129\]](#). See [id. at 1390-92](#).

[\[FN130\]](#). See [id. at 1393](#) ("It is not necessary that the general public have access to the culture prior to the issuance of the patent.") (emphasis added).

[\[FN131\]](#). See [id. at 1393 n.5](#) (citing a treatise). The PTO does have the authority to require deposit in addition to an enabling written description, but not instead of an enabling written description. [35 U.S.C. § 114](#) ("The Director may require the applicant to furnish a model of convenient size to exhibit advantageously the several parts of his invention. When the invention relates to a composition of matter, the Director may require the applicant to furnish specimens or ingredients for the purpose of inspection or experiment.").

[\[FN132\]](#). [In re Argoudelis, 434 F.2d 1390, 1392 \(C.C.P.A. 1970\)](#).

[\[FN133\]](#). *Id.*

[\[FN134\]](#). See *id.* ("As far as we are able to determine, an issue like the one facing us has never been decided by the courts in this country; therefore, as a matter of first impression, it requires that we analyze anew all of the statutes, law, and circumstances pertaining to this issue.").

[FN135]. [Enzo Biochem, Inc. v. Gen-Probe, Inc. \(Enzo II\)](#), 323 F.3d 956 (Fed. Cir. 2002) (panel reconsideration) (holding patent valid), vacating Enzo I, [285 F.3d 1013 \(Fed. Cir. 2002\)](#) (holding patent invalid for failure to fulfill written description requirement of [35 U.S.C. § 112 P1](#)). Enzo was an infringement case. The issue on appeal was the district court grant of summary judgment to the alleged infringer on the ground that the patent claims allegedly infringed were invalid for failure to meet the written description requirement of [§ 112, P 1](#). [Enzo I](#), 285 F.3d at 1015.

[FN136]. [Enzo I](#), 285 F.3d. at 1015.

[FN137]. [Id.](#) at 1021 (emphasis original).

[FN138]. [Id.](#) at 1018.

[FN139]. [Id.](#) at 1021. While I agree with Enzo I on the insufficiency of written description, I believe that enablement is also lacking. The statutory language clearly seems to require that the "written description" itself be enabling.

[FN140]. See [35 U.S.C. § 271\(a\) \(2000\)](#) ("making" and "using" a claimed invention both constitute infringement).

[FN141]. [Enzo II](#), 323 F.3d at 960 (Fed. Cir. 2002) (holding that disputed issues of material fact prevented summary judgment on the factual issue of sufficiency of a written description). Because the panel reconsidered, the case was not reheard en banc. See [id.](#) at 970.

[FN142]. See [id.](#) at 965 (discussing in re Argoudelis).

[FN143]. [Id.](#) at 964-65 (emphasis added).

[FN144]. J.E.M. is cited by the Enzo II dissent on a different issue. See [Enzo II](#), 323 F.3d at 977 (Rader, J., dissenting) (arguing that the Supreme Court in J.E.M. did not recognize a separate description requirement in [§ 112](#), P1).

[FN145]. The judges who dissented from the denial of rehearing en banc had no problem with

deposits, they wanted to eliminate any "written description" requirement separate from enablement. See [Enzo II, 323 F.3d at 977](#) ("In later [patent statutes], this notice function was assigned to claims, leaving enablement as the only purpose of the 'written description' language.").

[\[FN146\]](#). The code allows the PTO to require drawings, models, or deposits to supplement the [§ 112, P.1](#) enabling written description. [35 U.S.C. §§ 113-114 \(2002\)](#).

[\[FN147\]](#). See United States Patent and Trademark Office Website, at <http://www.uspto.gov/patft/index.html> (last visited July 19, 2004) (gateway to PTO patent search functions).

[\[FN148\]](#). [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 \(2001\)](#) (citing [37 C.F.R. §§ 1.801-809](#)); [37 C.F.R. § 1.808\(a\)\(2\) \(2001\)](#) ("Subject to paragraph (b) of this section, all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.").

[\[FN149\]](#). [37 C.F.R. § 1.808\(2\)\(b\)](#) ("The depositor may contract with the depository to require that samples of a deposited biological material shall be furnished only if a request for a sample, during the term of the patent: (1) Is in writing or other tangible form and dated; (2) Contains the name and address of the requesting party and the accession number of the deposit; and (3) Is communicated in writing by the depository to the depositor along with the date on which the sample was furnished and the name and address of the party to whom the sample was furnished."). But see [U.S. Patent No. 6,329,579 \(issued Dec. 11, 2001\)](#) ("Applicant imposes no restrictions on the availability of the deposited material from the [depository].").

[\[FN150\]](#). [35 U.S.C. § 271\(a\) \(2003\)](#) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.") (emphasis added).

[FN151]. See [35 U.S.C. § 271\(f\)\(1\)-\(2\)](#) (making infringing "suppl[ing] ... from the United States all or a substantial portion" of a patented combination in certain circumstances). See also *Schmeiser v. Monsanto Canada, Inc.*, 239 D.L.R. (4th) 271 (May 21, 2004) (holding that growing a plant containing a patented transgene is infringement of the patent on the transgene even though Canada does not allow utility patents on seeds or plants).

[FN152]. The early cases involving [§ 112](#) deposits involve deposit of material necessary to practice the invention, but not of the resclaimed in the patent. Such deposits have other uses than actions infringing the supported patent. This supporting material was required to be publicly available as soon as the patent issued. [In re Argoudelis](#), 434 F.2d 1390, 1394 (C.C.P.A. 1970) (allowing patent inter alia because depository is "under a contractual obligation ... to supply samples to anyone seeking them once the patent issues."); *Feldman v. Anunstrup*, 517 F.2d 1352, 1355 (C.C.P.A. 1975) (allowing patent inter alia because "the restrictions on access to [the deposit] were removed and the culture was made 'open to the public.'"); [In re Lundak](#), 773 F.2d 1216, 1222 (Fed. Cir. 1985) (allowing patent inter alia because depository provides "assurance of availability of the material to the public after the grant of the patent.").

[FN153]. The Solicitor General's statement to the J.E.M. Court on this subject seems misleading, though based on the accurate statement that deposits supporting PVPA certificates are not open to the public during the term of the certificate, while deposits supporting utility patents are technically available.

Seeds deposited in conjunction with a utility patent, by contrast to those tied to PVPA certificates, are immediately in the public domain, although no infringing use may be made of them until the patent term expires. See 37 C.F.R. §§ 1.801- 1.809 (1990) (rules for disclosure of biotechnology inventions through deposits); see generally [Ajinomoto Co. v. Archer-Daniels-Midland Co.](#), 228 F.3d 1338, 1345-46 (Fed. Cir. 2000) (discussing enabling disclosure through deposit). Petitioners therefore are incorrect in suggesting (Br. 29-30 n.10) that respondent has made a less complete disclosure of its patented inventions than would have

been required under the PVPA.

Brief of the United States as Amicus Curiae Supporting Respondent at *25 n.12, [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., No. 99-1996, 2001 WL 689516](#). Ajinimoto, furthermore, merely relies on Lundak which, as discussed infra text accompanying note 170, merely relies on Argoudelis. See [Ajinimoto, 228 F.3d at 1346](#).

[FN154]. The final rule was adopted effective January 1, 1990. See [54 Fed. Reg. 34864 \(Aug. 22, 1989\)](#) (adopting final rule) ("Where an invention is or relies on a biological material which cannot be described in writing alone, and access to the biological material is necessary to satisfy the statutory requirements for patentability under [35 U.S.C. § 112](#), these rules prescribe the procedures and conditions for making a deposit that will satisfy these requirements.").

[FN155]. Issued patents have been public records, publicly available since the first U.S. Patent Act. See Patent Act of 1790, § 3, 1 Stat. 109, reprinted in Walterscheid, *supra* note 20, at 463, 466 (making it "the duty of the Secretary" to allow "any person" to make a copy of a specification or model of any issued patent upon application). But see Walterscheid, *supra* note 20, at 281-304 (recounting Superintendent of Patents William Thornton's twenty-year refusal to release patent information despite contrary opinion of the Attorney General).

[FN156]. [37 C.F.R. § 1.806](#) provides:

A deposit made before or during pendency of an application for patent shall be made for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposit was received by the depository. In any case, samples must be stored under agreements that would make them available beyond the enforceable life of the patent for which the deposit was made.

[FN157]. H.R. 5598, 101st Cong. § 203 (1990).

[FN158]. *Id.* at § 204 ("[Section 101 of title 35, United States Code](#), is amended by adding before the period at the end a comma and the following: 'except that human beings are not patentable

subject matter.").

[\[FN159\]](#). Id. at Title IV.

[\[FN160\]](#). [H.R. Rep. No. 101-960, pt. 1](#), at 22, [1990 WL 201618](#); see also supra text accompanying notes 115-120.

[\[FN161\]](#). Hearing on H.R. 1556, Before the Subcommittee on Courts, Intellectual Property, and the Administration of Justice, of the House Committee on the Judiciary, 101st Cong. 189-90 (Oct. 31, 1989) (Letter from Donald J. Quigg to Rep. Robert W. Kastenmeier) Serial No. 76 (available as 1990 CIS fiche 521-57), reprinted in Transgenic Animal Patent Reform Act of 1989 [hereinafter "1989 Hearings"].

There is even the possibility that a statutory "research exemption" would not only fail to provide greater certainty [than case law] but could serve to enlarge the present narrow limitation on a patent owner's rights. The Administration would not favor legislation creating a "research exemption" ... because it could diminish the strong incentive provided by the patent system.

Id.

[\[FN162\]](#). Id. at 153 (statement of Donald J. Quigg, Commissioner, U.S. Patent & Trademark Office).

[\[FN163\]](#). Id.

[\[FN164\]](#). See [35 U.S.C. § 102 \(2000\)](#) ("A person shall be entitled to a patent unless"); see also Bagley, *supra*note 15, at 491 (agreeing that the PTO lacks power to prevent patents on human beings and citing recent statements by the PTO acknowledging this inability).

[\[FN165\]](#). Quigg refers to [35 U.S.C. § 6](#). 1989 Hearings, *supra*note 161, at 153 (statement of Donald J. Quigg, Commissioner, U.S. Patent & Trademark Office) ("This authority [to promulgate regulations] is already broadly conveyed by [section 6 of title 35, United States Code](#)."). [35](#)

[U.S.C. § 6 \(2004\)](#) currently deals only with the Board of Patent Appeals and Interferences; it does not mention any power to promulgate regulations.

[FN166]. [35 U.S.C. § 2\(b\)\(2\) \(2000\)](#).

[FN167]. See 52 Fed. Reg. 34080 (Sept. 9, 1987) (advance notice of proposed rulemaking); [53 Fed. Reg. 39420 \(Oct. 6, 1988\)](#) (notice of proposed rulemaking); [54 Fed. Reg. 34864 \(Aug. 22, 1989\)](#) (final rule).

[FN168]. See [35 U.S.C. § 114 \(2000\)](#).

[FN169]. [35 U.S.C. § 2\(b\)\(2\) \(2000\)](#).

[FN170]. Accord [Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 964 \(Fed. Cir. 2002\)](#) (recognizing that the PTO's Guidelines and its Manual of Patent Examining Procedure that discuss patentability issues "are not binding on [the] court, but may be given judicial notice to the extent they do not conflict with the statute") (emphasis added).

[FN171]. [35 U.S.C. § 2\(b\)\(2\)\(A\)](#).

[FN172]. See 1989 Hearings, *supra*note 161, at 190 (letter from Donald J. Quigg, Commissioner, U.S. Patent and Trademark Office) (relying on [In re Argoudelis, 434 F.2d 1390 \(C.C.P.A. 1970\)](#); [Feldman v. Aunstrup, 517 F.2d 1351 \(C.C.P.A. 1975\)](#); [In re Lundak, 773 F.2d 1216 \(Fed. Cir. 1985\)](#)). All of these cases deal with deposit of material necessary to practice the invention, but not of a product claimed in the patent. The deposits were available to the public on the issuance of the patent. See [In re Argoudelis, 434 F.2d at 1394](#) (allowing patent inter alia because depository is "under a contractual obligation" to "supply samples to anyone seeking them once the patent issues"); [Feldman, 517 F.2d at 1355](#) (allowing patent inter alia because "the restrictions on access to [the deposit] were removed and the culture was made 'open to the public'"); [In re Lundak, 773 F.2d at 1222](#) (allowing patent inter alia because depository provides "assurance of availability of the material to the public after the grant of the patent").

[FN173]. See [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 145 \(2001\)](#).

This figure is from the Solicitor General who supplies no details on its generation. See Brief of the United States as Amicus Curiae Supporting Respondent at *6, [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., No. 99-1996, 2001 WL 689516](#) ("As of April 2001, approximately 1800 utility patents included claims to plants, seeds, plant parts, or plant tissues. Approximately 1300 of those utility patents had an explicit claim to a plant seed."); see also *id.* at *15 n.8 ("More than 1600 utility patents claim transgenic plant technology including claims to plants, seeds, and plant tissues.").

[FN174]. See, e.g., [Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051, 1054 \(Fed. Cir. 2003\)](#) (explaining that a reference is "enabling" when it "teach[es] one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation").

[FN175]. See [J.E.M., 534 U.S. at 134](#) ("[I]n 1930 Congress believed that plants were not patentable under [§ 101](#) ... because in practice they could not meet the stringent description requirement. Yet th[is] premise[] w[as] disproved over time.") (emphasis in original); [id. at 135](#) (referring to PPA legislative history, "[w]hatever Congress may have believed about the state of patent law and the science of plant breeding in 1930, plants have always had the potential to fall within the general subject matter of [§ 101](#),") (emphasis in original); [id. at 141](#) (referring to PVPA, "[t]he relevant statements in the legislative history reveal nothing more than the limited view of plant breeding taken by some Members of Congress who believed that patent protection was unavailable for sexually reproduced plants").

Elisa Rives has argued that sexually reproduced entities are inherently incapable of [§ 112](#) enabling description because of the nature of sexual reproduction. See Elisa Rives, Comment, [Mother Nature and the Courts: Are Sexually Reproducing Plants and Their Progeny Patentable Under the Utility Patent Act of 1952?](#), *32 Cumb. L. Rev.* 187, 222-26 (2001-02) (arguing inherent indefiniteness of all sexually reproduced entities). Rives relies in part on a case involving [§](#)

[112](#), P2 (requiring claims which "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention."); see [In re Merat, 519 F.2d 1390, 1391 \(C.C.P.A. 1975\)](#) (affirming [§ 112](#), P2 final rejection of claims for a "Method of Improving Strains of Chickens."). While I am grateful to Rives for this argument, Merat involved indefinite identification of the parent lines, not the indefiniteness of progeny's characteristics. See [Merat, 519 F.2d at 1396](#) ("[T]he claim language is not precise enough to indicate which kind of cock to use to produce the result required by the claims"). If seed deposits are [§ 112, P 1](#) "written descriptions," deposit seems to identify progenitors clearly. Accord Ex parte [C, 27 U.S.P.Q.2d \(BNA\) 1492, 1495 \(B.P.A.I. 1993\)](#) (reversing rejection of plant related claims for similar lack of specific written description of progenitors on ground of seed deposit).

Rives also argues that the essence of sexual reproduction is the seemingly random combination of genes from each parent which are inherited by each separate offspring. According to Rives, seed deposits will not breed true for more than a single generation, specifying the two parent varieties to cross for a hybrid will not guarantee uniform genetic makeup of all progeny, and the problem would not be solved even if (counter factually at present) scientists could write down the entire gene map of the parents. See Rives, supra. The PTO database includes patents on hybrid plants whose specifications identify the parent lines. For example, U.S. Utility Patent on "Hybrid Maize Plant and Seed 33J56," (31 claims) held by Pioneer Hi-Bred International, Inc. is summarized as involving "a hybrid maize plant, designated as 33J56, produced by crossing two Pioneer Hi-Bred International, Inc. proprietary inbred maize lines GE514431 and GE483237." Both parent lines and the claimed progeny line are supported by deposits. See id. Unfortunately, I believe that good drafting should allow a sufficiently clear explanation of how covered progeny can be separated from progeny which do not contain the characteristics covered by claims. Therefore, I cannot support Rives's intriguing arguments.

[\[FN176\]](#). According to the PTO, 800/295 is the classification used when the claimed invention is a "plant, seedling, plant seed, or plant part per se." USPTO Classification Definitions, available at www.uspto.gov/go/classification/uspc800sched800.htm#C8005295000.

[FN177]. See database search results of March 3, 2004 (on file with author). The raw search result was 409, but I eliminated two because they were in subclass 296 or 297 (multicellular algae and mushroom). See *id.*

[FN178]. PTO regulations expressly state that use of a deposit in a patent specification does not create a presumption that the deposit is necessary to satisfy [§ 112](#), even though deposits are only required when necessary to fulfill [§ 112](#). See 37 C.F.R. § 1.802(b) (2003) ("Biological material need not be deposited unless access to such material is necessary for the satisfaction of the statutory requirements for patentability under [35 U.S.C. § 112](#)."); [37 C.F.R. § 1.802\(c\)](#) ("The reference to a biological material in a specification disclosure or the actual deposit of such material by an applicant or patent owner does not create any presumption that such material is necessary to satisfy [35 U.S.C. § 112](#) or that deposit in accordance with these regulations is or was required.").

[FN179]. Below are the claims for three such patents:

Soybean Variety APA94-31572

What is claimed is:

1. A soybean seed designated APA94-31572, a sample of said seed deposited under ATCC Accession No. PTA-5155.
2. A soybean plant, or a part thereof, produced by growing the seed of claim 1.
3. The soybean plant part of claim 2 wherein said part is pollen.
4. The soybean plant part of claim 2 wherein said part is an ovule.
5. A tissue culture of protoplasts or regenerable cells from the plant of claim 2.
6. The tissue culture according to claim 5, the cells or protoplasts of the tissue culture are obtained from plant tissues selected from the group consisting of leaf, pollen, cotyledon, hypocotyl, embryos, root, pod, flower, shoot and stalk.
7. A soybean plant regenerated from the tissue culture of claim 5 having all the morphological and physiological characteristics of soybean variety APA95- 15294.
8. A method for producing a progeny soybean plant comprising crossing the plant of claim 2

with a second soybean plant, harvesting the resultant soybean seed, and growing a progeny soybean plant.

U.S. Utility [Patent No. 6,632,985 \(issued Oct. 14, 2003\)](#).

Pepper Variety

What is claimed is:

1. A hybrid pepper plant grown from seed deposited with the ATCC under Accession No. PTA-2275.

2. Fruit harvested from the plant of claim 1.

3. Hybrid seed which can be grown to yield a pepper plant of claim 1.

U.S. Utility [Patent No. 6,498,287 \(issued Dec. 24, 2002\)](#).

Sun Devil Lettuce Variety

We claim:

1. Lettuce seed having ATCC Accession Number PTA-4008.

2. A lettuce plant produced by growing the seed of claim 1.

3. A lettuce plant having all the physiological and morphological characteristics of the lettuce plant of claim.

4. A method of making an F.sub.1 hybrid lettuce plant consisting of crossing Sun Devil [the seed in claim one] as a first lettuce parent plant with a second lettuce parent plant, wherein Sun Devil is grown from the seed of claim 1; harvesting the resultant F.sub.1 hybrid seed; and growing an F.sub.1 hybrid seed into an F.sub.1 hybrid lettuce plant.

5. Pollen of the plant of claim 2.

6. An ovule of the plant of claim 2.

7. Tissue culture of the plant of claim 2.

U.S. Utility [Patent No. 6,495,744 \(issued Dec. 17, 2002\)](#).

[\[FN180\]. Patent 6,495,744](#), supra note 179, at 8: Detailed Description of the Invention (last paragraph).

[FN181]. Dr. Chapela was an Assistant Professor in the Division of Ecosystem Sciences at the University of California, Berkeley until he was denied tenure in December of 2003. Critics have linked the denial to Dr. Chapela's public criticism both of biotechnology and of Berkeley's multi-million dollar ties with a biotechnology company. See Sharon Walsh, *Ignacio Chapela: Berkeley Denies Tenure to Ecologist Who Criticized University's Ties to the Biotechnology Industry*, *Chronicle of Higher Education* (Jan. 9, 2004), available at http://www.utwatch.org/oldnews/chroniclehighered_tenure_biotech_1_9_04.html (last visited Oct. 10, 2004). See also Ignacio Chapela, UC Berkeley ESPM Faculty, available at http://espm.berkeley.edu/directory/fac/chapela_i.html (last visited Sept. 22, 2004); *Background Articles on and by Ignacio Chapela*, at <http://www.mindfully.org/GE/2003/Ignacio-Chapela30jun03.htm> (last visited Sept. 22, 2004).

[FN182]. The primary plant involved in U.S. Utility [Patent No. 6,498,287](#) is created by non-transgenic breeding techniques. See No. 6,498,287, *supra* note 179, at Specification: Description of the Specific Embodiment ("The hybrid plants of the invention result from a cross of parental lines"). In contrast, U.S. Utility [Patent No. 6,646,184](#) ("Trichothecene-resistant transgenic plants"; assignee Syngenta Participations AG) involves four claims dealing with a transgene and plants which have been modified by insertion of material containing the transgene.

What is claimed is:

1. A plasmid designated pNOV1700 deposited as NRRL Accession No. B-30117.
2. An isolated nucleic acid molecule having the sequence of the 4117bp PvuII fragment in plasmid pNOV1700 (B-30117).
3. A plant cell comprising a nucleic acid molecule according to claim 2.
4. A plant comprising plant cell according to claim 3.
5. A plant according to claim 4, which is wheat or corn.

U.S. Utility [Patent No. 6,646,184 \(issued Nov. 11, 2003\)](#).

[FN183]. This statement is based on Dr. Chapela's comments at the Malthus, Mendel and

Monsanto Conference. Dr. Chapela has kindly approved it for publication. For those wishing a more technical explanation, Dr. Chapela asserts the following:

1. A specific insertion of DNA into a specific position within a specific genome is not achievable without strenuous trial and error. In other words, the insertion cannot be predictably and reliably described. Even careful methods, which are not used in commercial products because of their level of involvement, such as site-directed mutagenesis and site-specific transgenesis (e.g., Cre/lox-mediated site-specific gene integration) fit into this general observation.

2. Furthermore, the specific expression of any insertion of a transgenic DNA sequence cannot be predicted or reliably pre-ordained without strenuous trial and error. The actual mechanism through which such expression is achieved cannot be described in detail.

Under these circumstances there cannot exist a written description that can direct an expert in the art to reliably and reproducibly create a specific transgenic organism.

E-mail from Ignacia Chapela to Malla Pollack, Visiting Professor, Univ. of Ore. School of Law (Apr. 29, 2004 10:14 PST) (on file with author).

[\[FN184\]](#). Of course, the courts might again defer to PTO practice and patent holders' specific investment backed expectations. See [J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 144-45 \(2001\)](#) (referring to the PTO issuance of some 1,800 utility patents on plants).

[\[FN185\]](#). See TRIPS, *supra* note 88, art. 27, § 3(b).

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